Original Article

Implantable Devices and Magnetic Resonance Imaging

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The indications for cardiovascular implantable electronic devices (CIEDs) are ever expanding, seemingly in parallel to the similar widespread increase in the use of magnetic resonance imaging (MRI), where there are clear advantages of imaging with no ionizing radiation and superior tissue contrast. However, CIEDs have traditionally been considered an absolute contraindication to MRI, posing a major limitation to investigating various pathologies after implantation of such devices. In the last decade the traditional paradigm of avoiding MRI in patients with CIEDs has been challenged with studies demonstrating relative safety at 1.5 T under certain circumstances. Now with the recent approval of 'MR conditional' devices, it is becoming increasingly apparent that CIEDs should no longer be considered an absolute contraindication to MRI.

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Introduction

The use of cardiovascular implantable electronic devices (CIEDs), such as pacemakers and implantable-cardioverter-defibrillators (ICD), is growing, as new indications for heart failure, arrhythmia, and other cardiac conditions are established. The number of implanted CIEDs will continue to grow as the ageing population continues to increase globally. Additionally, now that there are greater numbers of adult survivors of repaired congenital heart disease, it can be expected that a greater number of younger patients will also require CIEDs in the future.

In the last decade, the use of magnetic resonance imaging (MRI) has increased exponentially [1]. Magnetic resonance imaging does not involve ionizing radiation and hence has no potentially cumulative effects where serial studies are required, and has unrestricted choice of two-dimensional or three-dimensional imaging plane. It is also superior to X-ray computer tomography (CT) in displaying soft tissue contrast of the various body organs, and can take advantage of gadolinium-containing contrast media. Thus MRI has become a very valuable and safe tool in evaluating central nervous system, musculoskeletal and cardiovascular pathologies. Therefore, it is estimated that there is a 50–75% probability of a patient with a pacemaker requiring MRI over a lifetime [2]. However, due to the ferromagnetic nature of CIEDs, as well as laboratory and clinical reports of harm, including 10 deaths in the late 1980s [2], multiple professional societies, and cardiac rhythm device manufacturers have continued to advise against MRI in patients with pacemakers and ICDs [3–5].

Laboratory and clinical studies since the mid-1990s till today, employing careful protocols on newer devices [6–10], have demonstrated no untoward complications in patients with CIEDs *in situ* undergoing MRI. This development, along with the recent regulatory approval of the first pacemaker specifically designed and proven to be safe in a MR environment [11], has assisted in the rethinking of the traditional and conservative paradigm regarding MRI of patients with CIEDs. Many professional societies have started to acknowledge that in some cases the benefit of MRI may outweigh the risks [3,4,12,13]. In the future, experience of MRI of patients with CIEDs in specialised centres is anticipated to grow for certain specified indications.

In this review, we will outline the theoretical effects of MRI on implanted CIEDs, and the results of recent major studies examining the issue of safety. We will also outline a practical check list for the safe performance of MRI in patients with CIEDs based on recent studies, as well as discuss issues related to the recently approved 'MR-conditional' pacemakers.

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Effects of MRI on Devices

Basic Physics of MRI

Water, and therefore hydrogen nuclei (protons) are abundant in the soft tissues of the human body. Magnetic resonance imaging applies a strong static magnetic field, for example 1.5 Tesla (T) (≈15,000 times the earth magnetic filed), such that otherwise randomly orientated protons within the body are aligned along the magnetic field. A radiofrequency (RF) pulse applied to the body will cause spatial changes in the axis of protons in the body and these protons will emit an RF signal detectable with a receiver coil placed on the body when the RF pulse is removed. The relaxation properties of protons after the RF pulse application are specific for different types of tissues and characterised by T1 and T2 constants, therefore allowing for the generation of image contrast. Additional fast switching magnetic gradient fields are applied to allow for slice selection or 3D encoding of the MR signal [12]. These three essential electromagnetic components of a MRI scanner may have significant effects on CIEDs, which are ferromagnetic and electroconductive.

Mechanical Effects

CIEDs usually contain small amounts of metals, such as iron, cobalt, or nickel, *etc*., and they are generally ferromagnetic [1]. Therefore, there is some concern that CIEDs may potentially move inside a MRI scanner. The newer generations of CIEDs are designed to be smaller, and consist of lesser amounts of ferromagnetic materials, therefore much unlikely to move. Even though the new-generation ICDs still attract 10 times higher magnetic force and torque than pacemakers, that force is similar to the gravity of the earth, and thus not considered to be a safety concern any more [6,14]. However, as a precaution, MRI should be delayed for at least six weeks after CIEDs implantation [15] to allow secure incorporation into tissues and hence minimising movement during MRI.

Effects on Sensing and Pacing

CIED function may be altered in the presence of strong magnetic fields. Typically effects may be due to (i) RF effects, (ii) magnetic reed switch activity, (iii) power on reset phenomenon, or (iv) induction effects.

RF EFFECTS. Oversensing of non-cardiac signals may occur, and result in inhibition of pacing and cause bradycardia–asystole in a pacemaker-dependent patient; oversensing of ventricular tachyarrhythmia by ICDs may result in inappropriate therapies, including shocks [15,16].

MAGNETIC REED SWITCH ACTIVITY. Most pacemakers and ICDs have built-in magnetic reed switches that are designed to turn ON and OFF circuitry in response to magnets. The presence of a strong background magnetic field, and fast switching magnetic gradient field inside a MRI scanner, may theoretically lead to reed switch activity becoming intermittent and unpredictable [15,17]. However, it is now accepted that these problems are mitigated by appropriately programming the CIED's prior to MRI.

POWER ON RESET PHENOMENON. The third concern is 'power on reset' phenomenon. This is a common design technique to enable a newly powered on electrical device to a known baseline state. In the circumstance of unusual input conditions such as too low or too high line voltages then a reset may be triggered for circuit stability. Cardiovascular implantable electronic devices have a variable susceptibility to resets and the mode that results is variable. Extreme magnetic fields can cause override of any previous programming in a CIED, and revert it back to factory setting, or other settings [15], which would be potentially dangerous for pacemaker-dependent patients or ICD patients. It should be noted that overall the incidence of resets is low and mostly occurs in a few known more susceptible devices. However, although a low risk, this is perhaps the greatest risk to the pacemaker dependent patient whose CIED is set to VOO mode which may reset to VVI mode, and then the CIED may stop pacing due to inhibition from RF interference. Similarly, ICDs may reset into VVI mode with tachy therapy turned on, and start inappropriately responding to RF interference.

INDUCTION EFFECTS. The lead system in a CIED is a wire, and fluctuating magnetic fields during MRI can induce a current in these leads, especially if they are of certain length or in the form of a loop or coil. The myocardial tissue near the lead tip can sustain thermal injury as the electrical energy is converted into heat [18], and cause oedema or even formation of scar tissue within the myocardium. The increase in temperature locally is limited to approximately 6° or less. Generally, by using established clinical MRI protocols, the lead tip may only heat up by <3.9 °C *in vitro*, and 0.2 °C *in vivo* [6]. Sensing and pacing threshold and impedance of CIEDs may subsequently transiently change according to these effects. In addition, the induced current can also stimulate the heart near the lead tip, so-called 'unintended cardiac stimulation' [15]. These potential risks may also occur in abandoned leads [15].

Clinical Studies of MR Effects on Implantable Devices

Pacemakers

Studies from 1980s to the mid-1990s had shown some adverse effects of MRI on CIEDs, including 10 deaths in the late 1980s [2,15–17,19]. However, the details of those deaths were not well documented, and no ECG data were available. Also, those early studies were using earlier generation pacemakers, which are no longer in use. Many prospective studies from the mid-1990s to today, using carefully designed reprogramming prior to MRI scan [1,9,10], have not found any clinically significant complications. The reported problems from these studies include: brief pacing output inhibition [20,21], temporary device communication failure [22], diminished battery voltage [10,11,23,24], reed switch activation [11,24], sensing or pacing threshold changes [9,10,22–24], and power-on-reset [24,25]; none of which led to clinically significant outcomes.