Provision of MRI Scanning for Patients With 'MR-Conditional' Cardiac Implantable Electronic Devices – an Unmet Clinical Need.

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ABSTRACT

Aims: Increasing need for magnetic resonance imaging (MRI) has driven the development of MR-conditional cardiac implantable electronic devices (CIEDs - pacemakers and defibrillators), however patients still report difficulties obtaining scans. We sought to establish current provision for MRI scanning of patients with CIEDs in England.

Methods: A survey was distributed to all hospitals in England with MRI, to assess current practice. Information requested included whether hospitals currently offer MRI to this patient group, the number and type of scans acquired, local safety considerations, complications experienced and perceived obstacles to service provision in those departments not currently offering it.

Results: Responses were received from 195 of 227 (86%) of hospitals surveyed. Although 98% of departments were aware of MR-conditional devices, only 46% (n=89) currently offer MRI scans to patients with CIED's; of these, 85% of departments perform ≤10 scans per year. No major complications were reported from MRI scanning in patients with MR-conditional devices. Current barriers to service expansion include perceived concerns regarding potential risk, lack of training, logistical difficulties and lack of cardiology support.

Conclusion: Provision of MRI for patients with CIEDs is currently poor, despite increasing numbers of patients with MR-conditional devices and extremely low reported complication rates.

Key words: magnetic resonance imaging, pacemaker, defibrillator, MR-conditional, safety

Condensed Abstract

Patients with 'MR-conditional' CIED's report difficulties with accessing MRI diagnostic services. This study found that overall less than half (46%) of MRI departments 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.

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 centers scanning more than 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.

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) 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 shows CIED implantation rates of 837 per million in England for 2013-14, a figure that is growing rapidly.(2) The need for MRI is often high in patients with CIEDs - up to 75% will need an MRI scan during the lifetime of the device, and 17% within the first 12 months.(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 3T MRI machines and are relaxing their safety precautions on 1.5T MR-conditional devices, to allow 3T 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,(4) an approach endorsed in 2013 by the ESC provided the risk-benefit ratio is favourable.(5)

Practically, a CIED MRI service requires cooperation between radiology and cardiology departments for the benefit of patients that are typically from another department (for example 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.

METHODS

Survey distribution

A list of all NHS Trusts and hospitals with MRI departments within England was obtained from NHS 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 (for example, 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 categorised according to comment themes.

Statistics

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

RESULTS

Survey response

Responses were received from 201 out of 233 (86%) of hospitals surveyed, representing 153 out of 158 (97%) of acute NHS trusts in England. Of these responses, 6 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 MRI scanning CIED patients

MR-conditional CIEDs: 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. 51 out 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). 7 sites performed MRI scanning in patients with CIEDs without onsite cardiology services.

Overall activity levels were low, Figure 1. 6% 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 3 departments scanned more than 20 patients per year. One department currently offers scans only to patients with devices implanted at the same hospital site.

Non MR-conditional CIEDs: only 4% (7 out 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%) 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, 22% blood pressure monitoring), 15% of departments reported imaging patients without any haemodynamic monitoring.

Reported complications from MRI in CIED patients

MR-conditional CIEDs: 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 MR-conditional CIEDs: 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 CIEDs

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, lack of evidence of safety, lack of training and logistical difficulties and 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 3T 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 recognise and address barriers.

Being able to perform MRI on patients with CIED is important. Approximately one in fifty people over the age of 75 have a CIED, with over 40,000 new devices implanted per year in England alone.(2,6) Given that nearly one in five of those patients with new devices will need an MRI scan within the first 12 months,(3) 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 amongst 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 patients are receiving sub-optimal imaging and therefore suboptimal 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. A more collaborative, possibly nationally planned approach seems needed and may facilitate service development – including available guidelines and template protocols for local adaptation. We would advocate improved interaction between radiology and cardiology departments – without the cooperation of both parties, it seems unlikely that the current underprovision of services will be addressed.

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 is 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. Summarised data from 14 studies (800 pacemaker patients), and 11 studies (300 ICDs) scanned at 1.5T had no major adverse events reported.(1) The MagnaSafe registry (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).(4) 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 1.5T. 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.(7) ESC 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).(5) 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 MR imaging, in almost all cases (Figure 4).(8,9)

The generalizability of the results of this survey to other countries and healthcare systems is difficult to predict as no data has 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 US and other European countries (2), 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 US has found that MRI utilization is lower in ICD patients compared to non-implant patients, despite similar co-morbidities – one in 25 ICD patients would have qualified for imaging for a recorded stroke/TIA, yet less than 1% received an MRI for this indication.(10) 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 opening up provision of MRI services to patients with CIEDs, however the importance of adhering to clear safety protocols should not be overlooked.

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

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

Reported complications from hospitals offering MRI scanning to patients with cardiac implantable electronic devices	**N (%)**
None	82 (92%)
Minor Complications (e.g. Device parameters altered and re-programming required)	5 (6%)
Serious Complications (e.g. Arrhythmias, pacemaker malfunction requiring replacement)	1* (1%)
Not specified	1 (1%)

Table 2. Considerations when imaging patients with MR-conditional cardiac implantable electronic devices using MRI (based on published guidance and literature)(5,11,12)

Before the scan
Can the clinical information be obtained using a different imaging modality?
Is the scanner 1.5T with maximum gradient slew rate <=200 T/ms^{-1}?
Are the generator and all leads confirmed to be part of a (manufacturer-specific) MR conditional system?
Has the device been implanted for > 6 weeks on the date of the scan?
Is the device located pectorally (no abdominal systems)?
Are all leads intact? No fractured, capped or abandoned leads, adaptors or devices?
Are lead/device parameters within limits and with adequate safety margins? • battery not approaching end of life • sensitivity, impedance and threshold of all leads within normal limits
Is there an external defibrillator with transcutaneous pacing capability available in the MRI suite, and are staff trained to use it?
Is there a suitably trained cardiac physiologist / cardiologist available to program the device to enable MR scanning?
Is the device programmed to MRI safe mode?
During the scan
Are all MR protocols run in 'Normal' mode (SAR ≤ 2.0 W/kg; head SAR ≤ 3.2W/kg)?
Is the patient being continuously monitored by at least one of ECG, BP or pulse oximetry?
After the scan
Has the cardiologist / physiologist checked the device parameters and reprogrammed the device to normal pacing mode?
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.

FIGURE LEGENDS

Figure 1: Number of MRI scans performed in patients with MR-conditional CIEDs per hospital in the preceding 12 months.

Figure 2: Reported safety precautions undertaken when scanning MRI conditional CIED patients (in departments who currently perform this service).

Figure 3: Reported reasons for not scanning patients with MRI conditional CIED's (from departments currently not offering the service)

Figure 4 Example cardiac MRI images obtained in patients with MR-conditional pacemakers implanted on the left side.

Panel A shows a still image from a standard short axis SSFP sequence acquired on a Siemens 1.5T MRI machine (Supplementary movie file 1). Artefact from the device generator and pacing lead within the right ventricle are visible (arrows), but do not limit image quality or interfere with diagnostic accuracy.

Panel B shows a still image from a standard 4-chamber SSFP cine in a different patient with artefact from the RA and RV pacing leads (arrows) but no artefact from the generator in this image. The images obtained from this study were of sufficient diagnostic quality to make the diagnosis of arrhythmogenic right ventricular cardiomyopathy (supplementary movie file 2).

Appendix

MRI and Implantable Cardiac Devices

A National Audit of Service Provision

1. What is your role within the department?
   - 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 MR-conditional pacemakers?
   - Yes
   - No
4. Does your hospital have a cardiology department (including pacing clinic) on site?
   - Yes
   - No
5. Does your unit scan patients with MR-conditional pacemakers?
   - Yes
   - No – Go to question 12
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 has your unit performed in patients with pacemakers in situ in the past 12 months?
   - 0
   - 1-10
   - 11-20
   - 21-50
   - 51+

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 (eg arrhythmias, pacemaker malfunction requiring replacement)
    - Yes, minor (eg device parameters altered required re-programming)
    - 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 MR-conditional devices
    - Concerns re patient risk
    - Lack of training
    - Lack of support from cardiology or pacing clinic
    - Lack of evidence-base 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)