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Review

Performing MRI on patients with MRI-conditional and non-conditional cardiac implantable electronic devices: an update for radiologists

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Pacemakers and implantable cardioverter defibrillators are commonly encountered in clinical practice, and entails special consideration when magnetic resonance imaging (MRI) is required. It is estimated that 50–75% of patients with cardiac implantable electronic devices (CIED) will have an indication for MRI during their lifetime. Radiologists may want to recommend MRI or may be consulted about the need to perform MRI in a patient with a CIED, at which point they may need to approve or at least provide guidance as to whether MRI may be performed safely. Even in situations where final clearance will not be provided by the radiologist, he or she can provide valuable information by reviewing radiographs and determining (a) whether a device is MRI-conditional and MRI may ultimately be permitted, (b) is not MRI-conditional and MRI using the standard workflow will therefore not be approved, or (c) when additional information will clearly be required. CIED identification and verification of leads can be accomplished through review of the medical record and/or evaluation of a chest radiograph. In patients with MRI-conditional CIEDs (as well as with legacy CIEDs in those institutions that perform MRI of these patients), specific imaging protocols must be adhered to in order to prevent death or injury to the patient or damage to the device. In this update, we provide details regarding the above topics and provide an algorithm for integrating this information into a clinical workflow to efficiently triage patients with CIEDs who are being considered for MRI.

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Introduction

Based on a survey in 2011, more than 700,000 pacemakers were placed worldwide in 2009, with virtually all countries demonstrating an increase compared to the prior survey.[1] When coupled to increasing lifespans, there will continue to be an increasing number of patients with cardiac implantable electronic devices (CIEDs), including permanent pacemaker and implantable defibrillators, who require magnetic resonance imaging (MRI). Based on an estimate in 2011, 1.8 million people in the United States had a CIED,[2] and it is estimated that 50–75% of patients with a CIED will have an indication for MRI during their lifetime.[3] The intersection of these trends has led to a growth of the number of MRI-conditional devices on the market and the need for institutions to develop protocols for MRI examinations of patients both with MRI-conditional devices and with devices that are not labelled as MRI-conditional. Adopting a workflow for MR of patients with CIEDs is essential so as not to deny needed imaging in patients who require it.[4]

The goal of this review is to provide radiologists with an up-to-date review of considerations related to MRI of patients with a CIED. Radiologists encounter these devices on routine chest radiography and may be called upon to identify these devices and opine as to whether MRI can be performed safely in these patients. We provide background on MRI-conditional device development, methods to identify CIEDs, and describe workflows for handling patients with MRI-conditional CIEDs. Lastly, we discuss the latest ideas regarding performance of MRI in patients with "legacy" CIEDs (also referred to as "MR non-conditional" in the Heart Rhythm Society guidelines of 2017[5]), which are not approved for use in an MRI environment by the US Food and Drug Administration (FDA). Although we provide background on approaches to the performance of MRI in patients with CIEDs, safe examination performance requires close coordination of multiple experts, including radiologists, MRI technologists, and cardiologists, as well as institutional protocols, which have been designed by MRI safety experts at the institution or MRI safety consultants.

MRI-conditional device development

Prior to the advent of MRI-conditional CIEDs, multiple deaths were documented in patients with CIEDs who underwent MRI.[6] The presence of a CIED was widely accepted as an absolute contraindication to MRI.[7] Modes of device failure that led to fatalities were hypothesised to include R-on-T phenomenon of tachyarrhythmia induction due to competitive pacing by the heart's intrinsic pacemaker and the CIED, movement of the pulse generator or lead(s), magnetic effects on switches, induced currents in leads, induction of arrhythmias, and heating effects on tissue.[8] For example, heating of tissue at the lead tip may lead to tissue necrosis and fibrosis causing capture loss or increase of the pacing threshold. Radiofrequency magnetic field effects may also cause inappropriate pacing, inappropriate inhibition of pacing, or inappropriate defibrillation.[9] MRI-conditional CIEDs were developed to permit safe conduct of MRI under specific controlled conditions.

The first MRI-conditional pacemaker system (Revo MRI SureScan, Medtronic, Minneapolis, MN, USA) became available in Europe in 2008 and in the United States in 2011.

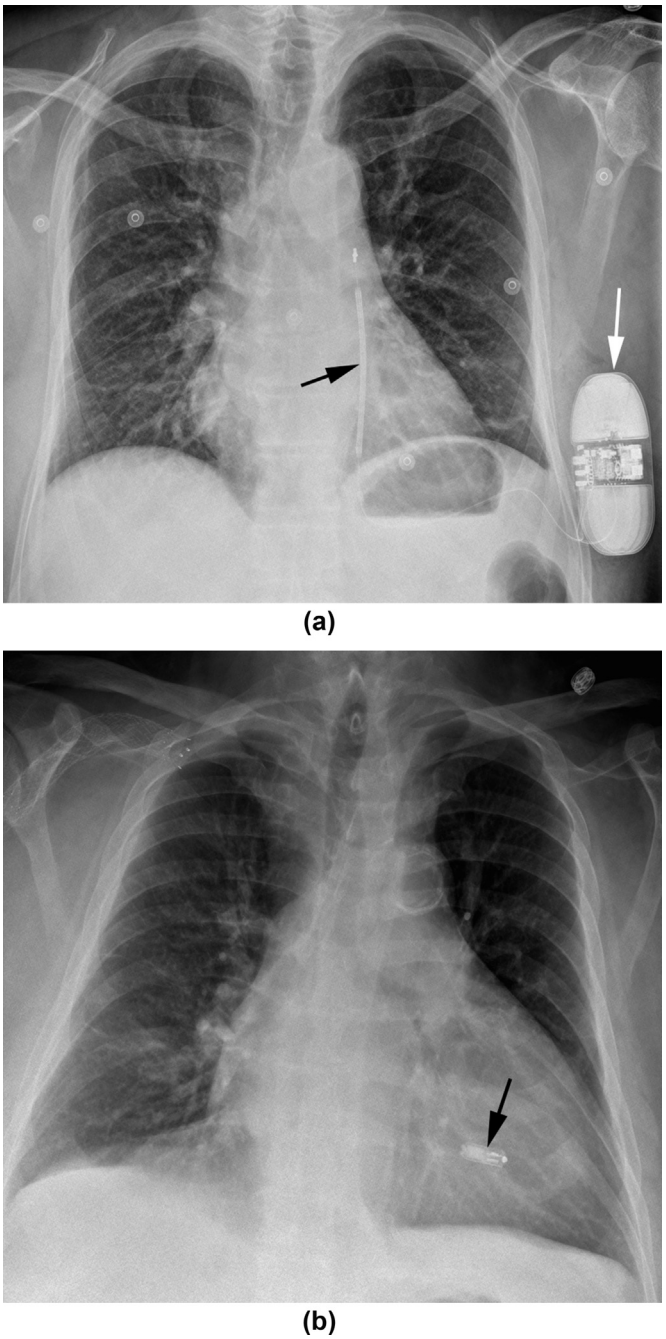

Figure 1 (a) Subcutaneous ICD in a 53-year-old man. The pulse generator (white arrow) is implanted along the left midaxillary line and the coil/electrode (black arrow) is implanted along the left parasternal border. (b) Micra leadless pacemaker in a 66-year-old man. The Micra device (arrow) is implanted in the right ventricle. Both of these devices are unique in their classes and are MRI-conditional. (Boston Scientific also marketed a leadless pacemaker named Nanostim; however, it was removed from the market in October 2016 due to cases of battery malfunction.)

MRI-conditional implantable cardioverter–defibrillators (ICDs) became available in Europe in 2011 (Lumax 740, Biotronik, Berlin, Germany) and in the United States in 2015 (Evera MRI™ SureScan® ICD System, Medtronic). Since then, based on strong market demands, MRI-conditional CIEDs have been introduced by virtually all device manufacturers. For example, at least 35 devices, including pacemakers, ICDs, and cardiac resynchronisation therapy devices, are now available in the United States.[8,10] MRI-conditional systems comprise matched sets of an implantable pulse generator (IPG) and one or more leads (with the exception of new "leadless" systems), which have been tested to function safely as a complete system under specific conditions. The devices typically contain minimal ferromagnetic components, employ optimised filtering, include leads that minimise current conduction and potential for tissue heating, and have specialised programming, which can be activated to minimise risk in the MRI environment.[11] The newest types of CIEDs, such as the subcutaneous ICD (Emblem MRI S-ICD System, Boston Scientific, Natick, MA, USA) and the Micra leadless pacemaker (Medtronic), are both MRI-conditional (Fig 1).

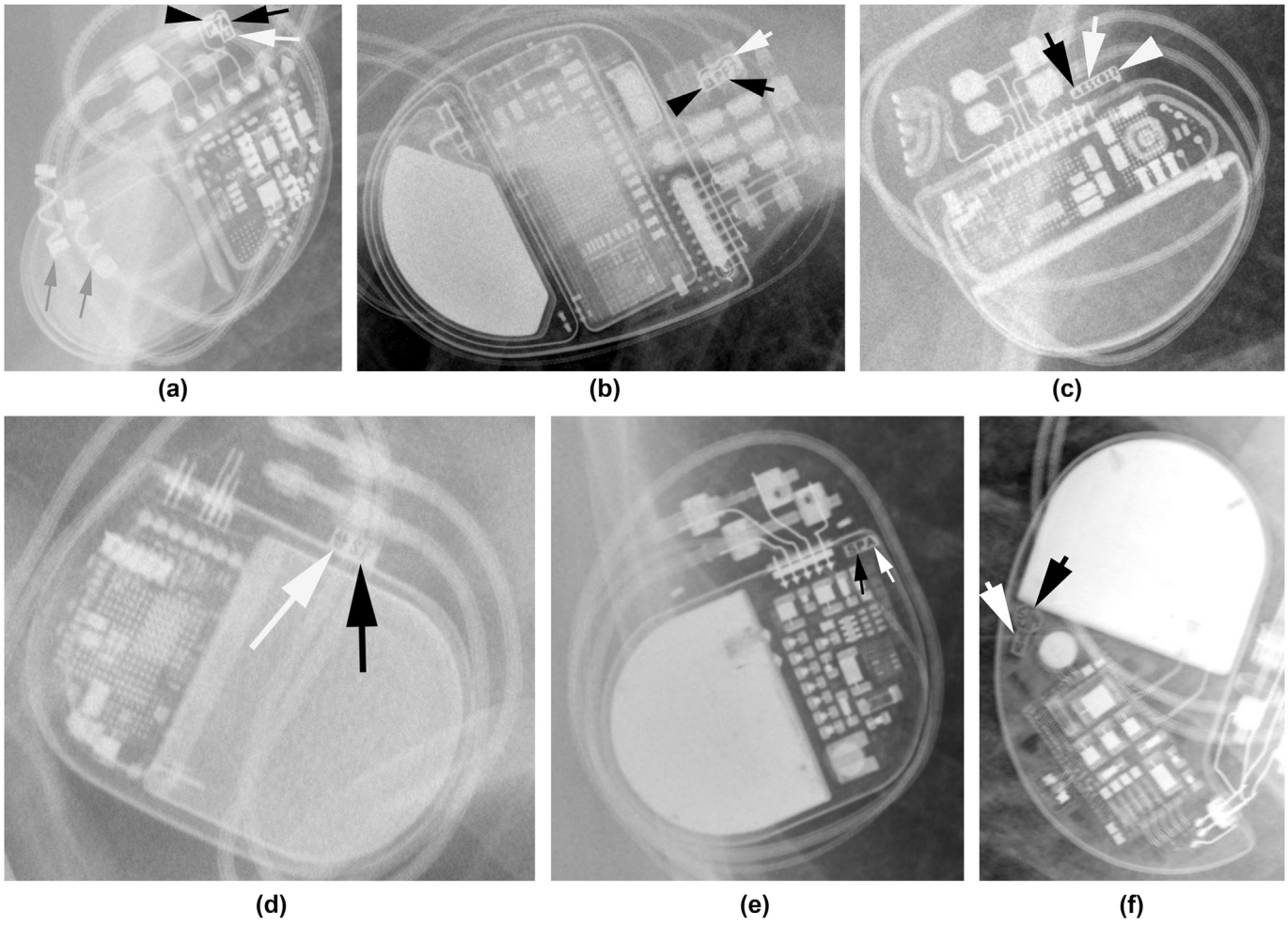

Figure 2 Six devices and their radiopaque tags. (a) Medtronic Revo MRI SureScan pulse generator. Note the Medtronic "M" symbol (white arrow) and "PTA" device identifier (black arrow) which indicates the Revo device. The wave symbol (arrow head) indicates that the device is MRI-conditional. Coils around the proximal leads (grey arrows) are characteristic of the Medtronic Surescan 5086 lead. (b) Medtronic Amplia MRI cardiac resynchronsation therapy pulse generator. Note the Medtronic "M" symbol (arrowhead) and "PFZ" device identifier (black arrow), which indicates the Amplia device. The wave symbol (white arrow) indicates that the device is MRI-conditional. (c) Boston Scientific Accolade MRI pacemaker. The triangle (black arrow) indicates that it is an MRI-conditional device. "BSC" (white arrow) indicates the manufacturer, Boston Scientific. For this vendor, the appended numerals "012" (arrowhead) indicate the programmer software application used for the device and is not a unique device identifier. (d) Biotronik Evia HF-T MRI-conditional pacemaker. This device does not have a unique MRI-conditional identifier. The white arrow points to the Biotronik logo. The black arrow points to "SF", the unique device identifier, which can be looked up to identify the device and determine its MRI-conditionality status. (e) Sorin Reply DR pacemaker. Sorin (now MicroPort CRM) devices marketed in the United States are not labelled as MRI-conditional. "SP" (black arrow) indicates Sorin Pacemaker, while "A" (white arrow) refers to the model. (f) St Jude Identity™ ADx XL DR Pacemaker. "SJM" (black arrow) indicates the manufacturers name and "VV" (white arrow) are code letters which vary by device. The tag cannot be used to determine MRI-conditionality as the same alphabetical code letters are used in multiple devices, some of which are and some of which are not MRI-conditional. The device in this figure is not approved as being MRI-conditional.

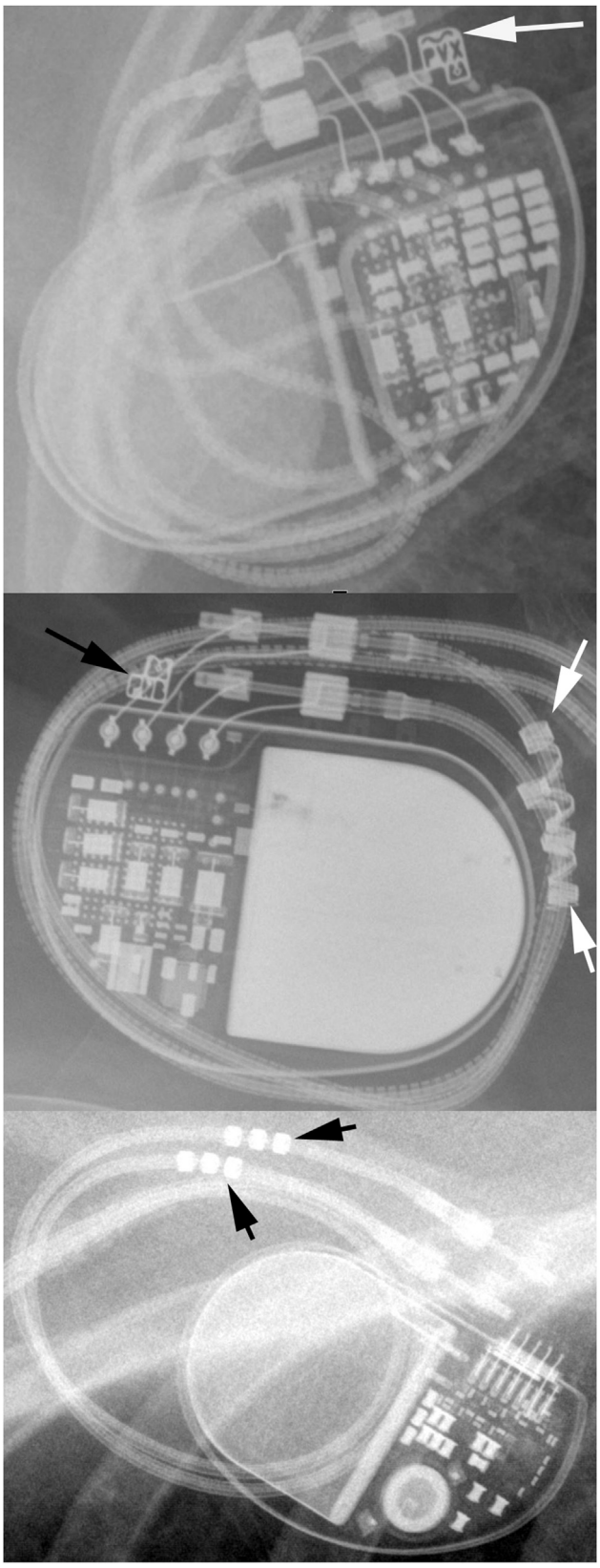

Figure 3 Lead markers in three devices. The top panel shows a Medronic Advisa MRI SureScan conditional pacemaker. The wave symbol (white arrow) indicates that the device is MRI-conditional. There are no lead markers. The medical record must be consulted to determine that these are Medtronic Surescan 5076 MRI leads. The middle panel shows coils on the proximal leads (white arrows) indicate that these are Medtronic Surescan 5086 leads. Still, this is still not an MRI-conditional system as the pulse generator (labelled with the Medtronic logo and "PWB", black arrow) corresponds to the Medtronic Adapta device, which is not MRI-conditional. The bottom panel shows the St Jude Assurity MRI pacemaker pulse generator, which has no easily discernible marker. Three squares on the proximal leads (arrows) confirm MRI-conditionality of the Tendril MRI leads.

CIED identification

Manufacturer certification and regulatory approval that a device will perform safely during MRI are specific to complete MRI-conditional systems. It is therefore essential to ascertain whether a patient is implanted with a complete MRI-conditional system prior to planning MRI. Medical records, including the patient's implant card, should be consulted. Some devices or components can be identified as MRI-conditional using radiography to visualise radiopaque alphanumeric labelling or symbols on the device (Fig 2).[12] MRI-conditional CIEDs by Medtronic, for example, have a radiolucent sine-wave symbol and Boston Scientific MRI-conditional CIEDs have a RADIOLUCENT triangle. Some devices (e.g., Biotronik) have a radiopaque device label, which can be used to identify the model; however, MRI-conditional status cannot be determined from the radiograph and must be determined from device literature. Other devices (e.g. from St Jude [Abbott, St Paul, MN]) exhibit radiopaque codes that are not device specific; both MRI-conditional CIED models and models not so approved may display the same code. In conclusion, radiography alone is not always able to determine MRI-conditional status or even definitively identify a CIED model, but may be helpful as a start.

Determination of the MRI-conditional status of CIED leads from radiographs is even more challenging than IPG determination. Few leads have specific markers to facilitate identification. Examples of leads that do bear identifying markings visible on radiographs include the Medtronic Surescan model 5086 leads, which display coils, and the St Jude Tendril MRI leads, which display three radiopaque squares (Fig 3). Many MRI-conditional leads, however, do not bear any radiographically visible markings. Inconsistency of lead markings occurs even for the same vendor. For example, coils are present on the Medtronic Surescan 5086 leads, but not on the Surescan 5076 leads, and some Boston Scientific Ingevity MRI leads have two radiopaque bands on the proximal end while others do not. The medical record must be used for determination of lead type followed by determination of the completeness of the entire CIED systems by consulting manufacturer documentation. Importantly, some "legacy" lead models not originally marketed as MRI-conditional have subsequently received approval for use in MRI. Finally, it is always essential to carefully review a recent chest radiograph to confirm the absence of broken, epicardial and abandoned leads as well as lead extenders.[12] Therefore, radiograph review and review of the medical record have adjunctive purposes. It is important to note that

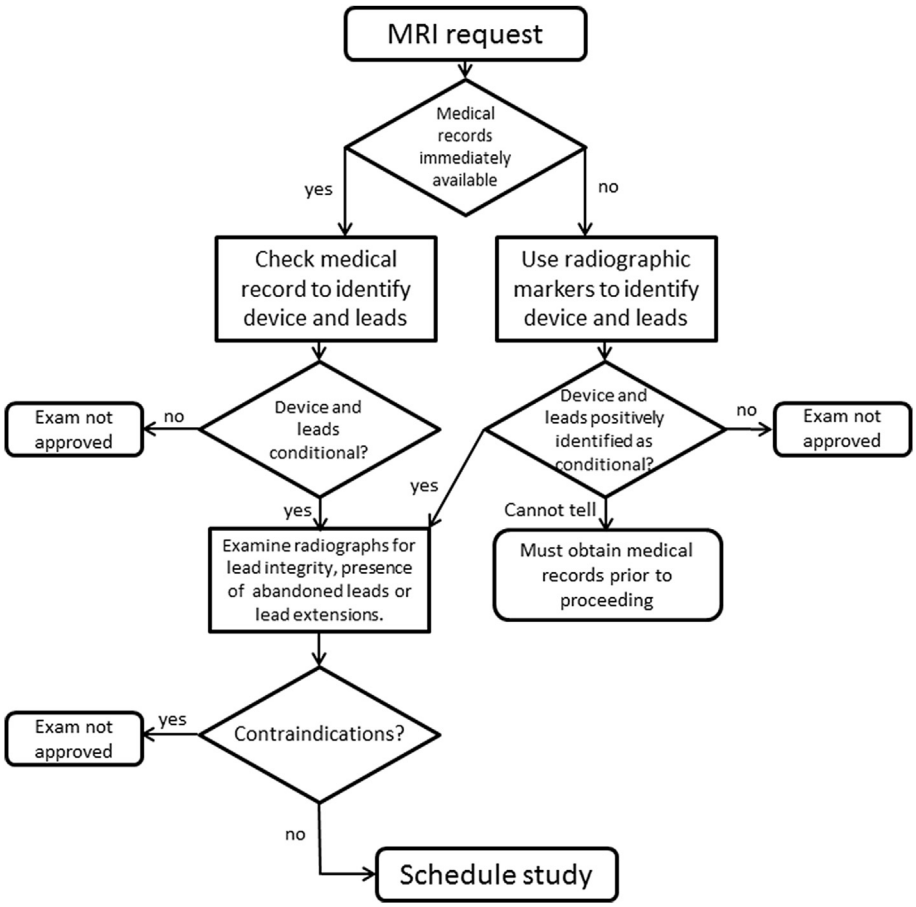

Figure 4 Workflow for approving or deferring MRI on patients with CIEDs.

thin epicardial leads implanted during open heart surgery and left partially in place post-recovery, are not considered "abandoned leads" for the purposes of MRI (Class IIa [moderate] recommendation in reference 5). Once CIED components are identified, relying heavily on the medical record and the patient's "wallet card" if available, product manuals or online resources, such as vendor-supplied configuration tools, must be consulted to determine the MRI-conditional status of the complete CIED system.

Workflow

Responsibilities are divided before, during, and after the MRI examination between the radiologist, cardiologist, and technologist to ensure a safe examination.[11] Before the examination is scheduled, the radiologist must verify that the entire CIED system, including both the pulse generator and lead(s), are MRI-conditional and that no additional leads or devices and no abandoned, epicardial, fractured or extended leads are present. A flow chart for approving an examination, rejecting an examination, or requiring additional information for a patient with a CIED requiring an MRI examination is shown in Fig 4. If criteria are met, the radiologist approves the examination under the MRI conditions allowed for the device. Prior to the examination, the cardiologist prescribes MRI-conditional mode programming for the device, and this programming is entered prior to the examination and reset after the examination by a vendor technician. Some devices (for example, Biotronik devices with the MRI AutoDetect feature) allow for pre-programming such that the device will enter MRI-conditional mode automatically when entering an MRI environment and will return to the original programming once the patient leaves the MRI environment. During the examination, the MRI technologist must follow the imaging protocol (to comply with the MRI conditions of the device), which includes magnetic field strength, area scanned, patient position, use of local versus whole-body radiofrequency transmission, power deposition (SAR or B_1+RMS), and gradient duty cycle. If necessary, the imaging protocol will be monitored to comply with the conditions. The patient's heart rate must be monitored during imaging by a clinician (commonly a cardiology fellow, physician assistant, nurse practitioner, or registered nurse) capable of recognising and treating an adverse rate or rhythm. Resuscitation equipment, including an external defibrillator, must be immediately available outside of the MRI room. Appropriate training of personnel to carry out these roles is required.[9] In a recent report, a team-based approach operating at a single location was able to markedly improve volume and decrease waiting times for MRI examinations on CIED patients.[13]

CIEDs not approved for use in MRI (legacy devices)

Although many (but not all) CIEDs currently on the market are MRI-conditional, most devices currently in patients are legacy devices, which are not labelled as MRI-conditional.[9,11] Packaging for these legacy devices typically warns against use in an MRI environment due to patient safety concerns and to avoid damage to the device. Two recent large studies describe the safe performance of MRI on patients with legacy CIEDs, under specific protocols, which include approaches to managing the CIED device, modifying the MRI protocol, and monitoring the patient during MRI.[14,15] The FDA has responded to the study and reassurance by its authors with a warning that caution should still be exercised due to unknown risks.[16] In a response, the authors contend that results from large patient cohorts support the practice of performing MRI on patients with legacy devices conditionally when using protocols designed to minimise patient harm.[16]

A recent consensus statement from the Heart Rhythm Society, which included radiologists has agreed with this position, stating, "It is reasonable for patients with an MR non-conditional CIED system to undergo MR imaging if there are no fractured, epicardial, or abandoned leads; the MRI is the best test for the condition; and there is an institutional protocol and a designated responsible MR physician and CIED physician.[5]" There have been subsequent reports of safety of legacy devices. For example, in a study of 952 patients with CIEDs undergoing thoracic MRI, there was no difference in adverse events between the 120 patients with legacy devices and the remaining patients with MRI-conditional devices.[17]

Conclusion

In summary, when imaging patients with MRI-conditional devices, medical records and radiography are used to conclusively identify the pulse generator, leads, and any other components of the CIED system. The manufacturer's guidelines should be adhered to regarding the imaging protocol. Institutions planning to image patients implanted with legacy devices must carefully consider the involved risks under the guidance of experts in MRI and electrophysiology, and develop a sound institutional protocol to ensure that all aspects of the process minimise potential hazards to the patient.[18] Understanding the roles of the medical record and information that can be extracted from radiography and knowledge of the imaging workflow will allow all radiologists to effectively participate in the safe MRI of patients with CIEDs.

Conflict of interest

The authors declare no conflict of interest.

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