Review article

MRI SAFETY AND MANAGEMENT OF PATIENTS WITH CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES: LITERATURE REVIEW AND CASE PRESENTATION

MAGNETNORESONANČNA VARNOST IN OBRAVNAVA PACIENTOV Z VSTAVLJENIMI KARDIOVASKULARNIMI ELEKTRONSKIMI NAPRAVAMI: PREGLED LITERATURE IN ŠTUDIJA PRIMERA

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Received: 30. 12. 2021
Accepted: 26. 7. 2022
https://doi.org/10.47724/MIRTJ.2021.i02.a002

ABSTRACT

Introduction: MRI has long been contraindicated in patients with CIED devices due to the risk of adverse effects through electromagnetic interference. Recent developments in engineering have led to the introduction of MRI conditional CIED devices that do not cause significant clinical harm to patients undergoing MRI, when specific imaging conditions are met. Safe access to MRI has become a crucial need for patients with CIED devices.

Aim: The purpose of this paper is to present an overview of how to manage patients with implanted CIED devices and to present a case report of a patient with CIED undergoing prostate MRI examination.

Methods: This paper explores MRI Safety and the management of patients with implanted CIED devices through an extensive literature review and case presentation. The literature search was conducted using medical scientific electronic databases such as PubMed, Cinahl, Wiley Online Library and ScienceDirect. We examined a patient with a CIED device undergoing a prostate MRI examination.

Results and discussion: We performed an examination of the described patient in accordance to the guidelines presented in this paper. The MR conditionality status was determined using the device identification card and the manufacturer's technical manual. The MRI examination of the patient was completed without complications; therefore, no adverse effects were reported. The MRI images were without artefacts.

Conclusion: Recent clinical studies and published guidelines suggest that MRI of the patients with either an MRI conditional or MRI non-conditional CIED device is relatively safe under specific conditions. Multidisciplinary pre-procedure planning, a strict screening process, monitoring and device evaluation protocols are of key importance for ensuring safe MRI imaging in patients with CIED.

IZVLEČEK

Uvod: Magnetna resonanca je dolgo časa veljala za absolutno kontraindikacijo pri MR preiskavah pacientov z vstavljenimi CIED napravami. Tehnološki napredek na področju razvoja CIED naprav je doprinesel k uveljavitvi MR pogojno varnih kardiovaskularnih elektronskih naprav v kliničnem okolju. MR pogojno varne CIED naprave ne predstavljajo kliničnega tveganja za paciente s tovrstnimi napravami, če so upoštevani specifični pogoji uporabe. Varna izvedba MR slikanja je postala ključnega pomena pri zdravljenju tovrstnih pacientov.

Namen: Namen te raziskave je predstaviti pregled področja obravnave pacienta z vstavljeno CIED napravo med MR slikanjem in predstaviti primer MR slikanja prostate pri pacientu s CIED napravo.

Metode: V študiji smo predstavili pregled literature na področju MR varnosti in obravnave pacientov z vstavljenimi CIED napravami. Predstavili smo tudi primer obravnave MR slikanja prostate pri pacientu s CIED napravo. Literaturo smo zbirali s pomočjo elektronskih podatkovnih baz PubMed, Cinahl, Wiley Online Library in ScienceDirect.

Rezultati in razprava: Preiskavo smo izvedli v skladu s priporočili, predstavljenimi v tem dokumentu. MR status naprave smo ugotovili na podlagi pregleda identifikacijske kartice naprave in proizvajalčevih priporočil o uporabi naprave v MR okolju. Preiskava je bila opravljena brez kliničnih zapletov. Na MR slikah ni bilo prisotnih popačenj zaradi prisotnosti CIED naprave.

Zaključek: Najnovejše klinične študije in izdana priporočila ugotavljajo, da je MR slikanje pacientov s CIED napravami relativno varno v specifičnih pogojih ne glede na to, ali gre za MR pogojno varne naprave ali ne. Ključnega pomena pri zagotavljanju varnosti pri MR preiskavah tovrstnih pacientov je predhodno multidisciplinarno načrtovanje preiskave, natančen varnostni pregled/screening pacienta, kakovosten nadzor nad pacientom med preiskavo in ocena delovanja naprave po preiskavi.

INTRODUCTION

Magnetic Resonance Imaging (MRI) is a non-ionizing radiation dependant imaging modality that provides excellent soft tissue spatial resolution. MRI has long been contraindicated in patients with cardiovascular implantable electronic devices (CIED) due to the risk of adverse effects through electromagnetic interference (1). Recent developments in engineering have led to the introduction of MRI conditional CIED devices that do not cause significant clinical harm to patients undergoing MRI when specific imaging conditions are met (2).

Classification of CIED

CIED is a term that comprises pacemakers (PPM), implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy devices (CRT). CIED system traditionally consist of two components – the pulse generator and thin insulated wires called leads (3). These devices have proven to be an invaluable tool in the practice of cardiology and treatment of a variety of cardiac arrhythmias. They can be divided further based on the functionality of the device and lead placement in the human heart. Therefore, we differentiate among single chamber CIED devices, dual chamber devices and biventricular (triple chamber) devices (4). Single chamber devices consist of a single lead that attaches either to the right atrium or right ventricle. Dual chamber devices use two leads that are placed in the right atrium and right ventricle. Biventricular CIED devices are divided into two groups: CRT-P devices, which stands for Cardiac Resynchronization Therapy Pacemaker and CRT-D devices, that stands for Cardiac Resynchronization Therapy Defibrillator. Biventricular devices deliver small electrical impulses to the left and right ventricle. Leads are placed into the right atrium, right ventricle and coronary sinus. The latter delivers electrical impulses to the left ventricle (3,5). Recently a new type of CIED device has been introduced for clinical use. Leadless pacemakers were designed to eliminate some of the complications associated with transvenous pacemakers and leads: pocket infection, hematoma, lead dislodgement and lead fracture. The device is 90% smaller than the transvenous system and it consists of a small cylindrical capsule that contains a battery, an electronic control unit and a single tip electrode. The leadless pacemaker is implanted into the right ventricle myocardium via a femoral vein transcatheter approach. The downside of this device is that it provides only single-chamber ventricular pacing and lacks defibrillation capacity (3,6,7).

MRI Safety Labelling of CIED

Safe access to MRI has become a crucial need for patients with CIED devices. An estimated 50-75% of these patients may have a clinical indication to undergo MRI after the implantation over their lifetime. For this reason, new generations of cardiovascular implantable electronic devices have been designed to allow such patients to safely undergo MRI provided that specific conditions are met during the scan (8). CIED devices that are labelled as MRI conditional need to be tested in a specific MRI environment, including induced torque and force, current induction, RF heating and potential electromagnetic interference. MRI conditional labelling for CIED devices generally includes requirements for static magnetic field strength, maximum spatial field gradient, maximum gradient slew rate, maximum specific absorption rate-SAR or an alternative RF exposure parameter such as $B1+_{RMS}$ (root mean square of the flip angle). The conditions of safe use also specify the configuration of the device, allowed implant locations, device reprogramming requirements during the scan, exclusion zones, specific patient monitoring demands and required staff for device programming and monitoring. Cardiovascular implantable electronic devices that do not meet the criteria for MRI conditional labelling are considered as non-MRI-conditional. This classification includes CIED devices that have one system component labelled as MR Conditional and the other component as non-MR conditional. For example, a system that has a pulse generator labelled as MRI conditional and pacing leads that do not have MRI-conditional labelling is considered as non-MRI-conditional (2,9).

Interactions of MRI environment with CIED

The interaction of the MRI environment with CIED systems has been the root cause of a historical contraindication to the presence of a cardiovascular implantable electronic device in patients undergoing MRI. These interactions include translational attraction or torque on device components due to the spatial magnetic field gradient (8). The magnitude of the translational force will vary based on the position of the device in the MRI scanner. Stronger translational forces are exerted on the device just outside the scanner bore. However, torque is strongest in the isocenter of the MRI scanner (10).

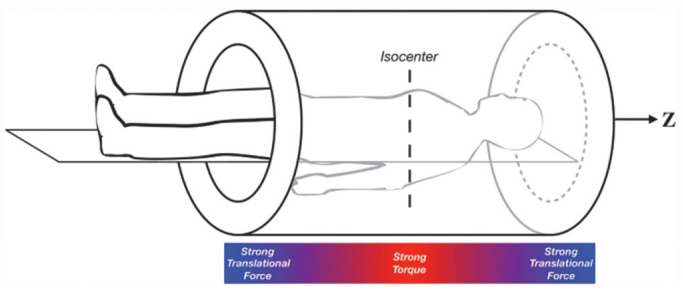

Figure 1: The schematic of excerted translational forces and torque on a CIED relative to the position in the scanner (10).

Radiofrequency pulses can cause ohmic heating via tissue absorption of the energy. This is measured using the specific absorption rate-SAR or an alternative method referred to as the root mean square of the flip angle $B1+_{RMS}$. SAR is a measure of the amount of RF energy the MR scanner produces and that may be absorbed by the tissue. The American Food and Drug Administration approves two SAR levels during an MRI examination; normal operating mode (≤ 2 W/kg whole-body SAR) and first-level mode (≤ 4 W/kg whole-body SAR). The specific absorption rate is a patient dependant measurement of RF energy deposit and SAR calculations vary between different MRI scanner vendors. The alternative method for estimating the applied RF energy is the time-averaged RF magnetic field measurement called root-mean-square or $B1+_{RMS}$. Root-mean-square is solely dependent on the MRI exam parameters and not patient specific parameters such

as height, weight, age and gender. It is calibrated by the MR system software during the pre-scan phase or measurements. Pacemaker leads can concentrate RF energy at their tip and potentially cause excessive heating, which can lead to damage of the local myocardium. In the literature, this occurrence is referred to as the antenna effect, where continual rotation of RF in a polarized magnetic field generates an electric field by Faraday's law of induction. This leads to the concentration of RF energy at the tip of the pacemaker lead. Gradient magnetic fields can induce a current in electrically conductive wires by turning on and off, which can result in myocardial stimulation (9-13).

Potential hazards to the patient with CIED

Initial reports of deaths in patients with CIED who were undergoing MRI are related to the absence of appropriate screening, reprogramming and patient monitoring. These reports, dating back to the late 1980s and early 2000s, contributed to the theory that CIEDs and the MRI environment were not compatible, and, therefore, were contraindicated. Other significant adverse events commemorated in early experience reports are dislodgements or movement of the device, radiofrequency heating of the hardware and surrounding tissue, activation of tachycardia therapies and increased pacing thresholds (14,15,16). Over the past two decades, CIEDs have been designed to reduce the potential risks associated with MRI. Preclinical and clinical studies of newer generation devices show that many issues noted with older devices are no longer present. Modern devices contain less ferromagnetic materials and better electromagnetic interference protection, resulting in a significantly lower rate of adverse events during the MRI examination (14,17). The European Heart Rhythm Association consensus on the prevention and management of interference due to medical procedures in patients with CIEDs has listed the possible effects of electromagnetic interference on these devices. Possible effects include inappropriate automatic mode switching, modification of measured pacing/sensing thresholds, over-sensing related adverse events, sudden battery depletion and power-on reset (16). Power-on reset is a specific type of reprogramming that reverts the device to the factory default settings when the battery voltage falls below a critical level (15). Recent clinical studies evaluated the safety of MRI examinations in patients with CIEDs according to the incidence of the mentioned possible effects. The MagnaSafe Registry was a prospective, multicentre study that was established to determine the frequency of cardiac-related clinical events and device setting changes among patients with non-MRI-conditional devices who underwent nonthoracic MRI at 1.5T magnetic field strength. It is the largest published registry that examined the outcomes of 1,500 patients with non-MRI-conditional CIEDs. Substantial changes in the device setting were infrequent and did not result in clinically adverse events; moreover, no device or lead failure was reported (18,19). Similar findings are presented in the systematic review and meta-analysis done by Munawar et al., that included 35 studies of non-conditional CIEDs in the MRI environment. The rate of adverse events was the highest in regards to significant changes in pacing lead impedance (incidence of 4.8%) and battery voltage (incidence of 2.2%). Findings of this meta-analysis are in accordance with the growing number of studies (1,11,15,18-25) demonstrating that comparatively minor device alterations such as a slightly depleted battery or altered pacing thresholds do not result in significant adverse outcomes.

While there is a growing body of evidence supporting the safety of MRI in patients with conditional and non-MRI-conditional devices, the evidence base supporting the safety of thoracic MRI examinations in such patients is limited to few single-centre studies (26-28). These studies demonstrate that with adherence to a standardized protocol and established exclusion criteria, thoracic MRI examinations in patients with CIEDs can safely be performed without clinically significant changes of device functions or adverse outcomes.

Recommendations for the management of patients with implanted MRI-conditional devices undergoing MRI (2,9,16,29).

1. Confirm the need for MRI: evaluate the risk-benefit ratio before making the decision to perform MRI on a patient with a CIED device. Factors that influence the risk-benefit ratio should be identified and discussed with the team of electrophysiologists and radiologists.
2. Determine whether the CIED system meets the MRI conditionality requirements. CIED systems that combine individual MR conditional leads and other device components from different manufacturers should be regarded as non-MRI-conditional. Another indicator of a non-MRI-conditional system is the presence of abandoned leads, extenders or adaptors, lead remnants or fractured leads.
3. Identify the manufacturer's specific instructions for safe use in the MRI environment. Manufacturer's instructions include a full evaluation of the CIED and leads. Conditions of safe use can include the region being scanned and associated exclusion zones, scanning parameter restrictions and active reprogramming of the device before and after the scan. In general, the majority of devices have been approved for scanning with 1.5T, gradient slew rate≤200 T/m/s, a maximal SAR ≤2 W/kg or alternative RF exposure parameter ($B1+_{RMS}$), and a limited number and length of imaging sequences.
4. Reprogramme the CIED system to one of the available company-specific pre-programmed settings. Pacing should be programmed to an asynchronous mode (VOO/DOO). Anti-tachycardia therapies and automated specialized algorithms must be switched off for all types of devices (16,29).
5. Monitor the patient using continuous real-time ECG and pulse oximetry. Device reprogramming can potentially impact the patient's rhythm status. For example, untreated tachyarrhythmia or absence of bradycardia pacing can occur. Therefore, it is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored. During the scan, professional oversight should be sought for the duration of time that the patient's device is reprogrammed. This professional oversight should be performed by personnel with the skill to perform advanced cardiac life support, including expertise in the performance of CPR, arrhythmia recognition, defibrillation, and transcutaneous pacing (2,29).

Recommended guidelines for non-MRI-conditional systems (2,9,16,29)

1. Confirm the need for an MRI scan.
2. Identify the MRI conditional status of the implanted device. Mind the presence of any abandoned, fractured or temporary pacing leads.
3. Determine whether the patient is pacing dependant or not. Patient pacing dependency is defined by the intrinsic heart rate. Pacing dependant patients are defined by an intrinsic heart rate below 50 beats per minute or by hemodynamic instability or symptoms of presyncope with device turndown (16,20). Reprogramming of the device should be based on this information.
4. Interrogate and reprogramme the device. Device interrogation include measures of lead impedance, pacing threshold, sensing amplitude and P- and R-wave amplitude. Pre and post MRI measures of this device parameters should not alternate. The cardiac electrophysiology team should determine the appropriate pacing mode for the patient. For patients who are not pacing dependant, it is required to reprogramme the device to either a nonpacing mode (ODO/OVO/OAO) or an inhibited mode (DDI/VVI/AAI). For patients that are pacing dependant, the required pacing mode will most likely be an ansynchronous mode (DOO/VOO/AOO) that does not compete with the intrinsic rate. Anti-tachycardia therapies and automated specialized algorithms must be switched off for all types of devices (2,29,30).
5. MRI is limited to 1.5T, using Normal Operating Mode for SAR. Local transmit/receive coils may only be used if they are not positioned directly over the CIED device. The gradient magnetic field slew rate is limited to ≤ 200T/m/s, the root mean square of the flip angle must not exceed 2.8μT (B1+RMS ≤ 2.8μT). The number and length of sequences should be minimized.
6. Monitor the patient using continuous real-time ECG and pulse oximetry. It is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored (2,29).
7. The CIED device should be reprogrammed to its original settings. Evaluate the device parameters as listed above (section 4). All changes in the device parameters and any adverse events, if observed, should be documented in the patient's medical record.

Implementation notes:

A. Patient monitoring hardware: It should be noted that although continuous monitoring of the cardiac rhythm is the primary objective, the electrocardiogram (ECG) might not be interpretable during the use of many MRI sequences. ECG and peripheral gating waveforms displayed on the MRI console are not sufficient for robust physiologic monitoring. Therefore, a dedicated MRI conditional patient monitoring system is likely required. Transcutaneous pulse oximetry which is relatively unaffected during MRI sequences can confirm a change in pulse rate in the absence of a technically adequate ECG signal (2,9,16,29).

B. Personnel requirements: Personnel who perform the interrogation of the CIED device prior and post scan, the evaluation of the patient and monitoring of the patient during the scan are required to complete basic and advanced life support training (BLS and ACLS). An external defibrillator should be located just outside Zone III. The institution must have a written plan for managing the patient, including immediate evacuation to this location in the event of a cardiac emergency. For patients that require higher level monitoring (pacing dependant patients) it is recommended that a cardiac electrophysiologist is present during the MRI study (2,9).

C. Presence of abandoned leads: Significantly higher heating in abandoned leads compared with leads terminated at the pulse generator have been discovered in some phantom studies. Currently, available guidelines do not provide specific recommendations for abandoned leads (2,16,29). However, the 2017 Heart Rhythm Society consensus does not exclude imaging of these patients when the clinical indication exists (29).

D. Pacing modes: Cardiovascular implantable electronic device pacing modes are denoted with a three-letter code. The first letter describes which area/chamber is being paced and the second letter stands for the area/chamber being sensed. The third letter describes how the device responds when a beat is being sensed. For example, in VOO (asynchronous mode) pacing, the ventricle is paced at the fixed rate with no device sensing. Therefore, the device paces at the programmed rate regardless of the intrinsic electrical activity of the heart (31).

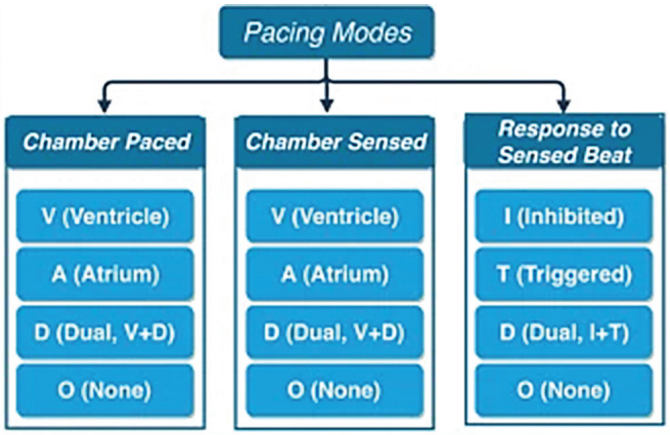

Figure 2: Types of pacing modes for CIED.

AIM

The purpose of this paper is to present an overview of the literature-based management of patients with CIED devices and to present a case of a patient with a CIED with exclusion zone requirement during a prostate MRI examination at our institution.

METHODS

This paper explores the MRI safety and managing of patients with implanted CIED devices through an extensive literature review and case presentation. The study was approved by the ethics committee of the Oncology Institute Ljubljana, Slovenia (research permission number: ERIDNPVO-0058/2022). The literature search was conducted using medical scientific electronic databases such as PubMed, Cinahl, Wiley Online Library and ScienceDirect during the period from January to

April 2022. The search used keywords of "magnetic resonance imaging" AND "pacemaker" OR "implantable cardioverter defibrillator" OR "cardiac resynchronization therapy" OR "CIED". The search was limited to articles in the English language and human studies. Published studies were reviewed manually for proposed diagnostic pathways/protocols, practice recommendations, guidelines and published manuals on MRI safety of CIED devices. Clinical studies were included if the following criteria were met: enrolment of patients with conditional and non-conditional CIEDs undergoing MRI, assessment of device alterations and adverse outcomes. Articles published before 2010 and clinical studies that included fewer than 10 patients were excluded from the review. The BIOTRONIK ProMRI technical manual was acquired using the Magresource online database that stores the MRI safety status of the implantable medical devices.

Case presentation

We examined a 52-year-old patient with a CIED device undergoing a classic prostate MRI examination. The scan was performed with a GE Optima™ MR450w 1.5T scanner using an anterior phased array for the pelvic region. The implanted device was a combination of a triple chamber pacemaker model called Entovis HF non-US and a lead model Solia S 53. The Biotronik ProMRI technical manual labelled this combination as MR conditional, under specific conditions. The permissible positioning zone had to be maintained during the MRI scan, denoting that the isocenter of the high-frequency coil had to be at the level of the greater trochanter for the duration of the scan. Other specific conditions included the limitation of the mean specific absorption rate to 2W/kg, limitation of the maximum slew rate (<200T/m/s) and use of a clinical MRI scanner with a closed bore, cylindrical magnets, and a static magnetic field strength of 1.5 T.

RESULTS AND DISCUSSION

We performed the examination of the described patient in accordance with the guidelines presented in this paper. The need for an MRI examination for this particular patient was confirmed by the referring physician, radiologists and anaesthesiology team at our institution. The pacemaker identification card was examined in order to acquire information about the type of device and attached leads. The presence of any abandoned leads, extenders or adaptors, lead remnants or fractured leads was not identified. The MRI conditionality status was determined using the device identification card and the manufacturer's technical manual. The latter was acquired using the Magresource database. The combination of the device (Entovis non-US) and pacemaker leads (Solia S53) was identified as MRI conditional under specific conditions that include the use of an exclusion zone.

On the examination day, the patient was first appointed to the pacemaker clinic where the anaesthesiology team interrogated the functionality of the device and patient device dependency. They discovered that the patient is not pacemaker dependant and in accordance with this, the CIED system was reprogrammed to the asynchronous mode DOO. Device parameters, capture threshold, lead impedance, sensing amplitude and battery status were measured.

	HF and HF-T	
	Entovis Evia	Eluna 8 Epyra 8 Etrinsa 8
Safio S / Setrox S 45; 53; 60	1.5 T EXZ	
Solia S / Siello S 45; 53; 60		
Solia JT / Siello JT 45; 53		
Solia T / Siello T 53; 60		
Corox (ProMRI) OTW BP 75; 85		
Corox (ProMRI) OTW-S BP 75; 85		
Corox (ProMRI) OTW-L BP 75; 85		
Sentus (ProMRI) OTW BP L 75; 85; 95		
Sentus (ProMRI) OTW BP S 75; 85; 95		

Figure 3: Combinations of device types and pacemaker leads that require an exclusion zone at 1.5T according to the Biotronik ProMRI technical manual.

Measurements were in the normal range for all parameters. After the device interrogation and reprogramming, the patient was appointed to the MRI department where we performed the standard MR safety screening process. MRI scanner conditions were adjusted according to the Biotronik ProMRI technical manual. The technical manual allows the use of a clinical MRI scanner with a closed bore and a static magnetic

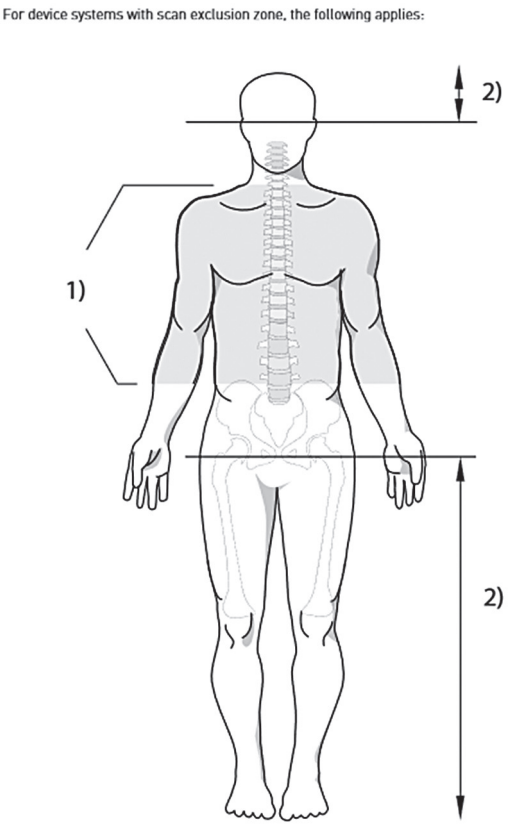

Figure 4: Defined isocenter levels and exclusion zones for CIED.

field strength of 1.5T for this particular device. The maximum slew rate of the gradient fields was limited to 200T/m/s and the mean specific absorption rate did not exceed 2W/kg. For this combination of the pacemaker model and attached leads, the permissible positioning zone must always be maintained for the duration of the MRI scan. In accordance with the manufacturer's technical manual, we adjusted the isocenter of the high frequency coil to the level of the greater trochanter as presented in Figure 4.

Patient monitoring was performed and maintained by the anaesthesiology team for the duration of the MRI examination. We used continuous real-time ECG monitoring and pulse oximetry consulting the technical manual and recommendations for the management of patients with implanted MR conditional devices presented in this paper. ECG monitoring was performed with the Invivo MRI Patient Monitoring System, Model 865214 that is compatible with the strong magnetic fields in the MRI environment. Monitoring was continued until the patient was removed from the MRI Scanner. The patient was appointed back to the pacemaker clinic where the anaesthesiology team reprogrammed the device to its original settings and interrogated the functionality of the device and possible changes in device parameters. No changes of device parameters were discovered. The MRI examination of the patient was completed without complications; therefore, no adverse effects were reported. MRI images were without artefacts.

CONCLUSION

In the past decades, cardiovascular implantable electronic devices shifted from being a complete contraindication in the MRI environment to not presenting a significant risk for MR conditional devices in controlled situations. This step forward was enabled by the advances in engineering to limit interactions between the device and MRI magnetic fields. Interactions were minimized with the use of optimised imaging and screening protocols for patients with a CIED undergoing MRI examinations. Recent clinical studies and published guidelines suggest that MRI of patients with either MRI conditional or non-MRI-conditional CIED devices are relatively safe under specific conditions. Multidisciplinary pre-procedure planning, strict screening process, monitoring and device evaluation protocols are of key importance for ensuring safe MR imaging in patients with a CIED. Multidisciplinary management requires cooperation between the referring physician, radiologist, radiographer and the cardiac electrophysiology team. The screening process and device evaluation protocols must determine the MRI conditionality of the device and patient device dependency status. Based on this information, appropriate device reprogramming should be performed. The MRI protocol for imaging MRI conditional CIED devices must be in compliance with manufacturer's technical manual recommendations. Some device models require the use of exclusion zones denoting that the isocenter of the high frequency coil must not be placed over this anatomic area (usually the thorax region). Recommendations for imaging MR non-conditional CIED devices include the limitation of a static magnetic field to 1.5T, limitation of the maximum gradient field slew rate to ≤ 200T/m/s and use of the Normal Operating Mode for specific absorption rate (<2W/kg). Patient monitoring must be performed using continuous real-time ECG and pulse oximetry. It is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored.

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