Heart, Lung and Circulation (2023) ■, ■–■
1443-9506/23/$36.00
https://doi.org/10.1016/j.hlc.2023.11.020

ORIGINAL ARTICLE

Access to MRI in Patients With Cardiac Implantable Electronic Devices is Variable and an Issue in Australia

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Received 13 June 2023; received in revised form 11 October 2023; accepted 9 November 2023; online published-ahead-of-print xxx

Aims This study aimed to characterise the level of access to magnetic resonance imaging (MRI) in Australian hospitals for patients with MR-conditional and non-MR-conditional cardiac implantable electronic devices (CIED), and to identify any barriers impeding this access.

Methods All Australian Tertiary Referral Public Hospitals (n=38) were surveyed with a mixed qualitative and quantitative questionnaire. Provision of MRI to patients with MR-conditional and non-MR-conditional CIEDs; patient monitoring strategies during scan and personnel in attendance; barriers impeding MRI access.

Results Of the 35 (92%) hospitals that completed the survey, a majority (85.7%) scan MR-conditional CIEDs, while a minority (8.6%) scan non-MR-conditional CIEDs. MR-conditional device scanning is often limited to non-pacing dependent patients, excluding implantable cardioverter–defibrillators. In total, 21% of sites exclude thoracic MR scans for CIED patients. Although most centres scan on 1.5 Tesla (T) machines (59%), 10% scan at 3T and 31% scan at both strengths. Sites vary in patient monitoring strategies and personnel in attendance; 80% require staff with Advanced Cardiac Life Support to be present. Barriers to service expansion include an absence of national guidelines, formal training, and logistical device support.

Conclusions Most surveyed Australian hospitals offer MRI for patients with MR-conditional CIEDs, however many still have exclusions for particular patient groups or scan requests. Only three surveyed sites offer MRI for patients with non-MR-conditional CIEDs in Australia. A national effort is needed to address the identified barriers including the development of national guidelines, formal training, and logistical support.

Keywords Magnetic resonance imaging • MR-conditional • MR-nonconditional • Safety • Pacemaker • Defibrillator

Introduction

Cardiac implantable electronic device (CIED) is an umbrella term for implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy, and pacemakers. In the prevention of sudden cardiac death, ICDs have demonstrated efficacy in reducing overall mortality [1,2] and pacemakers represent a cornerstone of cardiac arrhythmia management. There are approximately 8 million patients with CIEDs worldwide [3], and rates of new CIED

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implantation in Australia continue to climb from 819 per million in 2013 to 920 per million in 2017 [4]. Despite their prevalence, the presence of a CIED remains controversial for an increasingly vital diagnostic technique—magnetic resonance imaging (MRI). Historically, concerns included the possibility of magnetic interference impeding pacing or arrhythmia detection function [5] (where devices reset to electrical backup modes), the potential for induction of ventricular arrhythmias by inappropriate rapid pacing ("runaway" phenomenon) [6] or thermal cardiac-lead induced myocardial injury [7]. Consequently, CIEDs were considered a contraindication for MRI scans by regulatory bodies [8].

Emerging evidence regarding the safety of non-MR-conditional CIEDs challenges this notion, particularly for devices manufactured after 2002. Under specific protocols including careful device re-programming, monitoring and supervision during the scan, and minimising scanner field strength and specific absorption rate to which the device is exposed, patients with non-MR-conditional devices have been able to undergo MRI without major adverse reported events [9–12]. A systematic review and meta-analysis of over 5,625 patients [13] with non-MR-conditional devices similarly affirmed the safety of undergoing MR imaging under protocol.

Industry progress towards greater MRI safety has also led to MR-conditional device development—that is, devices demonstrated to pose no known hazards in a specifical MRI environment with specific conditions of use. Modifications including a reduction in a ferromagnetic material, battery circuit protection and automated or simplified pre-MRI programming settings enable these devices to be safely used at 1.5 and 3.0 T MRI without major adverse events [5]. Indeed, a large multi-centre randomised controlled trial found no clinically significant complications related to MRI [14] for patients with MR-conditional devices. Reflecting this consensus with MRI usage, the European Society of Cardiology recently published class I recommendations for MR-conditional devices, and class IIa for non-MR-conditional devices [15], with similar guidelines [16] published by the Heart Rhythm Society in the United States.

However, developments in safety data for non-MR-conditional devices and the technological capacity of MR-conditional CIEDs do not correlate with increased MRI scanning in clinical practice [17]. Despite ample clinical indications [15], the CIED patient population has lower MRI utilisation than the non-CIED population. Recent surveys demonstrate this disparity, with considerable implications for patient outcomes. Almost half of hospitals in England do not provide scans even to patients with MR-conditional CIEDs [18]. In Italy, the presence of a complete MR-conditional device did not increase the rate of MRI scanning relative to non-MR-conditional CIEDs [19]. Up to 75% of patients with a CIED will have a subsequent clinical indication for MRI in their lifetime [20], often the imaging tool of choice in orthopaedics, neurology and oncology. Unsurprisingly, paucity of MRI access is associated with later diagnosis, increased treatment expense and invasiveness, and poorer patient outcomes overall [21].

No comprehensive assessment of access to MRI for patients with MR-conditional and non-MR-conditional devices has been undertaken in Australia. As evidence indicates reduced MRI access across comparable world health systems, a similar scenario is anticipated in the Australian healthcare system. This study aimed to (a) characterise the access to MRI for patients with CIEDs (MR-conditional and non-MR-conditional) in Australian public tertiary-level hospitals, and (b) identify related barriers to the adoption and implementation of MRI for these patients.

Methods

This study surveyed all Australian public tertiary referral hospitals, which were identified using the Royal Australasian College of Physicians' "Adult Level 3 Accredited Teaching Hospital" guidelines [22] to provide a sample size of 38 hospitals. Each site was contacted directly in order to select an authorised clinician responsible for the MRI service at that site—either an MRI radiologist or cardiologist or a lead radiographer of the site. A secure online survey (via REDCap, Vanderbilt University, Nashville, TN, USA) was distributed to the selected representatives of each site. Survey responses for all sites were collected between March and November of 2020 (31/03/20 – 04/11/20).

The survey collected information characterising the services available for non-MR-conditional and MR-conditional CIEDs, and the strength of MRI used. Responses were recorded regarding the barriers to scanning CIEDs, and suggestions to improve access. The survey consisted of multiple-choice questions and free-text responses organised in broad response categories.

Ethics Approval

The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee (2019/PID13598), and completion of the survey implied informed consent from each site.

Results

Survey Response

Surveys were completed for 35 of 38 (92%) sites and carried out by a consultant cardiologist (43%), MRI Radiographer (23%), Chief Radiographer/MRI supervisor (20%), or radiologist (14%).

MR-conditional CIEDs

Access to MRI services

A majority of surveyed sites facilitate MRI scanning of MR-conditional CIEDs (85.7%), Figure 1A. 1.5 Tesla is the preferred field strength to scan MR-conditional CIEDs (59%), however, a proportion scan at 3.0 Tesla only (10%) or both

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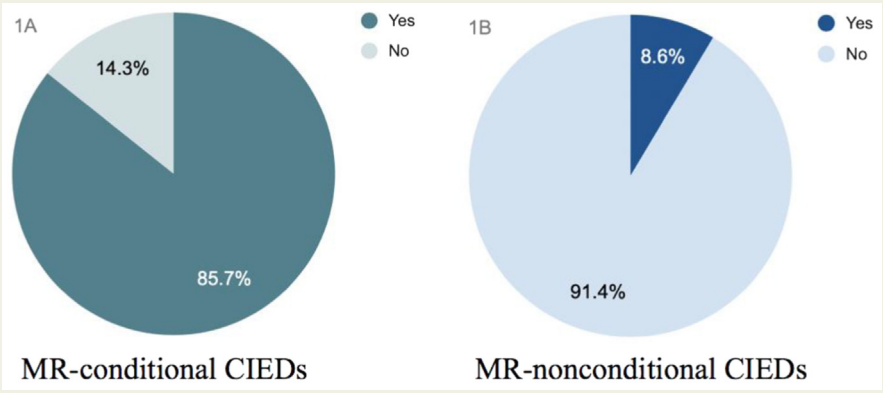

Figure 1 Proportion of Australian Tertiary Referral Public Hospitals offering MRI scans for patients with MR-conditional (A) and non-MR-conditional (B) CIEDs.
Abbreviations: CIEDs, cardiac implantable electronic devices; MR, magnetic resonance.

strengths (31%). Most sites do not distinguish between CIED subtypes for MRI access (54%), however, some locations only provide MRI to non-pacemaker-dependent patients (with stable underlying rhythms) (20%), or only those with pacemakers and not ICDs (3%), and few scan CIED-dependent patients (3%). A majority of sites (79%) offer both thoracic and extra-thoracic scanning.

Safety Protocols

Almost all sites (93%) that scan MR-conditional devices have formalised protocols for patient management, and a majority (66%) have a separate referral process for patients with CIEDs. A majority (80%) of units mandated at least one staff member in attendance with Advanced Cardiac Life Support (ACLS) certification, with no correlation to the strength of MRI machine used. Radiographers supervise the scan either alone (57%) or in conjunction with a radiologist (27%), pacemaker technician (27%) or Cardiovascular Magnetic Resonance cardiologist (23%), Figure 2. A majority of MR-conditional scans are undertaken with the pacemaker technician present, either before and after the scan (67%), or throughout (23%). Patient monitoring most commonly entails peripheral pulse oximetry waveform monitoring (66%), heart rate only via a peripheral monitor (53%), or continuous electrocardiogram (ECG) monitoring either via the display on the scanner (43%) or external hardware (43%), Figure 3.

Non-MR-Conditional CIEDs

Access to MRI services

Only 8.6% (n=3) of surveyed hospitals in Australia permit MRI scans for patients with non-MR-conditional CIEDs, Figure 1B. 1.5 Tesla is the only scanning strength used, and no units provided MRI for pacemaker-dependent patients with non-MR-conditional devices. Two of these three sites have a referral process for non-MR-conditional devices, however only one has a formalised protocol regarding non-MR-conditional patient management during the scan.

For the scan to occur, all sites require written acknowledgement that the MRI is essential for diagnosis and that its findings will alter management and written informed consent from the patient be obtained. Two of these three sites also involve cardiologist or multidisciplinary discussions regarding the case before the MRI takes place. A majority of sites (66%) offer thoracic and extra-thoracic MRI scans.

Safety Protocols

All sites have an ACLS-trained doctor in attendance, and all scans are supervised by a doctor—most often an electrophysiology cardiologist (66%), cardiac MRI cardiologist (33%) or radiologist (33%), Figure 2. All sites have a device technician in attendance for the scan, as well as a physician available to reprogram the CIED, either on-site or in attendance. These sites reported more involved patient monitoring, with all using continuous ECG monitoring via the scanner, and a majority with peripheral pulse via oxygen waveform monitoring (66%), Figure 3.

Barriers to MRI access

The barriers identified to facilitating MRI in patients with CIEDs were the absence of national guidelines (60%); the need for formal training (40%); the need for support from relevant experts including cardiologists and pacemaker technicians; logistical support; and, a lack of dedicated funding, Figure 4. Some sites highlighted that national guidelines would be specifically helpful in providing consensus on MRI suitability. Another site reported that they could only provide MRI to inpatients with CIEDs, as their outpatient facilities lacked essential cardiology and ACLS-trained personnel.

Discussion

This is the first study to assess MRI access for patients with CIEDs in Australia and reveals a diverging pattern based on

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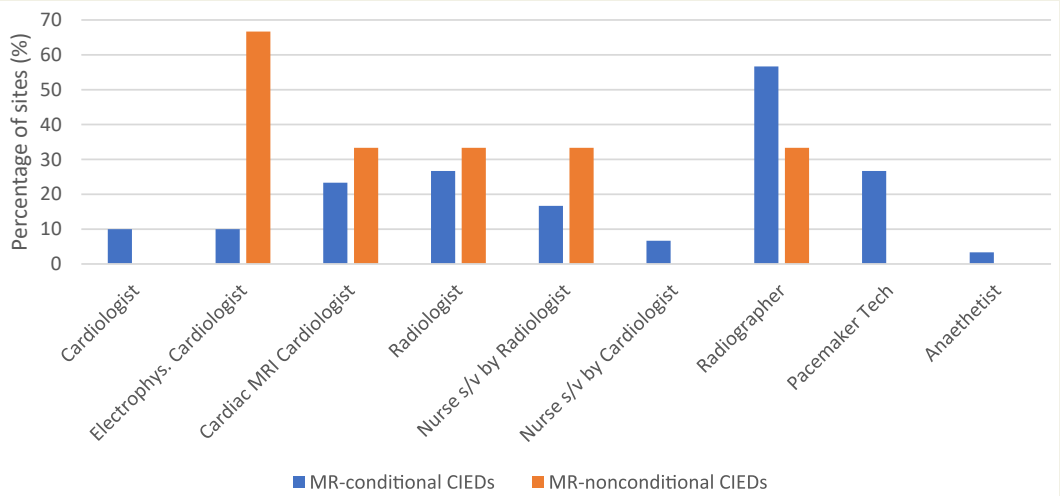

Figure 2 Reported personnel supervising MRI scans for patients with MR-conditional and non-MR-conditional CIEDs. (Note multiple personnel may be present during the scan so the total does not add up to 100%).
Abbreviations: CIEDs, cardiac implantable electronic devices; MRI, magnetic resonance imaging.

MR conditionality. A total of 85.7% of tertiary referral centres scan MR-conditional devices, yet only 8.6% (n=3) scan non-MR-conditional devices. This is a high figure for MR-conditional devices compared with international counterparts (53% in the UK [18] and 66% in Italy [19]). However, unlike the UK study that surveyed all hospitals in their National Health Service, our study focussed only on tertiary-level public hospitals and thus did not include smaller or regional public hospitals nor private hospitals, which presumably would have varying access to MR-conditional devices. Therefore, our high figure is likely to be an overestimate of the total accessibility.

Additionally, our study provides a comprehensive analysis of MRI access for non-MR-conditional devices, which are not always included in other MRI access surveys [19]. The limited data on scanning rates of non-MR-conditional devices is mixed. A study of all UK MRI units [18] reported a similar rate to ours, with 10% of sites scanning non-MR-conditional devices. By contrast, 45% of academic centres with extensive electrophysiological expertise in the European Heart Rhythm Association Research Network [23], scan non-MR-conditional CIEDs. The heterogeneity of MRI access in clinical practice, despite accumulating evidence for the safety of non-MR-conditional devices under certain MRI protocols

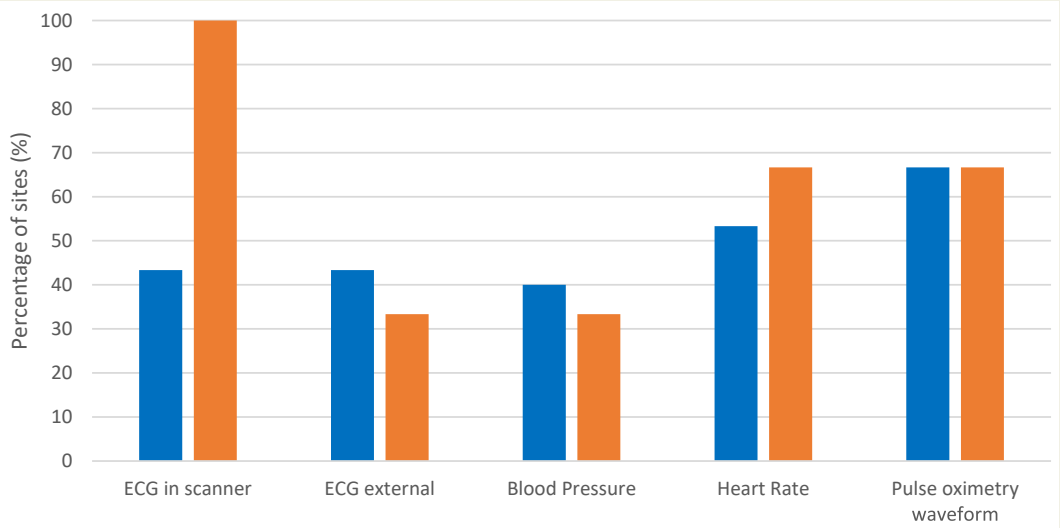

Figure 3 Reported patient monitoring during MRI scan for patients with MR-conditional (left, blue bars) and non-MR-conditional (right, orange bars) CIEDs.
Abbreviations: CIEDs, cardiac implantable electronic devices; ECG, electrocardiogram; MRI, magnetic resonance imaging.

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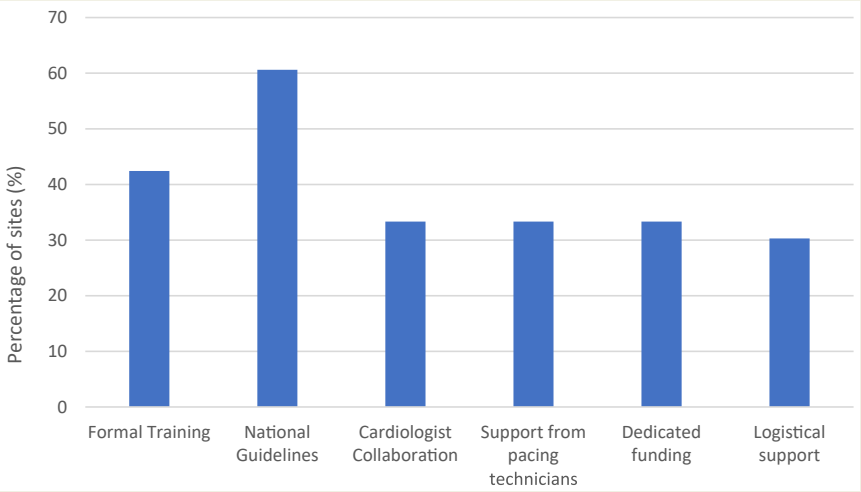

Figure 4 Reported strategies that would assist departments in providing MRI scans to patients with CIEDs. Abbreviation: CIEDs, cardiac implantable electronic devices.

(namely in the MagnaSafe registry [9]), is a global healthcare issue.

The three Australian centres that scan non-MR-conditional devices did so in accordance with recommendations from the literature, scanning at a strength of 1.5 T [9]. These sites require firm reasoning to approve non-MR-conditional devices for MRI, including written confirmation that the scan will alter treatment or diagnosis. While this increases departmental workload, its benefits are established. A recent study found that MRI provision for patients with non-MR-conditional devices changed diagnosis in 35% of cases, medical management in 31% of cases and notably obviated further investigations in 27% of cases [10].

Reported safety monitoring during scans also reflected consensus in the literature for both MR-conditional and non-MR-conditional devices. Current evidence recommends an ACLS-trained staff member is present for the duration of the scan [24], as was the case in 80% of sites scanning MR-conditional CIEDs and 100% of sites scanning non-MR-conditional devices. Continuous haemodynamic monitoring was performed for all devices, notably more rigorous for non-MR-conditional devices, per recommendations [24].

The limited number of sites that scan non-MR-conditional devices in Australia suggest recalcitrant barriers to MRI provision. Our study indicates the development of national guidelines would be the most helpful factor in ensuring greater access, followed by formal training and specialist collaboration/support. One previous study showed that fears over adverse events and the legal ramifications of "off-label" MRI provision for non-MR-conditional CIEDs [24] are other barriers. Issues with inter-specialty communication can further reduce access—another study that found that 86% of denied MRI examinations were decided by a radiologist [19] without input from relevant cardiology expertise relating to CIED MRI safety. Education across specialities regarding CIED MRI safety and scanning, particularly through Australia's leading cardiology and radiology societies, could streamline better health provision to this patient population. It is also important to highlight that barriers exist at the point of referral, where many referrers and patients with non-MR-conditional devices are unaware that MRI could be performed albeit under stringent safety protocols.

Overall, our study reflects a broader picture of reduced access to MRI as found in comparable health systems, particularly for patients with non-MR-conditional devices. The substantial response rate in this study (92%), higher than most similar surveys, paints a clear picture of MRI access in Australian public tertiary hospitals. However, the generalisability of these results must be interpreted with caution. These results from public tertiary hospitals of the major metropolitan areas represent only one segment of Australia's diverse healthcare landscape where MRI scans are performed, which includes the private health sector, outpatient and inpatient services in private hospitals, and outpatient private radiology practices, as well as smaller regional public hospitals. Indeed, one-third of all MRI services in Australia are privately funded [25], and a further third only receive public funding for a limited number of restricted indications—perhaps a factor in Australia's disproportionally low MRI usage among other Organisation for Economic Cooperation and Development (OECD) nations [25]. The inequity in MRI access may be more stark in the private sector, where reduced support in the event of complications makes scanning CIEDs unfeasible. A shortfall of technical and industry support may also be impacting MRI provision in smaller public hospitals outside of the tertiary teaching centres and private clinics, particularly in regional and rural Australia. Further investigation into this combined public–private system would add to the power of this survey's relatively small sample size (n=35). More individualised assessments would also provide clarity for protocol development, including the utility of MRI in shaping medical treatment plans [11].

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Conclusions

In summary, this is the first study to assess and characterise access to MRI for patients with CIEDs in Australia. The majority (85.7%) of surveyed Australian Tertiary Referral Public Hospitals provide an MRI service for patients with MR-conditional CIEDs, but only 8.6% offer this service to patients with non-MR-conditional CIEDs. This highlights the need for a national effort to guide the provision of MRI services for patients with CIEDs, including addressing the major barriers of the need for national guidelines and formal training in this area.

Funding Sources

We report no relevant funding sources associated with this manuscript.

Conflicts of Interest

There are no conflicts of interest to disclose.

Appendices

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.hlc.2023.11.020.

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