Provision of magnetic resonance imaging for patients with ‘MR-conditional’ cardiac implantable electronic devices: an unmet clinical need

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Introduction

Until recently, the presence of a cardiac implantable electronic device (CIED; pacemaker or implantable cardiac defibrillator, ICD) was considered an absolute contraindication to patients undergoing magnetic resonance imaging (MRI), because of the risk of harm.1,2 There is an increasing clinical need for MRI, which is the imaging technique of choice across a broad range of diseases (particularly within the spheres of neurology, orthopaedics, oncology, and cardiology). Recent national audit data show CIED implantation rates of 837 per million in England for 2013–14, a figure that is growing rapidly.3 This has led to two developments: firstly, there has been the development of MR-conditional CIEDs. These contain hardware and software tested and approved for use in an MRI setting (originally only in 1.5 Tesla MRI machines). First released in the EU in 2008 and subsequently FDA approved in 2011, these are rapidly being incorporated into clinical practice with MR-conditional CIED implantation now the standard of care in many centres. At least one manufacturer has recently reported that the majority of their CIED sales are now from MR-conditional devices, and manufacturers are now releasing CIED’s that are MR conditional in

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Cardiac implantable electronic devices (CIEDs; pacemaker or defibrillator) have historically been an absolute contraindication to MRI.

The need for CIEDs and the need for MRI scans co-segregate, with many CIED patients having multiple co-morbidities. Device manufacturers have therefore developed MR-conditional CIEDs.

Anecdotally, patients with MR-conditional CIEDs report difficulty accessing MRI scans. Current provision for MRI scanning in patients with MR-conditional CIEDs is unknown.

What’s new?

What is already known about this subject?

- Cardiac implantable electronic devices (CIEDs; pacemaker or defibrillator) have historically been an absolute contraindication to MRI.
- The need for CIEDs and the need for MRI scans co-segregate, with many CIED patients having multiple co-morbidities. Device manufacturers have therefore developed MR-conditional CIEDs.
- Anecdotally, patients with MR-conditional CIEDs report difficulty accessing MRI scans. Current provision for MRI scanning in patients with MR-conditional CIEDs is unknown.

What does this study add?

- Less than half of MRI departments in England will scan patients with MR-conditional cardiac devices—with only 1 in 7 of those centres scanning >10 patients a year.
- Reported complication rates are extremely low.
- Cardiology and Radiology need to work together to break down current barriers so that all eligible patients can benefit from MRI.

Methods

Survey distribution

A list of all NHS Trusts and hospitals with MRI departments within England was obtained from NHSE England (www.nhs.uk). Contact details for the superintendent radiographer (lead radiologic technologist), lead radiologist for MRI, or lead cardiologist for cardiac MRI were obtained. The survey was distributed electronically using an online dedicated survey software tool.

Data collection

Participating departments were asked to complete a short (13 question) survey of closed response questions plus some limited free text answers (Appendix). Information was requested about overall awareness of MR-conditional CIEDs, and local hospital infrastructure (e.g. the presence of onsite cardiac services) to scan. For those departments already providing a CIED MRI service, the type, number of scans, and safety precautions taken were requested. Departments were also asked to disclose whether they had the ability (in terms of infrastructure and protocols in place) to scan non-MR-conditional CIEDs. Finally, departments not currently offering MRI to CIED patients were asked to provide reasons. Free text answers were broadly categorized according to comment themes.

Statistics

Data are presented as n (%). Comparisons between groups were made using χ² test. Analysis was performed using Graphpad Prism version 6 (GraphPad Software, Inc., CA). A P-value of <0.05 was considered significant.

Results

Survey response

Responses were received from 201 of 233 (86%) of hospitals surveyed, representing 153 of 158 (97%) of acute NHS trusts in England. Of these responses, six submissions provided data across two hospital sites for a single trust therefore the results of the survey are based on 195 responses. The survey was completed by the superintendent radiographer (lead radiologic technologist) in 79%, lead MRI radiologist 9%, lead cardiologist for cardiac MRI 10%, and unspecified in 2% of cases.

Provision for magnetic resonance imaging scanning cardiac implantable electronic devices

Magnetic resonance-conditional cardiac implantable electronic devices

Although 98% of departments were aware of MR-conditional CIEDs, less than half (46%, 89 departments) currently provide an MRI service to this patient group, Figure 1. Fifty-one of the 89 departments (57%) offering CIED scanning also performed cardiac MRI studies, and such departments were more likely to perform thoracic studies (80 vs. 33%, P = <0.001). Seven sites performed MRI scanning in patients with CIEDs without onsite cardiology services.

Overall activity levels were low (Figure 1). Six per cent of departments who say that they offer the service scanned no patients in the preceding 12 months; 76% of departments scanned between 1 and 10 patients, and only three departments scanned >20 patients per year. One department currently offers scans only to patients with devices implanted at the same hospital site.

Non magnetic resonance-conditional cardiac implantable electronic devices

Only 4% (7 of 195) of departments currently offer MRI scans to patients with non-MR-conditional CIEDs in situ.

Safety considerations

There were a range of protocols and safety precautions in place for scanning CIED patients, Figure 2. The majority of departments (87%)

3 T MRI machines and are relaxing their safety precautions on 1.5 T MR-conditional devices, to allow 3 T scanning. The protocol for scanning MR-conditional CIEDs is straightforward, however, the manufacturer and device type needs to be known and typically a cardiac physiologist is needed to program the device before and after the scan, with potential risk if this is not complied with.

The second development is that there is now accumulating evidence particularly from the MagnaSafe registry that, under a fairly broad range of conditions, patients with non-MR conditional CIEDs, can safely undergo MRI, an approach endorsed in 2013 by the ESC provided the risk–benefit ratio is favourable.

Practically, a CIED MRI service requires cooperation between radiology and cardiology departments for the benefit of patients that are typically from another department (e.g. neurology). Anecdotally, patients with CIEDs of all types are reporting access difficulties. We therefore set out to establish the current provision of MRI scanning for patients with both MR-conditional and also non-MR-conditional CIEDs, and to explore current obstacles to service expansion.
had a formal written protocol; 69% had a cardiologist or cardiac physiologist (able to programme the device) present on site during the scan with 64% ensuring their physical presence in the MRI department. Although most departments monitor CIED patients’ observations during scanning (69% continuous ECG monitoring, 61% continuous pulse oximetry, and 22% blood pressure monitoring), 15% of departments reported imaging patients without any haemodynamic monitoring.
Reported complications from magnetic resonance imaging in cardiac implantable electronic device patients

Magnetic resonance-conditional cardiac implantable electronic devices
There were no major complications (defined as arrhythmias or damage to the device requiring revision) Table 1. Five departments experienced minor complications (defined as changes in the parameters of the device, requiring programming changes).

Non-magnetic resonance-conditional cardiac implantable electronic devices
There was one serious complication—a transient pause in pacing with syncope in a pacing-dependent patient, with no longer-term sequelae. Subsequent analysis of the print out detailing the pre-procedure programming changes showed that the patient had not been appropriately programmed to VOO mode, leading to pacing inhibition and transient asystole.

Reasons for not scanning cardiac implantable electronic devices
Of the 106 departments not currently offering MRI scans to patients with MR-conditional CIEDs, a number of different reasons were provided, Figure 3. These included concerns about risk, the lack of evidence of safety, the lack of training and logistical difficulties, and the lack of cardiology support. Three departments cited a lack of monitoring equipment. Nine departments did not offer this service as it was already provided by a nearby hospital, and one department had only 3 T MRI. Five departments reported that they were in the process of developing a service, and seven cited that currently there was a lack of demand to warrant providing this service.

Reported factors likely to encourage departments to start scanning included formal training, publication of UK guidelines, more evidence of safety, and better collaboration with cardiology colleagues (although 79% of these hospitals do have onsite cardiology services present).

Discussion
This first survey of MRI provision for patients with CIEDs shows that despite the widespread availability of MR-conditional devices and increasing evidence of non-MR-conditional device safety, less than half of MRI departments in England offer scans to this patient group, and overall number of patients scanned remains extremely low. With increasing rates of device implantation and broadening MRI indications, there is a clear need to recognize and address barriers.

Table 1 Complications reported by MRI units scanning patients with implantable cardiac devices

<table>
<thead>
<tr>
<th>Reported complications from hospitals offering MRI scanning to patients with cardiac implantable electronic devices</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>82 (92%)</td>
</tr>
<tr>
<td>Minor complications (e.g. device parameters altered and re-programming required)</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>Serious complications (e.g. arrhythmias, pacemaker malfunction requiring replacement)</td>
<td>1* (1%)</td>
</tr>
<tr>
<td>Not specified</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

*Reported complication from MR imaging in a patient with a non-MR conditional device.

Figure 3 Reported reasons for not scanning patients with MRI conditional CIED’s (from departments currently not offering the service).
Table 2 Considerations when imaging patients with MR-conditional cardiac implantable electronic devices using MRI (based on published guidance and literature) \(^6,8,9\)

<table>
<thead>
<tr>
<th>Before the scan</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Can the clinical information be obtained using a different imaging modality?</td>
<td></td>
</tr>
<tr>
<td>Is the scanner 1.5 T with maximum gradient slew rate (\leq 200 \text{ T/m}\cdot\text{s}^{-1})?</td>
<td></td>
</tr>
<tr>
<td>Are the generator and all leads confirmed to be part of an (manufacturer-specific) MR conditional system?</td>
<td></td>
</tr>
<tr>
<td>Has the device been implanted for (&gt;6) weeks on the date of the scan?</td>
<td></td>
</tr>
<tr>
<td>Is the device located pectorally (no abdominal systems)?</td>
<td></td>
</tr>
<tr>
<td>Are all leads intact? No fractured, capped or abandoned leads, adaptors or devices?</td>
<td></td>
</tr>
<tr>
<td>Are lead/device parameters within limits and with adequate safety margins?</td>
<td></td>
</tr>
<tr>
<td>• battery not approaching end of life</td>
<td></td>
</tr>
<tr>
<td>• sensitivity, impedance, and threshold of all leads within normal limits</td>
<td></td>
</tr>
<tr>
<td>Is there an external defibrillator with transcutaneous pacing capability available in the MRI suite, and are staff trained to use it?</td>
<td></td>
</tr>
<tr>
<td>Is there a suitably trained cardiac physiologist/cardiologist available to programme the device to enable MR scanning?</td>
<td></td>
</tr>
<tr>
<td>Is the device programmed to MRI safe mode?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>During the scan</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Are all MR protocols run in ‘Normal’ mode (SAR (\leq 2.0 \text{ W/kg}; \text{head SAR } \leq 3.2 \text{ W/kg}))?</td>
<td></td>
</tr>
<tr>
<td>Is the patient being continuously monitored by at least one of ECG, BP, or pulse oximetry?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>After the scan</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Has the cardiologist/physiologist checked the device parameters and reprogrammed the device to normal pacing mode?</td>
<td></td>
</tr>
</tbody>
</table>

**Additional considerations for patients with non-MR conditional devices**

- Have all alternative imaging modalities been considered?
- Has the referring clinician stated in writing that the information will materially change management/outcome/quality of life to outweigh the risk and discussed this with the patient’s cardiologist?
- Has the patient consented in writing with the uncertainty of risk communicated?
- Pre-MRI device interrogation and programming:
  - Non-pacing-dependent patients should be programmed to non-tracking/non-pacing mode (OOO) if available, or otherwise inhibited mode (VVI/DDI).
  - Pacemaker-dependent patients should be switched to asynchronous mode (VOO/DOO), with maximum output settings.
  - All anti-tachycardia/shock therapies should be programmed off for ICD patients.

Being able to perform MRI on patients with CIED is important. Approximately 1 in 50 people over the age of 75 have a CIED, with over 40,000 new devices implanted per year in England alone.\(^2,7\) Given that nearly one in five of those patients with new devices will need an MRI scan within the first 12 months,\(^7\) 7000 patients with new devices should be undergoing CMR scans per year based on current figures (17% of 40,000); a factor of 7 greater than are currently being performed, and this calculation ignores all those with existing devices who may also need scans.

Currently, less than one in two MRI departments in England provide scanning for patients with MR-conditional CIEDs, and just one in 28 departments for those with non-MR-conditional CIEDs. The barriers appear multiple. Part of it appears to be demand: there is a lack of awareness among radiology, cardiology, and referring physicians concerning the potential for MR in patients with MR-conditional CIEDs. It is likely that this lack of awareness is meaning that patients are receiving sub-optimal imaging and therefore sub-optimal healthcare with potential detrimental sequelae. Increased education and guidelines directed at a wider medical population are needed to increase referrals and to stimulate imaging departments to develop the infrastructure with which to provide MRI services to patients with MR-conditional devices.

Despite the modifications that have been made to render CIEDs MR-conditional, scanning still requires adherence to strict protocols, precautionary measures and planning, Table 2. Meeting these criteria requires coordination between radiology and cardiology services and local champions. A lack of cardiology support was the most frequently cited reason for not scanning, although the majority of departments had a local cardiology service and/or pacing clinic onsite. A more collaborative, possibly nationally planned approach seems needed and may facilitate service development— including available guidelines and template protocols for local adaptation. There may be limited capital costs needed also—15% of departments reported not using either ECG or oximetry monitoring while scanning when this is required.

For non-MR-conditional CIED scanning, data to support ‘off label’ MRI are growing. The harmful effects of MRI seen in the early reports were frequently due to scans being performed without knowledge of the presence of a device. Summarized data from 14 studies \(800\) pacemaker patients and \(11\) studies \(300\) ICDs scanned at \(1.5\) T had no major adverse events reported.\(^1\) The MagnaSafe registry \(\text{(http://www.magnasafe.org)}\) is the largest study assessing the safety of non-thoracic MRI scanning in pacemaker and ICD patients (with non-MR-conditional devices).\(^7\) Preliminary findings based on
1500 studies, performed in 19 different US centres, demonstrate no deaths, loss of capture, or ventricular arrhythmias during non-thoracic MRI at 1.5 T. Potentially, clinically relevant change in device parameters (changes to lead impedance, sensitivity and thresholds, or battery voltages) were however seen in 12% of pacemaker patients and 29% of ICD patients, although no clinically significant durable device parameter changes were noted. European Society of Cardiology guidelines suggest that in patients with conventional cardiac devices, MR at 1.5 T can be performed with a low risk of complications if appropriate precautions are taken (class IIb indication). We would recommend that careful consideration should be given as to whether the benefit of MRI scanning is deemed to outweigh the potential risk on an individual patient basis, and that each case is discussed between the cardiologist, radiologist, and referring clinician. We would advocate clear documentation of written informed patient consent to scanning, to ensure that patients are made aware of the (albeit small) potential risks. Additional safety measures are also recommended for scanning all cardiac devices (both MR conditional and non-MR conditional) including having a cardiologist or cardiac physiologist available to reprogramme the device, an external defibrillator with transcutaneous pacing available within the department and continuous monitoring throughout the scan.

There have previously been concerns regarding degradation of image quality (particularly of thoracic and cardiac MRI scans) from artefacts arising from the device generator and leads, thereby limiting the diagnostic quality of studies. Recent published evidence and anecdotal experience suggest that image quality is generally diagnostic, even in cardiac MRI, in almost all cases (Figure 4). The generalisability of the results of this survey to other countries and healthcare systems is difficult to predict as no data have previously been published. However, the response rate to this survey is significantly higher than is usually expected from such surveys (86% of hospitals approached provided responses, representing 97% of acute NHS Trusts in England). We can therefore be confident that these results illustrate contemporary practice in NHS hospitals. Published data on CIED implantation rates suggest that England lags behind the USA and other European countries, and patients are also less likely to undergo MRI scanning in general. In addition, NHS-funded secondary care in England is generally provided via general hospitals in which most specialities, including MRI and cardiology, are co-located. Recently published epidemiological data from the USA have found that MRI utilization is lower in ICD patients compared with non-implant patients, despite similar co-morbidities—one in 25 ICD patients would have qualified for imaging for a recorded stroke/TIA, yet <1% received an MRI for this indication. Together, this suggests that the problem of access to MRI scans in CIED patients is likely to be similarly shared by other countries and healthcare systems.

**Conclusion**

This is the first report of the national provision of MRI scanning for patients with implanted cardiac devices. Overall less than half (46%) of MRI departments in England currently offer a service for patients with MR-conditional CIED’s, and only 4% of departments will scan patients with non-MR-conditional devices, despite extremely low reported complication rates. Given the rising numbers of patients with implantable cardiac devices and the increasing clinical need for MRI scans, there appears to be both under-referral and under-provision of MRI services for this patient population. Cross-discipline education and collaboration may hold to key to open up provision of MRI services to patients with CIEDs; however, the importance of adhering to clear safety protocols should not be overlooked.

**Supplementary material**

Supplementary material is available at Europace online.

**Funding**

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**Conflict of interest:** none declared.
Appendix

MRI and Implantable Cardiac Devices
A National Audit by The Heart Hospital

1. What is your role?
   ○ Radiologist
   ○ Cardiologist
   ○ Superintendent Radiographer

2. Which hospital is your MRI unit based in, and as part of which NHS Trust?

3. Is your unit aware of MRI-conditional pacemakers?
   ○ Yes
   ○ No

4. Does your hospital have a cardiology department (including pacing clinics) on site?
   ○ Yes
   ○ No

5. Does your unit scan patients with MRI-conditional pacemakers?
   ○ Yes
   ○ No - Go to Q12

6. Does your unit perform cardiac MRI scanning?
   ○ Yes
   ○ No

7. Does your unit acquire thoracic/cardiac (in addition to extra-thoracic) scans in pacemaker patients?
   ○ Yes
   ○ No

8. How many scans have you performed in patients with pacemakers in situ in the past 12 months?
   ○ 0
   ○ 1-10
   ○ 10-20
   ○ 20-50
   ○ 50+

9. Which of the following precautions are taken when scanning these patients?
   ○ Request discussed with cardiologist
   ○ Written standard operating procedure in place
   ○ Cardiologist / cardiac physiologist present on site
   ○ Cardiologist / cardiac physiologist present in the department
   ○ Radiologist present in the department
   ○ Continuous ECG monitoring
   ○ Continuous BP monitoring
   ○ Continuous pulse oximetry monitoring
   ○ Other (please specify)

10. Have you ever had any complications scanning these patients?
   ○ Yes, serious (E.g. Arrhythmias, pacemaker malfunction requiring replacement)
   ○ Yes, minor (E.g. Device parameters altered and re-programming required)
   ○ No

11. Does your unit scan non-MR conditional pacemakers/defibrillators?
   ○ Yes
   ○ No

12. What is/are the reason(s) for not scanning patients with MR-conditional pacemakers?
   ○ Unaware of MRI-conditional devices
   ○ Concerns re patient risk
   ○ Lack of training
   ○ Lack of support from cardiology or pacing clinic
   ○ Lack of evidence based for safety
   ○ Logistical difficulties
   ○ Other (please specify)

13. What would encourage you/your unit to start scanning these patients?
   ○ Formal training
   ○ NICE guidance
   ○ More evidence of safety
   ○ Better collaboration with the local cardiologists
   ○ Other (please specify)

References