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Safe use of MRI in people with cardiac implantable electronic devices

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ABSTRACT

MR scanning in patients with cardiac implantable electronic devices (CIEDs) was formerly felt to be contraindicated, but an increasing number of patients have an implanted MR conditional device, allowing them to safely undergo MR scanning, provided the manufacturer's guidance is adhered to. In addition, some patients with non-MR conditional devices may undergo MR scanning if no other imaging modality is deemed suitable and there is a clear clinical indication for scanning which outweighs the potential risk. The following guidance has been formulated by the British Heart Rhythm Society and endorsed by the British Cardiovascular Society and others. It describes protocols that should be followed for patients with CIEDs undergoing MR scanning. The recommendations, principles and conclusions are supported by the Royal College of Radiologists.

INTRODUCTION

MRI is used increasingly for diagnostic purposes and to assess responses to treatment.[1] Formerly, MR scanning of patients with cardiac implantable electronic devices (CIEDs; insertable cardiac monitors, pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy devices (CRT-P/D)) was felt to be contraindicated because of the risk of harm to the patient or device.[2–4] However, the recognition that many patients with a device will have a lifetime indication for an MR scan has led to the development of *MR conditional* CIEDs which allow patients to undergo MR scanning safely. In addition, selected patients with *non-MR conditional* CIEDs have undergone MR scanning without deleterious effects on either the patient or on device function.[5 6] The presence of a CIED is, therefore, not an absolute contraindication to an MR scan.

Permanent cardiac pacemakers, ICDs and CRT devices are implanted as 'systems' comprising the device generator and lead or leads, which connect the device to the cardiac muscle. Manufacturers can describe a system as *MR conditional* only when the whole system is made by the same manufacturer—mixed manufacturer systems have not been tested in this way. In those with non-MR conditional devices, additional precautions apply, as outlined below.

This document sets out to clarify the protocols which should be followed in order for a patient with a CIED to undergo an MR scan safely. Special attention must be made to ensure the device manufacturer is identified and manufacturer-specific conditions are adhered to.

BACKGROUND

After the introduction of MR into the clinical environment in the 1980s, imaging of patients with cardiac pacemakers, ICDs and CRT devices was felt to be contraindicated due to the following concerns:[3]

1. Damage to the device causing temporary or permanent modification of function
2. Movement and/or vibration of the pulse generator or lead(s)
3. Excessive heating of the leads
4. Induced currents in the leads
5. Inappropriate sensing, triggering or activation of the device
6. Electrical reset and reed switch malfunction

These effects could potentially lead to inhibition of pacemaker output, asynchronous pacing, rapid paced rates or induction of ventricular fibrillation. However, many of the deleterious effects seen in early reports were in patients who underwent MR scanning without being recognised to have had a CIED, which had not therefore been appropriately reprogrammed for the procedure.[2 7 8]

MR scanning in patients with MR conditional devices

The development of MR conditional devices has allowed patients with specified implantable cardiac monitors, pacemakers, ICDs and CRT-P/D devices to undergo MR scanning safely. These devices include hardware modifications including a reduction in the ferromagnetic content of generators and leads, the replacement of reed switches with solid state technology and bandstop filters in the generator casing or lead to prevent damage to the device circuitry. In addition, software changes such as a dedicated MR pacing mode allows simple reprogramming of the device for the MR scan. MR 'safe' activation reprogrammes the device to OOO for non-pacing dependent patients or VOO pacing for dependent patients, reducing the risk of inappropriate pacing inhibition. Furthermore, most devices in MR 'safe' mode will pace with an increased pulse amplitude and duration to reduce the risk of loss of capture.

Patients with MR conditional systems undergoing scans within the indications of the device should have the device programmed according to the manufacturer's instructions and the patient monitored appropriately. There is little or no risk of significant harm to the patient. Implantable cardiac monitors (ECG loop recorders) should also be interrogated and the stored data downloaded, as it is likely to be erased by the strong magnetic field.

See box 1 for checklist for patients with MR conditional devices who require MR scanning.

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Box 1 MRI: cardiac implantable electronic device checklist for imaging MR conditional devices

This checklist is in addition to a standard MR safety questionnaire.

Before the scan:

- Is the scanner 1.5 T with maximum gradient slew rate ≤200 T/m/s?
- Is the pacemaker or defibrillator documented as MR conditional?
- Are the leads all documented to be MR conditional?
- Are leads and generator part of a manufacturer-specific 'pacing system?', that is, no mixing of different manufacturer's devices and leads
- Have generator and lead parameters been recorded as within acceptable limits as per manufacturers guidance?
- Date implanted (must be >6 weeks before MR scan, unless urgent clinical need):
- Implanted position (must be either right or left pectoral implant) Specify which:
- Confirm there are no other leads (previously abandoned), adaptors or devices, or lead fractures.
- Are at least two MR radiographic staff present and are they aware of the evacuation procedure and trained in MR safety?
- Is there an external defibrillator with external pacing capabilities in the MR suite, and are trained staff available to use it?
- Is there a suitably trained cardiac physiologist/cardiologist present on site responsible for programming the device to enable MR scanning, and download device data that may be erased by the scan (N.B. implantable loop recorders)?
- Is the device programmed to MR 'safe' mode?

During the scan:

- Are all MR protocols run in 'Normal' mode (SAR ≤2.0 W/kg; head SAR ≤3.2 W/kg)?
- The patient is *not* positioned on his or her side within the scanner. Confirmed?
- Local transmit or transmit/receive coils are *not* placed over the pacing system, when possible. Confirmed?
- Is the patient monitored (results should be recorded) by at least one of the following means—pulse oximetry and/or ECG?

After the scan:

- Has the radiologist confirmed the patient is stable?
- Has the cardiologist/physiologist checked the device parameters and reprogrammed to normal device mode?

MR conditions for use

Each device manufacturer has issued guidance on the protocols required for patients with MR conditional devices undergoing an MR scan. Currently, the following general principles apply:

MR scanner requirements

- Hydrogen proton MRI equipment with a static magnetic field of no greater than 1.5 T (exceptionally 3 T) currently (excitation frequency 64 MHz)
- Radiofrequency magnetic fields of approximately 64 MHz in a 1.5T static magnetic field
- Horizontal closed-bore cylindrical magnet
- Gradient system with a maximum gradient slew rate performance per axis of ≤200 T/m/s
- Whole-body specific absorption rate (SAR) as reported by the MR equipment ≤2.0 W/kg and head SAR ≤3.2 W/kg (ie, 'Normal' operating mode should be selected)

Patient and device requirements

- Clear documentation of the device and lead type in the patient's notes or on the patient identity card (this is also available via the national database held by British Heart Rhythm Society and National Institute for Cardiovascular Outcomes Research, if required). Both device and leads must be confirmed as MR conditional prior to scanning (check manufacturer's website prior to scan—see online supplementary appendix). Most MR conditional devices allow whole-body MR scanning, but some have a thoracic exclusion zone. MR scanning should not be completed on a body part for which the device is not labelled. If this is required on clinical grounds the device should be treated as a non-MR conditional (see below). Radiographic markers that indicate an MR conditional device may be used to confirm its presence, prior to scanning (figure 1)
- Pacing/ICD/CRT system implanted in either the right or left pectoral region, with endovascular leads. MR scanning is contraindicated in the presence of surgical epicardial leads, and 'free floating' superior vena cava (SVC) coils. For patients with a 'leadless' pacing system MR scanning may be performed safely if the device is MR conditional (see manufacturer's website for details)
- Implanted device in place for more than 6 weeks (<6 weeks may be acceptable for emergency MR scanning if clinical need dictates)
- No other implantable devices (including old pacemakers or abandoned leads)
- Absence of broken leads, lead extenders or adaptors
- Patient should *not* be required to be positioned on their side within the scanner

Programming to MR 'safe' mode

- All MR conditional devices should be programmed to MR 'safe' mode prior to scanning. It is important to record the lead and/or device parameters prior to scanning. This should be performed by a cardiac physiologist or cardiologist with

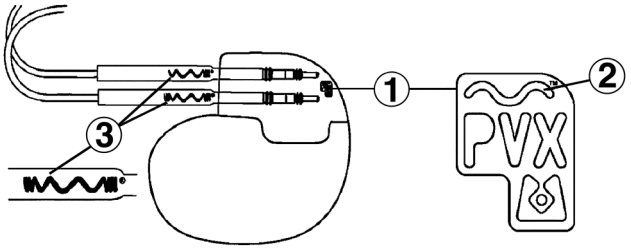

Figure 1 Example of MR conditional device and lead radiographic markers. 1—Location of device radiopaque symbol. 2—Device radiopaque MR conditional symbol. 3—Lead radiopaque MR conditional symbol (not present on all lead products). Radiographic markers that indicate an MR conditional device are illustrated above and may be used to verify the presence of an MR conditional device, prior to scanning. These are manufacturer specific and should be confirmed by reference to the websites in the online supplementary appendix. Not all MR conditional leads will have these markers.

specific training in this programming procedure. Some devices may be rendered MR 'safe' through an activating device or automatically in the presence of a strong magnetic field (see manufacturers' websites in online supplementary appendix).

Patient safety during MR scan

- The patient's heart rhythm should be monitored using ECG and/or pulse oximetry
- An external defibrillator with external pacing pads should be available within the MR suite

Note: If the patient's hemodynamic function is compromised during the MR scan, the scan should be discontinued and appropriate measures taken. This should be directed by the supervising radiologist.

MR scanning in patients with non-MR conditional devices

MR scans should not be performed in patients with non-MR conditional CIEDs unless there is no alternative method to obtain important clinical information and the information will change clinical management. In order for practicing clinicians to be able to make an informed judgement about risk and benefit, they need to be well informed about the risks of MR in patients with a device.

Patients with non-MR conditional devices may undergo MR scanning if there is a clear clinical need for this imaging modality and only at 1.5 T. In these circumstances the benefit of MR scanning must be deemed to outweigh the potential risk and each case should be considered on an individual risk/benefit ratio depending on the status of the patient and device. This is best provided by a multidisciplinary team consisting of a cardiologist, radiologist, MR responsible person and MR safety adviser (MRSA). The MRSA may liaise with the patient's device manufacturer to establish the risks of MR scanning on a case-by-case basis.

The MagnaSafe registry was a prospective multicentre study designed to determine the safety of non-thoracic MR scanning in patients with implanted non-MR conditional CIEDs.[9 10] A total of 1500 clinically indicated non-thoracic MR studies (spine 41%; brain 35%) were performed at 21 sites (1000 pacemakers, 500 ICDs, with a total of 2923 leads) with no reported deaths, device failure, generator or lead replacement, loss of capture or ventricular arrhythmia. Pacemaker-dependent patients with non-MR conditional ICDs were excluded from the registry because not all tachycardia therapies can be disabled during pacing in this group. A clinically significant device parameter change was seen in 12% of pacemakers and 29% of ICDs, with no clinically significant device parameter changes noted at 6 months. This is the most robust estimate of risk available and should be weighed and discussed with individual patients in the decision whether to undertake MR scanning.

Patients not fulfilling the MagnaSafe inclusion criteria are the most difficult group in which to quantify risk as there are no robust published data. The verified estimate available is that there is a 1%–5% risk of a serious adverse event, including death, and a 10%–15% (pacemaker) to 20%–30% (ICD) requirement to reprogramme the device following the scan. An individual decision on risk versus benefit should be made in such patients and scans should be performed only in centres with experience in this area with an appropriately trained cardiologist and physiologist present. For pacemaker-dependent patients with non-MR conditional ICDs, and those with non-MR conditional pacemakers implanted before 2002, the risks of inappropriate tachycardia therapies, or pacing inhibition, during MR scanning are unacceptably high, and alternative imaging modalities should be sought, if possible.

Box 2 MRI: cardiac implantable electronic device checklist for imaging non-MR conditional devices

This checklist is in addition to a standard MR safety questionnaire

Before the scan:

- Have all alternative imaging modalities been considered?
- Has the clinician stated in writing that the information will materially change management/outcome/quality of life to outweigh risk?
- Will device metal significantly interfere with image quality?
- Are there additional device risk factors for MR scanning?
  - Abdominal system
  - Retained leads/fractures
  - Implanted less than 6 weeks
- If so, patient-specific increased risks should be documented.
- Are lead/device parameters within limits and with adequate safety margins?
  - Battery not approaching end of life
  - Lead impedance/capture threshold well within normal limits
- Underlying rhythm/tachycardia therapies?
  - If adequate rhythm—switch off advanced modes and programme to OVO, ODO
  - If bradycardic (<40 bpm), programme to VOO or DOO mode
  - If no underlying rhythm, patient-specific increased risks should be documented
  - Tachycardia therapies should be disabled
- Has patient consented in writing with the uncertainty of risk communicated?
- Is cardiologist or cardiac physiologist immediately available?
- Is crash trolley with external pacing in the department and available?

During the scan:

- Is the patient being monitored by at least one of the following means—pulse oximetry or ECG?

After the scan:

- Have all pacing parameters been checked and programming changes reversed?
- Have parameters changed? If so arrange follow-up in the device clinic.

Subcutaneous ICDs are not currently MR conditional, but a recently published case series demonstrated the feasibility of MR scanning in this group of patients, with no reported device malfunction.[11] Further studies are required to confirm the safety of MR scanning in this patient group.

The checklist for patients with non-MR conditional devices who require MR scanning is illustrated in box 2. The additional safety measures that we would recommend include obtaining written documentation of the need for the investigation, written consent and having a cardiologist or cardiac physiologist present during the scan.

CONCLUSIONS

There is strong evidence that MR scans can safely be performed in patients with MR conditional CIEDs provided appropriate measures are undertaken. The evidence for patients with

non-MR conditional CIEDs is growing and it is now reasonable to consider MR scans, where clinically important, in such patients on an individual basis where a decision on risk versus benefit can be made.

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