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Current guidelines for MRI safety

in patients with cardiovascular implantable electronic devices

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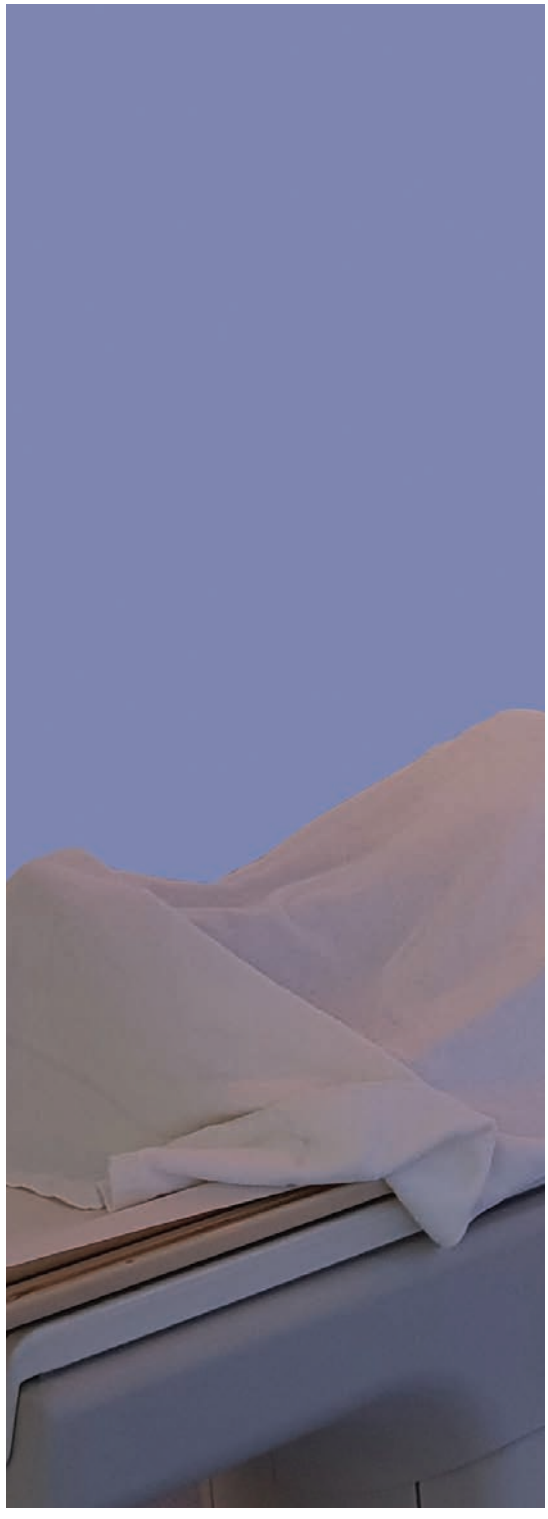
Abstract: Historically, MRI was contraindicated in patients with cardiovascular implantable electronic devices because the devices' metallic components made this imaging study unsafe. Advances over the last decade have now made MRI safe for many of these patients. This article examines the risks of MRI technology for this patient population and reviews recent guidelines from the Heart Rhythm Society.

Keywords: cardiac resynchronization therapy, cardiovascular implantable electronic device, CIED, CRT, ICD, implantable cardioverter defibrillator, magnetic resonance imaging, MRI, permanent pacemaker, PM

CURRENTLY, ABOUT 8 million people worldwide are living with a cardiovascular implantable electronic device (CIED) such as a permanent pacemaker (PM) or an implanted cardioverter defibrillator (ICD).[1] An estimated 50% to 70% of patients with one of these devices will need MRI in their lifetime.[2]

In the past, MRI was unsafe for patients with CIEDs due to metallic components and other factors. Consequently, it was contraindicated for these patients, regardless of their diagnosis or health status. Over the last decade, however, industry and medical science have worked in concert to develop MRI-compatible CIEDs that improve safety for patients with implanted devices (see *Evolving CIEDs*).

Responding to these advances in technology, the Heart Rhythm



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Society (HRS) published a game-changing expert consensus statement in 2017, expanding the indications for MRI. This article reviews CIED technology and the HRS consensus statement guidelines.

Defining CIEDs

CIEDs include PMs, ICDs, and cardiac resynchronization therapy (CRT) devices with or without defibrillation capacity.[3] A ***PM*** is used to treat a variety of bradydysrhythmias. An ***ICD***, which may be a transvenous or subcutaneous system, senses and terminates potentially lethal dysrhythmias, such as ventricular tachycardia or ventricular fibrillation.[3] These represent a common treatment option for preventing sudden cardiac death.[4] ***CRT*** is another technique for cardiac pacing used to treat patients with left ventricular systolic dysfunction and dyssynchronous ventricular activation that provides simultaneous or nearly simultaneous electrical activation of the left and right ventricles, also called biventricular pacing, or by stimulating the left ventricle alone.[5]

Basic components of CIEDs include the leads, electrodes, header, and a pulse generator.[6]

- Leads are insulated wires that deliver electrical impulses between the pulse generator and the heart.
- Electrodes at the distal end of each lead sense the intrinsic cardiac rhythm and deliver electrical impulses to pace the heart when needed.
- The header is the component where the leads attach to the pulse generator.

Evaluation of CIED programming should be performed after MRI, and all follow-up protocols should be reviewed with patients.

- The pulse generator, which is implanted subcutaneously, usually in the left upper chest area, contains circuitry and a battery encased in a titanium metal body.

In addition, an ICD contains a capacitor within the pulse generator, which stores energy for a defibrillator charge.[6]

MRI technology

MRI represents the clinical application of nuclear magnetic resonance (MR) spectroscopy. These scans map the geography of water and adipose tissue in the body. To create an image, the MRI scanner triangulates three elements: the static magnetic field, the radiofrequency (RF) pulsed waves, and the magnetic field gradients.[1]

- The static magnetic field serves to orient protons.
- RF pulsed waves are the energy source, which are manipulated to generate an image, distinguish tissue, and pinpoint the area of interest.
- Magnetic field gradients focus the signal once the RF energy source has been powered off.

Due to the ferromagnetic composition of both the CIED pulse generator and leads, as well as exposure to the powerful magnetic and RF fields generated during scans, patients with CIEDs who underwent MRI risked serious injury; for example, micromyocardial thermal burns from component heating.[1]

Patients may also be at risk for atrial and/or ventricular dysrhythmias and inappropriate pacing, as well as inhibition of defibrillation therapies and pacing due to the magnetic effects. Similarly, electromagnetic interference and RF energy can cause inappropriate ICD shocks or inappropriate pacing inhibition, causing asystole in PM-dependent patients. An electrical reset may result in device reprogramming. Premature battery depletion or failure is also a potential hazard. Epicardial lead placements and fractured or abandoned leads require further evaluation to determine a patient's MRI status, as these may be prone to overheating.[1,7] Rather than removing old leads, surgeons typically cap and abandon them during replacement.[8]

Questionable device or lead systems may be confirmed via chest X-ray.[1] As CIEDs are enclosed within the pectoral pocket, magnetic field-induced force presents little

Evolving CIEDs[1,12,14-16]

In 2008, the first FDA advisory for patients with CIEDs undergoing MRI was released. Since then, substantial research has been conducted to make MRI safe and available for these patients. The first MRI-compatible PM received a conditional designation from the FDA in 2011. Advances in biomedical engineering continued, and the first MR conditional ICD was approved in 2014. These were followed by other CRT devices and subcutaneous ICDs in 2016.

risk for device movement. Similarly, there is little risk for lead dislodgement due to minimal ferromagnetic composition.

Safer technology opens doors

In the context of MRI safety, the 2017 HRS consensus statement divides environments and objects, including CIEDs, into four groups:[1]

- ***MR safe*** refers to an environment free of any danger due to magnetic attraction. For example, plastic is used over ferromagnetic or iron-containing metals to ensure safety. No CIED has an MR safe designation.
- ***MR conditional*** systems refer to FDA-approved CIEDs that are considered safe only when specific MRI criteria have been met. These criteria include a magnetic field strength of 1.5 T, a specific absorption rate of 2.0 W/kg, and a maximum magnetic field slew rate of 200 T/m/s.[1] The magnetic field slew rate determines image resolution.[1]

Compared with older devices, MR conditional devices feature several improved design elements. These include circuitry and sensor revisions, reduced ferromagnetic content, enhanced lead design for a smaller diameter and reduced coils, automatic pacing system integrity checks, increased energy delivery for pacing capture during MRI, and ease of programming in returning the device to its original settings after an MRI.[9]

- ***Non-MR conditional*** systems refer to CIEDs that do not meet the criteria for MR conditional labeling; for example, when an MR conditional pulse generator is combined with non-MR conditional leads for battery replacement.[1] Leads that have been abandoned, fractured, or in the epicardial position are considered non-MR conditional. Similarly, any active noncardiac devices in the MRI field are considered non-MR conditional.[10] These may include deep brain; gastric; bone; and vagal, phrenic, and sacral nerve stimulators.[10]
- ***MR unsafe*** refers to CIEDs that pose a known danger in MRI environments.[1] MR unsafe refers to ferromagnetic items within the MRI field that may be heated, shifted, or twisted. These include cochlear implants, orthopedic implants with external fixation systems, jewelry, coins, and hair clips. Additionally, scissors and steel oxygen tanks may be hazardous, as they can become dangerous projectiles.[11,12]

Improvements in CIED technology have addressed many of the safety issues created by older technology. For example, the reduction of ferromagnetic components and enhanced shielding diminish impairment of the circuitry and power supply. A dedicated MR safe mode may also minimize risks by simplifying preprogramming to turn on and off selected settings before and after MRI.[1]

Design modifications may be necessary to decrease lead tip heating, which can cause changes in pacing function and/or myocardial damage, and to reduce the antenna effect, which occurs when a wire is exposed to RF and can induce dysrhythmias.[13] These modifications may allow in-use leads to achieve MR conditional status.[1] Similarly, MRI utilization policies and procedures may decrease adverse reactions by incorporating lower static magnetic fields and gradient slew rates, as well as limiting RF power, transmission, and deposition rates.[1]

Taking steps to ensure safety

When a patient with a CIED is being considered for MRI, the healthcare provider must carefully evaluate the risks and benefits. According to the HRS, "A standardized institutional policy should be developed that includes an assessment of the benefits of MR imaging compared with alternative imaging modalities, protocols for pre-scan and post-scan CIED evaluation, appropriate programming during the scan based on device and patient characteristics, and procedures in the event of an adverse clinical event."[1]

Many healthcare organizations have implemented a safety checklist for patients with CIEDs who are undergoing MRI, documenting information on the pulse generator and lead system, the MR status of the device, and pre- and post-MRI device parameters. These checklists should consider the facility's location and resources based on the unique communities it serves.[1]

Checklists should first be completed and kept on hand during MRI. Scans must be aborted in the event of CIED inhibition in patients dependent on pacemakers, or in the development of symptomatic bradycardia, asystole, or ventricular dysrhythmias. Advanced cardiovascular life support (ACLS) protocols should be instituted as soon as these patients are safely removed from the MRI suite.[1]

Similarly, employee safety must be addressed for any healthcare professionals with a CIED who may come in proximity to an MRI scanner. HRS recommends incorporating clear, discernable signage around the MRI suite regarding safe environmental boundaries for these caregivers.[1] In adult patients with a CIED due to congenital heart disease, consultation with an adult congenital heart disease specialist is recommended.[1]

Several algorithms for managing patients as they undergo MRI are available. HRS highlights a review of the device's MR conditional status and programming, the patient's pacing dependency, ACLS training for the staff, patient monitoring,

Sample MRI checklist[1]

Below are sample guidelines for patients with CIEDs who require MRI.

Pre-MRI screening:

- Confirm the MR conditional status of the PM or ICD system.
- Verify the PM or ICD manufacturer and identify any MRI features.
- Confirm that the PM or ICD has been implanted into the left or right pectoral area for a minimum of 6 weeks for lead maturation.
- Confirm that there are no extraneous device components such as lead adaptors and extenders, or any active, abandoned, or fractured leads.
- Confirm that the patient has no noncardiac implanted devices in the CIED region.
- Confirm that the CIED battery status is not indicated for elective replacement or at the end of its life.
- Confirm the utilization of a closed-bore MRI scanner, which features a narrow tunnel opening that is approximately 60 cm in diameter and a magnetic field strength up to 1.5 T.

Pre-MRI programming:

- Ensure the pre-, intra-, and post-MRI presence of healthcare professionals trained in CIED programming and performing MRI.
- Confirm that MRI programming and thresholds are satisfactory.
- Verify if patients are PM-dependent and that their pacing functions have been appropriately programmed.
- Confirm that emergency resuscitation equipment and ACLS-trained staff are readily available.

Intra-MRI:

- Monitor patient vital signs, including cardiac monitoring and pulse oximetry.
- Provide additional visual and voice contact during MRI.

Post-MRI programming:

- Confirm that the programming thresholds remain satisfactory.
- Assess patients for any MRI-related adverse reactions, such as changes in vital signs, hearing, or mental status.
- Confirm that the original pre-MRI programmed parameters have been restored in PMs and ICDs.

Follow-up:

- Remote CIED monitoring is performed the day after MRI, and data are sent to the provider. Significant differences in post-MRI parameters should be reported to the provider within a week.
- Educate patients to carry their CIED information card at all times.

and the availability of code carts.[1] A handheld magnet may also be included with the emergency supplies to restore pacing in patients with PMs. Magnets should not be utilized in patients with ICDs, however, as they may cause the device to revert to an inappropriate function.[1]

All necessary personnel for safe MR procedures should be present, including physicians who are familiar with the device function and programming and are capable of inserting temporary transvenous pacemakers, as well as the provider supervising the MRI. Evaluation of CIED programming should be performed after MRI, and all follow-up protocols should be reviewed with patients (see *Sample MRI checklist*).[1]

Nursing considerations

Nurses must educate patients regarding the importance of having and keeping their CIED identification card with them at all times. These cards are device-specific, with information on the device manufacturer, serial number, MR status, and date of implantation. They should also include the name, address, and phone number of the CIED-monitoring provider. Patients should present them to any and all healthcare providers for a complete health history in case MRI becomes necessary.

Patient education

Patients should be informed of what to expect during an MRI, including an explanation of the loud noises, and hearing protection or earplugs should be provided. If contrast is utilized, all allergies must be noted. Nurses must ascertain whether patients have any body piercings or metal implants other than a CIED, and the removal of any jewelry, clothing, pocket items, and hairpins is necessary. For those with a history of claustrophobia, other MRI options such a large-bore or open MRI scanners may be considered, or sedation may be necessary.[12]

During the scan, patients should be in constant visual and vocal contact. The HRS consensus experts recommend monitoring electrocardiography and pulse oximetry until the CIED settings have been restored.[1] Remote follow-up may be performed the day after MRI with data sent to the provider. If the programmed CIED settings have been significantly altered from pre-MRI settings, patients should follow up with their provider within a week of the scan.[1]

Looking forward

In the future, the care of CIED-dependent patients may encompass safety improvements such as an automatic MR safe mode to protect patients as they approach the scanner, as well as the ability to enable programming during MRI. Some current technologies have already implemented MR safe modes that may be programmed manually, others do not.[7] Increasing compatibility between devices from different manufacturers should also be a priority, along with continued research to address abandoned hardware and the development of clinical registries for patients with non-MR conditional CIED systems.[1]

Although further research is necessary, the advent of MRI-compatible CIEDs has already led to improved patient care. By implementing protocols, algorithms, and checklists to ensure safe MRI practices for patients with CIEDs according to HRS guidelines, healthcare organizations can help foster optimal patient outcomes. Similarly, the role of healthcare professionals remains crucial in monitoring and treating these patient populations. ■

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