

Safety of cardiovascular magnetic resonance in patients with cardiovascular implants and devices

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Cardiovascular magnetic resonance is very safe, but occasional serious complications may occur in patients with some implants or devices. Pacemakers currently present the largest problem, but new research shows that the perceived dangers have been overestimated and in particular new lead solutions are emerging. Common implants that may be scanned safely include sternal and epicardial wires, prosthetic valves, and stents.

while some metals and all non-metals are diamagnetic, indicating that they are slightly repelled by a magnetic field. Clinical issues of safety of CMR relate only to devices with ferromagnetic components. It is important, however, to distinguish between iron and high grade steel. Iron is ferromagnetic whereas the steel used in human implants is usually not, because of impurities added to the iron to give it strength and prevent rusting.

Magnetic field interactions

Any ferromagnetic object placed in a magnetic field will be subject to forces of deflection, attraction, and torque. This has the potential to lead to injury in two ways. The first potential for injury is from projectiles. Objects made with low grade steel which retains ferromagnetic properties, such as scissors, oxygen cylinders, and wheelchairs, can be attracted into the magnet. These and other metallic objects are therefore routinely banned from MR suites. Specially designed wheelchairs, trolleys, and anaesthetic equipment made of aluminium are available and must be unequivocally labelled as MR safe, and not released from the MR suite. As a corollary to this, resuscitation of patients suffering cardiac arrest in the MR suite must begin with evacuation of the patient from the MR scanner room.

The second potential for injury is with implanted devices, because of the possibility of movement. Translational attraction is measured by the deflection angle test.² Factors affecting it are mainly the strength of the magnetic field, the degree of ferromagnetism of the object, its mass and location, and the presence of retentive tissues such as fibrosis, skin, sutures, or bone. At 1.5T, CMR can be performed safely if the metallic object is non-ferromagnetic or is weakly ferromagnetic, whereby it is only minimally attracted by the magnetic field in relation to its in vivo application. That is to say that the attractive force is insufficient to move the implant in situ or affect its intended function. Ex vivo evaluation of devices by manufacturers and safety regulatory bodies provides information on this. An example of a safe implant would be a hip prosthesis. One example where there may be problems is the neurovascular clip. These are placed on delicate neural vessels—for example, after subarachnoid haemorrhage—and cases of dislodgement have occurred. If CMR is required in such patients, it is usually possible, but advice should be taken from expert centres

Cardiovascular magnetic resonance (CMR) is a new and important tool for the evaluation of patients with cardiovascular disease. Because of relative unfamiliarity, some cardiologists may not be fully conversant with safety issues associated with this technique in patients with cardiovascular implants and devices. The aim of this article is to summarise where the problems are and what solutions are available or forthcoming. In some areas, we will also dispel myths which are sometimes held in the absence of any actual evidence and present a common sense approach which has been adopted by expert centres in clinical practice using 1.5 Tesla (T) scanners.

The basic principle of MR relies upon the application of radiofrequency pulses (RF) within a strong magnetic field. Hydrogen nuclei absorb the RF, and re-emit it after a short delay as a detectable signal which can be converted into images. Because there are no *x* rays, there are no known genetic effects or changes in chemical binding. Thus CMR shares with ultrasound an inherent safety advantage over *x* ray techniques. However, unlike either ultrasound or *x* ray techniques, there is interaction of the magnetic field with ferromagnetic materials (potential for movement) and electronic circuits (dysfunction or damage), and the RF may produce heating under certain limited circumstances.¹ These phenomena require special attention for CMR.

GENERAL PRINCIPLES

Ferromagnetism

The prefix *ferro-* in ferromagnetism relates to the element Iron (Fe). Iron is, however, not the only magnetic element and four other transition metals are also strongly magnetic: cobalt (Co), dysprosium (Dy), nickel (Ni), and gadolinium (Gd). In addition, there are a relatively large number of ferromagnetic alloys and oxides. Most metals are paramagnetic, which indicates that they are weakly attracted by a magnetic field,

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Abbreviations: CMR, cardiovascular magnetic resonance; ICD, implantable cardioverter-defibrillator; RF, radiofrequency; T, Tesla

with full details of the manufacturer and type of clip implanted.

Induced electrical currents

CMR of patients with devices containing conducting materials exposes these materials to RF and pulsed gradient magnetic fields which have the potential to cause harm by inducing electrical currents. RF pulses can induce heating if there is sufficient coupling to the RF wavelength. This includes pacing wires, guide wires, and indwelling catheters with metallic components such as thermodilution catheters.³ Pacemaker leads are a particular issue because of their chronic indwelling use and their length, which at high field strengths begins to approach the wavelength of the RF. This may allow significant coupling and therefore heating. The dimensions, orientation, shape, and location of the metallic implant all play a role.⁴ Finally, exposure to the electromagnetic field used by CMR scanners may inhibit or modify the operational or functional settings of an electronic implant.

SAFETY OF CARDIOVASCULAR DEVICES

Patient screening before CMR

Proper screening of patients before CMR is essential, and this should be in the form of a questionnaire,⁵ which is completed and signed by the patient, and cross signed by the CMR staff.

ECG leads

Standard metallic ECG tabs may induce burns during CMR, and should not therefore be used. Carbon based ECG electrodes and leads with a higher impedance are available which are safe for CMR and do not produce artefact.

Sternal and epicardial pacing wires

Scanning patients with sternal wires is safe.^{6,7} In patients with retained epicardial pacing wires following cardiac surgery, there are no reports of adverse events or arrhythmias during CMR up to 1.5T with conventional pulse sequences.⁸ There is a small artefact but this is localised and rarely interferes with image analysis.

Heart valve prostheses and annuloplasty rings

At 1.5T, all heart valve prostheses and annuloplasty rings are CMR compatible.⁹ Those tested at 3T so far are also compatible.² Magnetic field interactions are either nil or very small and are minimal compared to the force exerted by the beating heart. Induced currents and RF heating do not appear to be problematic.¹⁰ No documented adverse patient incidents have been reported. Previous concerns about the Starr-Edwards Pre-6000 prosthesis were unfounded. Prosthetic valves cause localised artefact but this rarely affects image interpretation.

Coronary stents

CMR could in theory lead to heating or movement of coronary stents. Sophisticated in vitro trials show that the heating effect is tiny, and would have no clinical effects.¹¹ Dislodgement is also a possibility that could, in principle, increase exposure of metallic coronary stent material to platelets which might trigger stent thrombosis. However, the majority of available coronary stents are made from non- or weakly ferromagnetic materials (316L stainless steel, nitinol, or titanium), and in vitro trials show very minimal magnetic attraction.¹² In the Mayo series of patients who underwent MR at 1.5T for severe co-morbidity less than eight weeks after standard coronary stent placement, no case of thrombosis was identified and there was no increased risk of mortality over a 30 day period post-deployment.¹³ In a study of patients at day 3 post-coronary stent deployment, there was no increase in adverse events compared to control groups after

seven months follow up.¹⁴ These clinical studies support animal work showing that coronary stent migration is absent or minimal.¹⁵

The development of new mixed alloy coronary stents incorporating cobalt and other metals will need evaluation for CMR compatibility, but as the mass of the stent is small, it is unlikely that results will be different. Therefore, for correctly deployed coronary stents, there is a very low likelihood of movement or heating and it is safe to perform CMR immediately after placement. However, the product insert for many of these coronary stents indicates a period of 6–8 weeks after placement before CMR. We have found nothing in the published literature to support this apparently arbitrary assertion and there are no reports of attributable adverse events associated with early CMR. Established practice worldwide is for CMR to be performed at any time after implantation, and all the available evidence supports this approach. A small artefact may be seen at the site of a coronary stent, which is sometimes useful for localisation.

Other vascular stents, and coils and filters

Non-coronary intravascular stents (such as those used in the aorta), as well as coils and filters can be imaged at any time after implantation if they are non-ferromagnetic.^{3,16} For stents which have some magnetic attraction, it has been stated that it is prudent to delay CMR for approximately six weeks,³ although there is no evidence to support this assertion, and early CMR has been reported without adverse effect.¹⁷

Occlusion devices

Metallic occlusion devices are used for closure of shunts. Provided the correct sized device has been deployed, the retentive forces due to the shape of the device and later from tissue growth outweigh those from the applied magnetic field. When the device is made of non-ferromagnetic alloy (for example, MP35N), patients may be scanned immediately after implantation. For devices made of weakly ferromagnetic steel, a delay of six weeks has been recommended but evidence in this area is very limited.¹⁸

Cardiovascular catheters

Ex vivo evaluation of a number of different catheters has been carried out. Catheters with any form of metallic component including internal or external conductive wires present a contraindication to CMR.⁷ In general those made out of polyurethane and polyvinyl chlorides are safe. Certain thermodilution pulmonary flotation catheters include a conductive wire which may malfunction and cause injury through excessive heating.³

Guidewires

Conventional guidewires are made from stainless steel or nitinol. The RF may induce excessive heating and consequent damage. For the growing field of interventional CMR, specially designed guidewires with RF decoupling are used which restricts the heating.¹⁹ Care should also be exercised with the choice of sequences used.

Intra-aortic balloon pumps and left ventricular assist devices

Due to their high metallic content, these devices with their associated equipment are not considered suitable for CMR, although there is little evidence in the literature. Problems include mechanical malfunction, heating, and the risk of tissue damage.

Pacemakers

The issue of CMR in patients with pacemakers is not straightforward and is currently in a stage of re-evaluation and change. The simplest summary edict is that in 2004,

“pacemakers are a strong relative contraindication to CMR”. However, this statement merits further expansion in order to explain the absence of “absolute contraindication”, which many would consider appropriate.

The reasons for the contraindication of CMR in patients with pacemakers are at least fivefold. First, the magnetic field may cause movement of the pacing box. This is not particularly problematic, because experience has shown that the pacemaker pouch has sufficient strength to hold the pacemaker in position, but if necessary, superficial strapping can be used. Second, RF induced heating of the pacing leads might cause injury to the myocardium or vessels. This is known to be significant and in the experimental setting, and lead temperatures of more than 60°C have been recorded.²⁰ While this is ameliorated in vivo by the constant flow of blood over the lead, this clearly is of concern. Third, the RF and gradient magnetic fields may induce interference with the electronic circuits of the pacemaker,²¹ or induce currents in the pacemaker lead which might be interpreted by the pacemaker as myocardial electrical activity leading to inhibited or very rapid pacing. Fourth, at least in older pacemakers, both temporary and permanent alteration in pacemaker settings have been described.²² Finally, the most important evidence for the contraindication of CMR in pacemaker patients is the documented mortality that has occurred.^{23–25} It is thought that this was related to pacing inhibition, malfunction of the magnetic reed switch, or induction of rapid pacing rates that are incompatible with sustaining cardiac output as a consequence of induced electrical currents.^{7 26}

However, having noted all of the above problems and the documented mortality, there are now a growing number of more up-to-date reports of CMR being performed safely in pacemaker patients in field strengths from 0.35–1.5T,^{27–30} with 54 patients in the largest and most recent trial at 1.5T.³¹ How can this be explained? One key issue is that the mortality reports suggest that the heart was not the organ under examination by MR. Although not explicitly stated, it is highly likely that this means that no ECG was being monitored during the MR, and that no measures were taken to reduce the risk of the MR scan. In the modern environment, CMR is always performed with continuous ECG monitoring, which would readily identify any arrhythmia. In addition, blood pressure and oxygen saturation monitoring are normally available in CMR centres. Under these circumstances, it is inconceivable that a patient could die unnoticed as a result of cardiovascular collapse from pacemaker malfunction. Secondly, we and others have shown that in non-pacemaker dependent patients who have implanted pacemakers, the pacemaker can be turned off for the duration of the scan and the lead set to bipolar mode.^{29 30} No deaths and no significant complications have resulted from CMR scans being performed in this manner at low field, gradient, and RF sequence settings.

Thus returning to the issue of whether the presence of an implanted pacemaker is an absolute contraindication to CMR, we are forced to conclude that since safe scanning has been performed in several centres, that it can only be the case that CMR is a strong relative contraindication. However, it is important that there is no mistaking our position on this issue. The fact that it is even possible for pacemaker patients to die while undergoing MR explicitly means that such a procedure should not be undertaken outside of expert CMR centres with full pacing facilities, in circumstances where the balance of benefit unequivocally outweighs the risk, and after full informed written consent has been obtained from the patient. Our experience is that few patients fall into this category, although many patients with pacemakers are undoubtedly disadvantaged by having CMR declined. In the

event of inadvertent exposure of a pacemaker patient to MR, it is important to check the pacing function as soon as possible.

Implantable cardioverter-defibrillators (ICDs)

ICDs are subject to similar risks of pacemakers but notably with greater translational attraction.³² There is one report of the safe performance of CMR in these patients.³³ The safety is therefore largely unknown and CMR should be considered to be contraindicated until more information is available.

Insertable loop recorder systems

Devices such as the Reveal loop recorder are usually inserted subcutaneously in the upper chest area. The combination of the magnetic and RF field may erase or corrupt stored data.³⁴ Mechanical forces may cause some local movement of the device. CMR is not contraindicated in these patients provided these considerations are addressed.⁷

Scanning the unstable cardiac patient

Acutely ill patients are often the group where a definitive diagnosis will make the biggest impact on management and outcome. With proper precautions, these patients can be scanned quickly and safely. Only piped oxygen must be used in the CMR scanner room. Under no circumstances should oxygen cylinders be taken into the scanning room because they may be ferromagnetic. Intravenous pump machines should remain in the control room and connected to the patient with long lines passed through a waveguide. All anaesthetic and trolley equipment should be fully MR compatible.³⁵

3-Tesla scanners

RF heating and mechanical field interaction are related to field strength and are likely to be more problematic at 3T.³⁶ Implants with weak ferromagnetic properties at 1.5T may demonstrate increased magnetic field interactions at 3T. Much of the current safety assessments cannot therefore simply be extrapolated to the higher field strengths and stricter safety criteria are required.⁷ Certain devices such as heart valve prostheses appear safe at 3T, but wider more definitive evaluation of devices in both long and short bore scanners is still underway and therefore caution should be applied in scanning patients. There is very little clinical CMR being performed at 3T in 2004, and no clinical indications at this stage for its use in preference to 1.5T where the safety issues are much better documented.

Device evaluation

In the UK, the main regulatory body is the National Radiation Protection Board (NRPB) which acts as the official advisor to the Department of Health. They provide information on the safety of specific implants and devices.³⁷ A comprehensive list of implants that have been tested for MR safety or compatibility is readily available.⁷ There are other additional sources of reference available.^{38–40}

Future strategies

Research efforts are underway to improve the safety of CMR studies in patients with pacemakers and ICDs. This includes the use of fiberoptic cardiac pacing leads in place of standard metallic leads, and a low power semiconductor laser to stimulate the heart.⁴¹ The optic cable is very robust and is not affected by the magnetic field or RF heating. Alternatives include decoupling the pacemaker lead to prevent RF heating, as has been achieved for MR interventional guide wires, and improving the immunity of the electronics from interference. It is likely that these new devices will undergo clinical evaluation within the next few years. Work is also underway on artefact-free stents to enable better in-stent visualisation.⁴²

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