DOI: 10.7860/JCDR/2026/78401.23246

Short Communication

Radiology Section

Magnetic Resonance Imaging in Patients with Cardiac Implantable Electronic Devices: Enhancing Safety and Standardising Practices

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Keywords: Implantable defibrillator, Magnetic resonance imaging safety, Pacemaker

INTRODUCTION

MRI has evolved as an indispensable and multifaceted diagnostic tool in radiology since its introduction in the 1980s [1]. Technological advancements have expanded its applications in diagnosis and treatment planning, significantly improving clinical outcomes. CIEDs, such as permanent pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronisation therapy devices, are widely used for treating arrhythmias [2].

Historically, CIEDs were deemed an absolute contraindication to MRI due to the concerns regarding mechanical forces, tissue heating, and potential device malfunction resulting from the strong magnetic fields [1,3]. Despite the introduction of newer and safer device models with fewer risks, barriers persist at multiple levels, from the referring consultants to radiologists. Consequently, patients with CIEDs are often less likely to be referred for MRI, and scans are often inappropriately denied or delayed [1,4]. This short communication reviews the current guidelines and provides recommendations for a standardised workflow for managing MRI referrals in patients with CIEDs, aiming to improve MRI safety protocols and clinical practice in this population.

SAFETY

Within the MRI environment, the following terms are globally recognised for categorising medical devices:

- MR safe: An item that poses no hazard in an MRI environment.
- MR conditional: An item that poses no known hazards in a specified MRI environment with specific conditions of use.
- MR unsafe: An item that poses unacceptable risks to the patients or medical staff in an MRI environment.
- MR unconditional (legacy devices): As defined in the 2017 Heart Rhythm Society (HRS) guidelines, devices that have not been declared MR conditional [5].
- MR unlabelled: An item without MR safe, MR conditional, or MR unsafe labelling.

None of the currently available CIEDs are classified as MR safe, as they contain electrically conductive materials [1]. The Food and Drug Administration (FDA) approved the first MR-conditional CIED in 2011, marking a major shift towards safer imaging options for these patients [6].

CIEDs generally consist of two main components: a generator (battery) and leads that connect to the heart. MR labelling applies to the entire system; therefore, an MR-conditional CIED must include a generator and leads implanted by the same manufacturer and tested as a combined unit. A combination of an MR-conditional generator with leads from different manufacturers does not constitute a conditional system, as such configurations have not been tested for conditional labelling [1]. Other components considered non conditional include permanent epicardial leads, abandoned leads, and fractured leads [5].

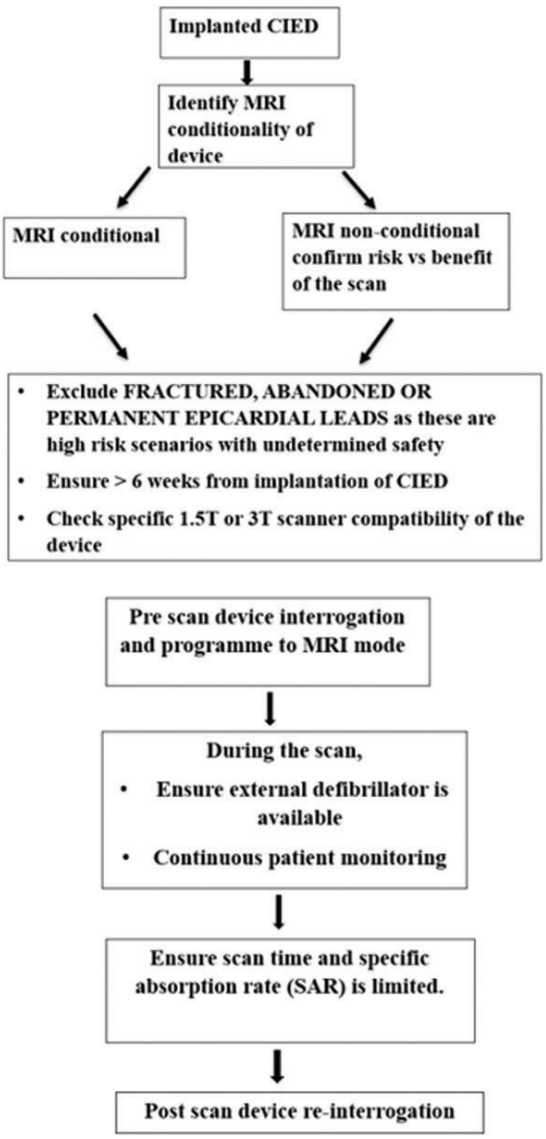
Potential periprocedural events relating to MRI scans in patients with CIEDs include heating-related symptoms, electrical reset, lead or generator failure, inappropriate pacing or shock delivery, and, rarely, death [3]. These events can be substantially mitigated through appropriate patient screening, device reprogramming, and continuous monitoring protocols. Several studies have demonstrated the safety of MRI scans in both MR-conditional and non conditional CIEDs [3,4,7]. A large systematic review and meta-analysis involving 5,625 patients with MR non conditional CIEDs who underwent MRI at 1.5 T reported an electrical reset rate of 1.43%, with less than 1% of patients experiencing heating, inappropriate pacing, or generator failure [3].

The 2017 Heart Rhythm Society guidelines outline recommendations for MRI in patients with CIEDs. For MR-conditional systems, the guidelines provide a Class I (strong) recommendation, highlighting the importance of a standardised institutional workflow and appropriate device programming to MRI mode. For MR non conditional systems, a Class IIa (moderate) recommendation suggests that it is reasonable to perform if there are no fractured, abandoned, or epicardial leads are present and if a standardised workflow is strictly followed [5].

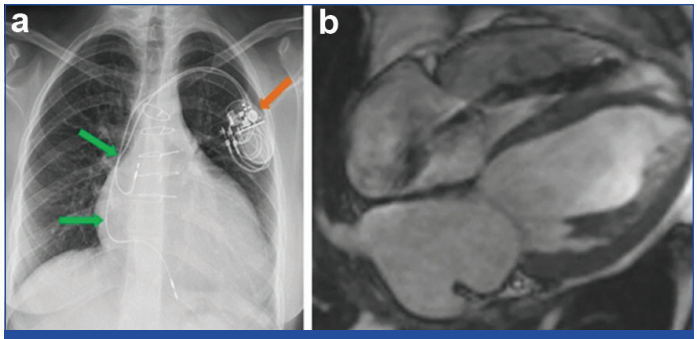
MRI should typically be performed at least six weeks post-CIED implantation to allow for fibrosis at the lead-myocardial interface, thereby minimising the risk of lead displacement. However, in cases with a strong clinical indications and careful monitoring, MRI may be feasible even during the early postimplantation period, as many manufacturers now offer more flexible scanning conditions during this timeframe [8]. MRI in patients with fractured, abandoned, or permanent epicardial leads is considered high-risk, and safety in these scenarios remains undetermined due to limited clinical evidence. Nevertheless, temporary postsurgical epicardial leads, which are often partially removed, are relatively common and are generally not considered contraindications to MRI scanning [5].

Recommendations for MRI workflow in patients with CIEDs: A standardised institutional protocol is essential for ensuring safe and effective MRI in patients with CIEDs. [Table/Fig-1] provides a comprehensive workflow for managing patients with MRI referrals. The key steps are outlined below:

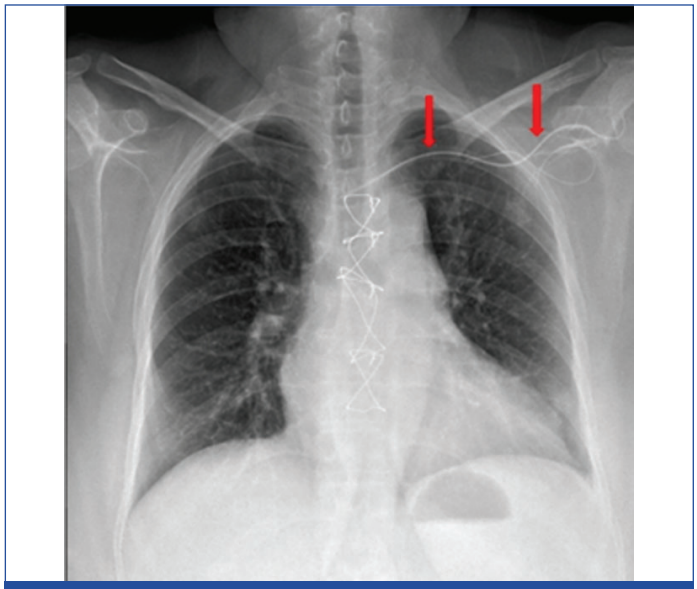
1. **Check device compatibility:** Verify the MRI compatibility of each patient's device components, specifically for 1.5 T or 3 T systems. This information is routinely available on the device manufacturers' websites and centralised at www.



[Table/Fig-1]: Comprehensive workflow for managing patients with MRI referrals.



[Table/Fig-2]: a) Frontal chest radiograph of a 33-year-old female with MRI-compatible pacemaker leads (green arrows) and generator (orange arrow). She successfully underwent MRI after interrogation of the device to MRI mode; b) Cardiac MRI image of the same patient.



[Table/Fig-3]: Frontal chest radiograph of a 50-year-old female with abandoned pacemaker leads (red arrows), a high-risk scenario for MRI.

mrimypacemaker.com, which offers quick access to patients and clinicians with tutorial videos and information leaflets.

2. **Interrogate and screen:** All CIEDs should be interrogated and screened for high-risk scenarios, including fractured, abandoned, or permanent epicardial leads; recent device implantation; or presence of other metallic devices (like lead adapters or extenders) that may not meet MR-conditional requirements. A chest radiograph may be performed as a part of screening process to identify additional hardware and assess lead position [Table/Fig-2,3].
3. **Risk assessment and benefit analysis:** When MRI is choice due to its diagnostic superiority over other modalities, it can be conducted for patients with non conditional or unlabelled CIEDs, provided that high-risk scenarios (as mentioned above) are absent [1,5]. This approach is supported by evidence demonstrating the safety of MRI even in patients with non conditional CIEDs [3,9]. A thorough risk assessment and risk-benefit analysis involving both a cardiologist and a radiologist is crucial.
4. **Prescan preparation:** On the day of the MRI, the CIED should be programmed according to the manufacturer's instructions. Setting the CIED to "MRI mode" reduces the risk of complications such as inappropriate pacemaker or defibrillator activation or inhibition of pacing. Interrogation and programming should be performed by a trained cardiac electrophysiologist or a cardiologist should perform the interrogation and programming of the CIED with documentation of the prescan parameters for postscan comparison [1].
5. **In-scan monitoring:** Before initiating the MRI scan, the MRI operator or technician must confirm that all scanning prerequisites have been met. Continuous verbal communication with the patient and continuous monitoring using electrocardiography, blood pressure measurement, and pulse oximetry are essential. An advanced cardiac life support should be present throughout the procedure, regardless of whether the CIED is MR conditional. An external defibrillator with pacing capability must also be readily available.
6. **Scan parameters:** Ensure the use of a static magnetic field with a cylindrical bore, maintain a maximum whole-body Specific Absorption Rate (SAR) of 2 W/kg, a maximum head SAR of 3.2 W/kg, and a maximum gradient slew rate of 200 T/m per second [10].
7. **Postscan reprogramming:** After the scan, reinterrogate and reprogram the CIED to restore the initial settings. Correct pacing capture thresholds must be verified before the patient is discharged.
8. **Emergency protocols:** In emergency setting where MRI is performed outside regular working hours, the same protocols as elective scans must be strictly followed, including appropriate device programming and patient monitoring, regardless of the time of day.

CONCLUSION(S)

The clinical demand for MRI in patients with CIEDs is high; however, access remains limited due to barriers such as inadequate availability, variability in institutional protocols, and ongoing concerns regarding

device safety. Addressing these challenges is vital for improving patient outcomes and meeting the growing need for MRI in this patient population. Authors advocate for extreme prudence and a multidisciplinary approach for performing MRI scans on patients with a CIED. Adhering to comprehensive workflows—including meticulous device interrogation and programming, specific MRI scanning restrictions, and continuous patient monitoring—is pivotal to ensure patient safety and optimise the diagnostic effectiveness of MRI procedures.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Feb 03, 2025
- Manual Googling: Jun 07, 2025
- iThenticate Software: Jun 09, 2025 (16%)

ETYMOLOGY: Author Origin

EMENDATIONS: 5

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? No
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Feb 01, 2025**
Date of Peer Review: **Apr 19, 2025**
Date of Acceptance: **Jun 11, 2025**
Date of Publishing: **May 01, 2026**