



MRI of Patients with Cardiac Implantable Electronic Devices

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Abstract

Purpose of Review The purpose of this review is to clarify the risks associated with MRI exams for patients with cardiac implantable electronic devices (CIEDs) and to provide information regarding the MRI examination protocol for patients with CIEDs.

Recent Findings Several prospective studies evaluated the feasibility of MRI exams for patients with CIEDs and reported no adverse events. These studies suggest that by following a specific MRI examination protocol and monitoring both CIED parameters and the patient's symptoms, an MRI exam can be performed by appropriately trained personnel with an acceptable benefit-to-risk ratio.

Summary Both MR unsafe and MR conditional CIEDs are commercially available, but there are no MR safe CIEDs. The potential risks faced by patients with CIEDs during an MRI exam are always present and warrant careful monitoring. Three magnetic fields in the MRI scanner interact with the device in ways that can damage the CIED or harm the patient. Due to safety concerns and out of an abundance of caution, the majority of MRI exams for patients with CIEDs are currently denied. However, when following a specific MRI exam protocol, these risks can be mitigated.

Keywords Magnetic resonance imaging · Cardiac implantable medical devices · Pacemaker · ICD · MRI safety · MRI protocol

Introduction

Cardiac implantable electronic devices (CIEDs), such as pacemakers and implantable cardioverter defibrillators (ICDs), are widely used for treating cardiac arrhythmias—the most common heart disorder. Each year, 63 patients per million require CIED therapy [1].

According to the Food and Drug Administration (FDA, 21CFR870.3610), CIEDs are categorized as a class III

medical devices because of the use a source of electrical energy or a battery, to function (i.e., active device). Depending on the patient's needs, CIEDs can have different wire leads and pulse generators that can be programmed in various modes to target a specific type of arrhythmia (Fig. 1).

For patients with cardiac arrhythmias, it is expected that other medical complications will arise during their lifetime. Therefore, patients with CIEDs may be referred for a clinical MRI exam during the device lifetime for any number of reasons. Due to safety concerns and out of an abundance of caution, the majority of MRI exams for patients with CIEDs are currently denied. Nevertheless, the indications for an MRI exam for patients with CIEDs are numerous. In fact, it is expected that up to 75% of patients with CIEDs will need an MRI exam during the lifetime of the device, and 17% will need an MRI exam within the first 12 months [2]. The need to improve CIED safety during MRI exams has led to a tremendous amount of industrial and academic work that resulted, in part, to clear labeling of CIEDs using an accepted terminology.

The objectives of this review are as follows: (i) to clarify the different categories for labeling CIEDs, (ii) to explain the interactions between the MRI scanner and the CIED that confer potential risk to the patient's safety, and (iii) to review

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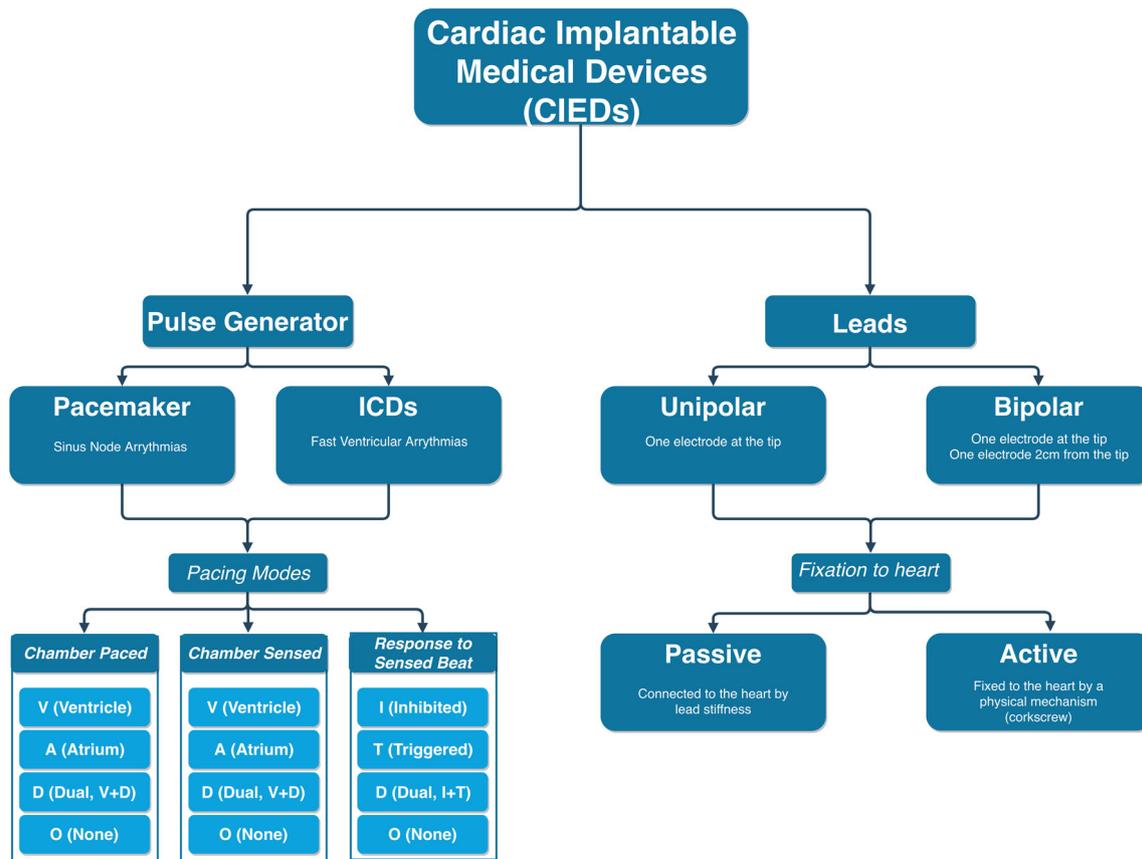


Fig. 1 Illustration of different CIED characteristics

current information on the MRI exam protocols for patients with MR unsafe and MR conditional CIEDs.

Device Terminology

To categorize the hazardous risk associated with a CIED in an MRI scanner, the following specific terminology has been defined by American Society for Testing and Materials (ASTM) [3]:

- i) *MR safe*—Devices that do not pose any hazard in the MR environment and are therefore safe to scan.
- ii) *MR conditional*—Devices that are proven to be safe in the MR environment when specific conditions are met. According to FDA indications, all MR conditional devices intended to operate in presence of the MR system must be “labeled”
- iii) *MR unsafe*—Devices under this label are known to pose hazards in all MR environments; thus, it is not recommended to perform an MRI exam with the device present.

Note, around 6 million people worldwide have implanted CIEDs that are not MR conditional labeled. At least half of these patients will have a clinical indication for an MRI exam

[3]. MRI examinations for patients with legacy devices are widely considered absolutely contraindicated. The term “legacy CIED” corresponds to commercially available CIEDs that were marketed and sold before the existence of the ASTM device terminology. These CIEDs were not designed to be safe for MRI examinations, and their behavior in the MRI environment is not widely understood. Therefore, legacy CIEDs are considered MR unsafe. In this paper, the term “MR unsafe CIED” refers to both MR unsafe labeled and legacy CIEDs. Importantly, the terminology “MR compatible” remains persistently used colloquially, but it is not an accepted term. This term is not formally recognized and should not be used.

To date, there are around 75 commercially available CIEDs [4]. From these, there are no commercially available MR safe CIEDs and it is unclear if such a device could be engineered. Currently, the available CIEDs are labeled either MR conditional or MR unsafe (or unlabeled), with the first MR conditional CIED approved by the FDA in 2011 [5].

Device Risks

The interactions between CIEDs and the MRI scanner have been previously described [6]. These interactions raise

potential safety concerns related to CIED damage or risk to the patient. CIEDs interact with the following three magnetic field components in the scanner each of which is required to generate clinical MR images: (1) main magnetic field (B_0); and the time varying magnetic fields: (2) gradient magnetic field gradient and (3) radiofrequency (RF) magnetic field.

Main Magnetic Field (B_0)

The main magnetic field (B_0) is the static magnetic field that is always active. The main magnetic field polarizes the hydrogen nuclei (i.e., spins) so that they are amenable to being imaged. For clinical MRI scanners, the B_0 strength is typically 1.5 T or 3 T. The adverse interaction between a CIED and B_0 include (1) substantial physical forces (attraction or torque) that move the CIED resulting in device displacement and patient discomfort; (2) activation of the device therapy (activation of the reed switch sensor).

Physical Forces

In the presence of B_0 , ferromagnetic components will be attracted to the scanner when sufficiently close. Depending on the position of the device within the MRI scanner, the magnitude of the force of attraction will be different. Stronger translational forces will be exerted on the device just outside the scanner bore. Moving closer to isocenter, translational forces decrease; however, torque becomes stronger [7]. Figure 2 shows the schematics of the physical forces exerted by the B_0 field on a CIED relative to position in the scanner.

The main component subjects to translational forces are the ferromagnetic materials in the pulse generator, whereas the majority of the pacing leads are made of alloys that reduce ferromagnetic interactions with B_0 . Therefore, the main concerns are translational forces and torques on the components in the pulse generator. Notably, however, patients with MR unsafe CIEDs evaluated at 1.5 T prior of 2001 did not report

any adverse effects related to the B_0 field [8]. The tissue that surrounds the pulse generator can help hold the device in place despite the presence of the B_0 field. Therefore, guidelines suggest waiting 4 to 6 weeks after device implantation before performing an MRI examination [9].

Reed Switch Sensor

Reed switch sensors are components inside some MR unsafe CIEDs. When activated, the CIED is forced to stop sensing and pace in an asynchronous mode. In order to be activated, reed switch sensors were designed to be activated through the use of external magnets. Thus, the interaction between the CIEDs and the MRI scanner may lead to the erroneous activation of the sensor. This activation can lead to incorrect pacing or therapy inhibition [3]. An incorrect pacing mode can also lead to battery depletion in ICDs.

Time-Varying Magnetic Fields

MRI scanners use two different types of magnetic fields that are rapidly activated: gradient fields (used to encode images) and radiofrequency (RF) fields (used to excite spins). These magnetic fields generate time varying electric fields that can interact with the CIEDs in different ways.

Gradient Field

The gradient fields enable spatially encoding, which is required for image formation. The majority of clinical MRI scanners have gradient systems that generate a magnetic field whose peak strength varies between 40 and 80 mT/m. The speed at which a gradient can be turned on and off is given by the slew rate which is in range to 100 to 200 T/m/s. When the gradient magnetic field is rapidly turned on and off (as is required for imaging), it generates a time-varying electric field (E-field) that

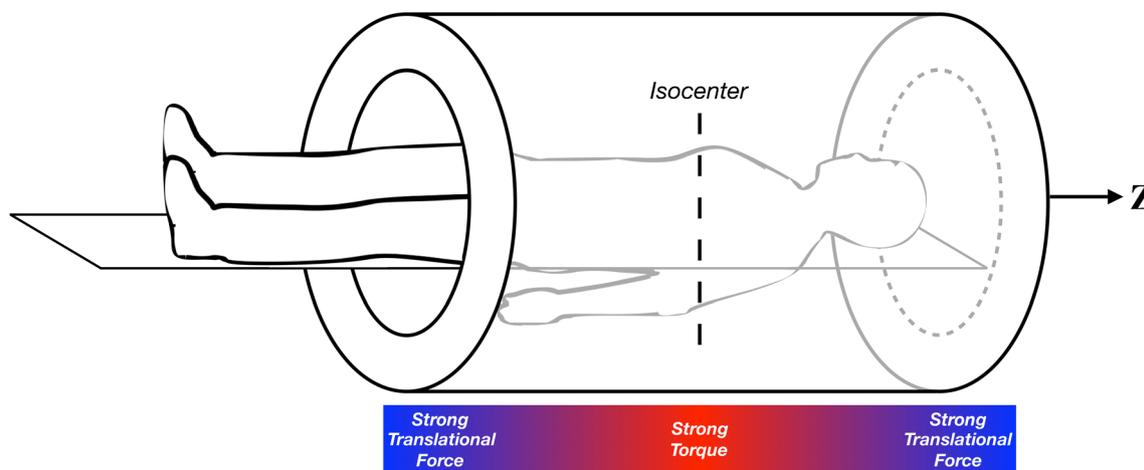


Fig. 2 Diagram of the physical forces exerted on a CIED by the B_0 field inside the scanner bore

creates electric currents. These currents can, for example, result in peripheral nerve stimulation with or without a CIED present. In the presence of CIEDs, the currents can interfere with the device sensing and may result in an undesired stimulation event. The CIED characteristics, such as the sensing mode and type of lead (bipolar or unipolar), lead path, and gradient strength along with its periodic duration can contribute to CIED oversensing [10]. When the device is in a synchronous pacing mode, the gradients can inhibit pacing or inappropriately apply ICD anti-tachycardia therapy. It has been observed that monopolar leads will be more susceptible to oversensing, whereas bipolar leads have a higher threshold [11].

RF Field

RF fields excite the hydrogen spins, thereby tipping them so they can be detected by a coil and measured for image formation. Highly conductive and lengthy components, such as the CIED leads, can act as antennae. The RF induced E-field generates currents that will travel along the lead. Because the myocardial tissue proximal to the lead-tip has a lower conductivity, these electric currents will be converted to thermal energy. Consequently, the so-called lead-tip heating (LTH) can potentially cause thermal damage to the surrounding tissue. This thermal damage may eventually lead to an increase in pacing threshold, capture loss, or arrhythmia induction produced by the CIED. LTH can be influenced by factors such as implant geometry [12], lead path [12, 13], lead characteristics [14], abandoned leads [15], scanning sequence type [16], and imaging landmark [17]. Generally speaking, the greatest LTH will occur when the CIED is placed at isocenter [18]. Hence, the thoracic examinations may generally be avoided. In addition to LTH, RF interference can lead to battery depletion due to erroneous sensing of multiple RF pulses as arrhythmic episodes [19].

SAR and B1+RMS

Regardless of the presence of pacing leads and CIEDs, the RF field deposits energy in all tissues that can result in tissue heating. The specific absorption rate (SAR, W/kg) is a measure of the amount of RF energy the MR scanner produces and that may be absorbed by the tissue. The FDA approves examinations under two SAR levels, normal operating mode (≤ 2 W/kg whole-body SAR) and first-level mode (≤ 4 W/kg whole-body SAR). SAR, however, is patient dependent (height, weight, age, and gender) and its calculation varies between different MRI scanner vendors. Some MR conditional devices have SAR specific labeling constraints (i.e., only MRI exams with SAR ≤ 0.5 W/kg). The time-averaged (root-mean-square) RF magnetic field (B1+RMS) is an alternative for estimating the applied RF energy. B1+RMS, however, is only dependent on the MRI exam parameters [20] (not patient

specific parameters). It is important to note that SAR and B1+RMS are only a means to estimate the whole-body deposited RF energy, and these values do not estimate the real thermal energy at the CIED lead-tip. Notably, CIEDs with B1-RMS limits are clinically more straightforward because an MRI exam protocol that meets the B1-RMS condition can be designed before the exam itself. SAR conditional labeling typically requires patient-specific protocol refinement, which can be time consuming and ultimately costly.

MR Conditional CIEDs

In 2011, the first FDA-approved MR conditional pacemakers became available [21]. To date, the number of MR conditional CIEDs has dramatically increased. These pacemakers have been modified and tested to mitigate potential risks in the MRI environment when specific conditions are met. To reduce the potential for translational forces and torquing, the number of ferromagnetic components has been reduced. The reed switch sensor has been replaced with a hall sensor; thus, the activation of the device therapy in presence of the B_0 field has been diminished. MR conditional CIEDs include another pacing mode that can be activated during an MRI scan. This so-called MR-mode allows the CIED to pace at a controlled rate during an MRI examination. All MR conditional CIED components and devices have been extensively tested over a wide range of exam conditions. Information needed to establish safety and combability of active devices in the MR environment has been published by the FDA [3]. Despite the availability of MR conditional CIEDs, the switch from implanting MR unsafe to MR conditional CIEDs has not occurred rapidly and confusion regarding safe MRI exams for these patients persists. The ProMRI study reported that nearly 45% (14/33) of MRI referrals were denied, despite MR conditional CIED device labeling [22]. The main reason for denying these examinations is likely related to the absence of MRI examination protocols for MR conditional CIEDs combined with the fact that the conditional guidelines may be unclear and provide insufficient guidance on how to modify MRI protocols to be acceptable.

MR Imaging with CIEDs

A protocol for performing MRI examinations with MR unsafe CIEDs while mitigating adverse effects has been previously reported [23]. Following this protocol, several prospective studies [24••, 25–27, 28••] have analyzed the effect of MRI on MR unsafe CIEDs. The MagnaSafe prospective multicenter study [24••] evaluated outcomes for patients with a CIED from 2009 to 2014 who underwent a clinically indicated MRI exam. In this study, non-thoracic MRI examinations

were performed in 818 patients with MR unsafe non-pacing-dependent pacemakers and 428 patients with ICDs. Patients with pacing-dependent pacemakers were excluded from the study due to the risks of battery depletion. After the MRI examination, a follow-up evaluation was performed at 6 months in 93% of the participants. The MagnaSafe study reported no significant damage to the CIED and an MRI protocol to scan MR unsafe devices was suggested [25]. Recent studies [26] suggest that MR unsafe pacing-dependent pacemakers manufactured after 2002 do not experience battery depletion during an MRI exam. A single-center study [27] reported no adverse effects in either pacing- and non-pacing-dependent patients with CIEDs when specific MRI protocols are followed. A prospective study from Johns Hopkins University and the National Institutes of Health (NIH) [28••] reported the analysis of 2103 examinations with MR unsafe CIEDs. In this study, both pacing- and non-pacing-dependent MR unsafe CIEDs were included (880 pacemaker, 629 ICDs, 137 pacing dependent), and thoracic MRI examinations were not excluded (257 of 2103 exams). Only nine examinations resulted in power-on reset. Furthermore, an association between thoracic imaging and change in sensing and threshold was not found.

Safety of MR conditional CIEDs under an MRI examination has also been evaluated [29]. No adverse effects were reported. It is also suggested that after CIED implantation, the percentage MRI examinations are expected to be ~73% over the CIED lifetime.

MRI Exam Protocol

To mitigate the risk of damaging the CIED or harming the patient during an MRI exam, it is important to follow a specific MRI exam protocol, depending on whether the patient has an MR unsafe [23] or MR conditional [30] CIED. The exam protocol should carefully consider safe

procedures pre-exam, during the exam, and post-exam. Generally, guidelines for a CIED MRI protocol should comply with the following [31]:

Pre-Exam Procedures

To evaluate whether or not the MRI examination resulted in CIED damage, it is necessary to analyze the CIED’s electrical parameters (e.g., battery status, stimulation thresholds, and lead impedance) along with the electrical signal [32] before and after an examination (Tables 1 and 2).

Figure 3 shows an example workflow to follow before an MRI examination. For both MR unsafe and MR conditional CIEDs, an assessment related to the CIED status is performed. In order to perform the MRI examination, it is expected that the CIED has been implanted for at least 6 weeks and that broken or abandoned leads are not present. In the case of MR conditional CIEDs, it is mandatory that all the CIED components (pulse generator and leads) are labeled as MR conditional and that the labeled conditions are completely understood and followed. Currently, there are no reports regarding MRI exams for patients with MR conditional pulse generators attached to MR unsafe leads (or vice versa). The programming of the CIED into a specific mode is then performed by a clinical cardiac electrophysiologist or nurse trained in ACLS with CIED expertise.

During and Post-Exam Procedures

For patients with CIEDs, at least two trained personnel need to be present during an MRI examination. The personnel need to be aware of an evacuation procedure and the location of an external defibrillator with external pacing pads. The patient’s heart rhythm (electrocardiogram and pulse oximetry) and symptoms need to be continuously monitored. Blood pressure should be monitored periodically. If the patient’s

Table 1 Parameters and respective conditions to follow when scanning MR conditional devices

Parameter	Condition	Units	Note
Main magnetic (B ₀) field	B ₀ strength	[T]	Main magnetic field strength (typically 1.5 T or 3 T)
	Spatial magnetic field gradient	[T/m]	Change in B ₀ strength with respect to distance from the scanner isocenter (not related to gradient field)
Gradient field	Slew rate (dB/dt)	[T/m/s]	Only for active devices
Radiofrequency (RF) Field (B ₁)	Specific absorption rate (SAR)	[W/kg]	Normal operating mode (NOM) ≤ 2 W/kg
	Time-averaged (root-mean-square) RF magnetic field (B ₁ +RMS)	μT	First-level operating mode (FOM) ≤ 4 W/kg
Miscellaneous	Type of coils	Transmit (Tx) Receive (Rx)	TX/Rx or Rx
	Imaging restrictions	[Landmark, LM]	Avoid certain examinations
	Examination time	[s or min]	Do not exceed required time

Table 2 Parameters to evaluate change in function of CIEDs after an MRI exam

Parameter	Reason	Limit
Battery status	Voltage reduction?	≤ 0.04 V
Lead impedance	Battery depletion or loss of CIED capture.	
	<ul style="list-style-type: none"> Decreased impedance? Insulation failure or lead fracture. Increased impedance? Lead or CIED problem. 	Pacing lead $\geq 50 \Omega$ High voltage lead $\geq 3 \Omega$
Stimulation threshold	<ul style="list-style-type: none"> Lead or CIED problems Decrease threshold? Tissue damage. 	≥ 0.5 V
Heart signal	<ul style="list-style-type: none"> Increase threshold? myocardial infraction Decreased P/R waves? Lead or CIED problems. 	P wave $\leq 50\%$ R-wave $\leq 25\%$

hemodynamic status is compromised during the MR exam, then the examination should be discontinued and appropriate measures taken. Figure 4a shows the workflow to follow during an MRI examination. Once the examination has finished, it is necessary to perform a second interrogation of the CIED parameters. If a change in the parameters is observed, then a follow-up in the CIED clinic is warranted. The CIED is then restored the original programming mode (Fig. 4b).

If more than one CIED parameter change was observed, it is recommended to assess the performance of the CIED after the MRI examination [33]. Three follow-ups need to be scheduled at 1 week, 3 months, and 6 months after the MRI

examination. If no CIED parameters changes are observed, then only one follow-up is needed between 3 and 6 months after the MRI examination.

The increase of blood troponin levels has been suggested as a biomarker to estimate myocardial damage due to the RF-induced heating [34]. A study performed in 348 scans analyzed troponin levels, pacing threshold, and lead impedance values before and after an MRI examination [35]. The results showed no significant changes in lead impedance and pacing thresholds values. However, an increase of troponin levels (≥ 0.002 ng/mL) was reported for 6.35% of the exams. Mollerus et al. [36] studied the change of troponin levels in patients with

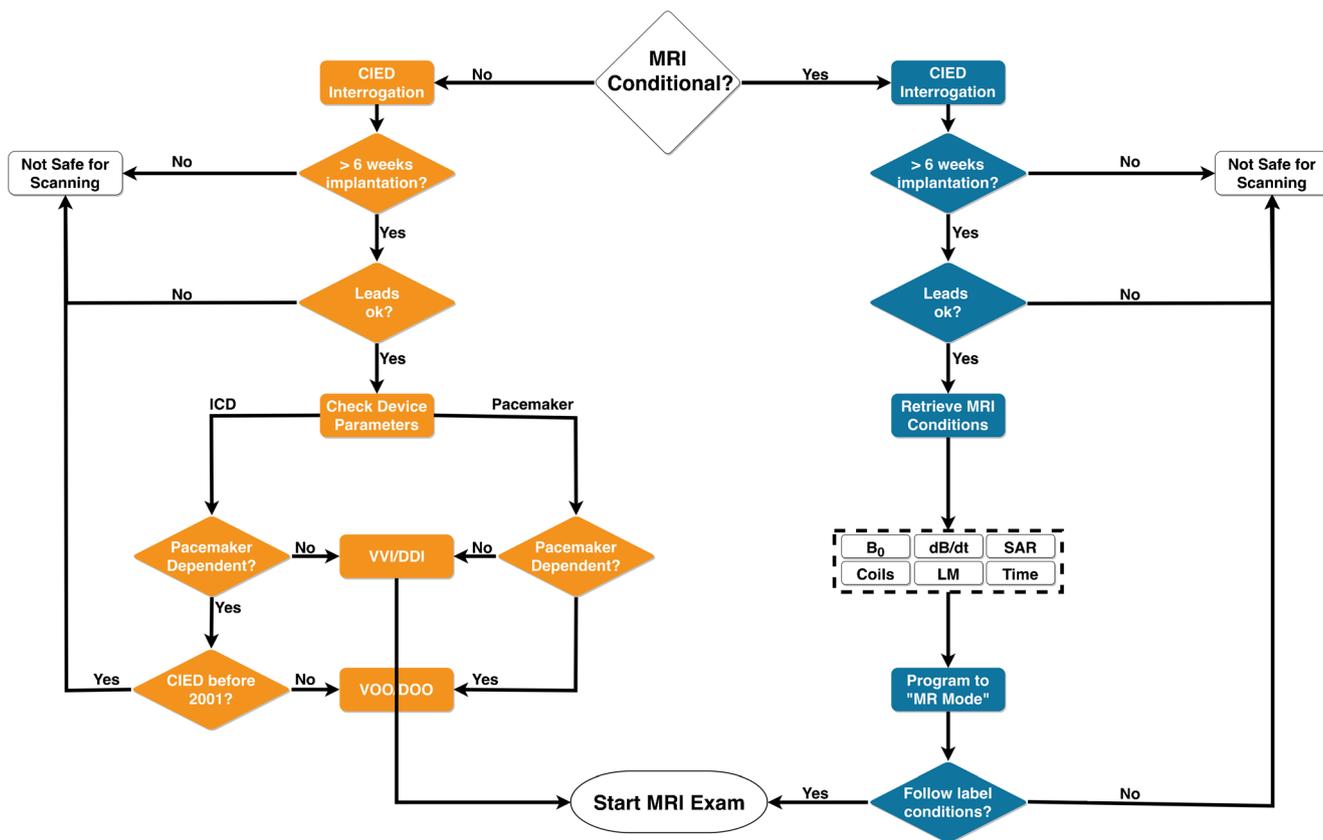


Fig. 3 Workflow to assess safety and initial status of the CIED before an MRI examination

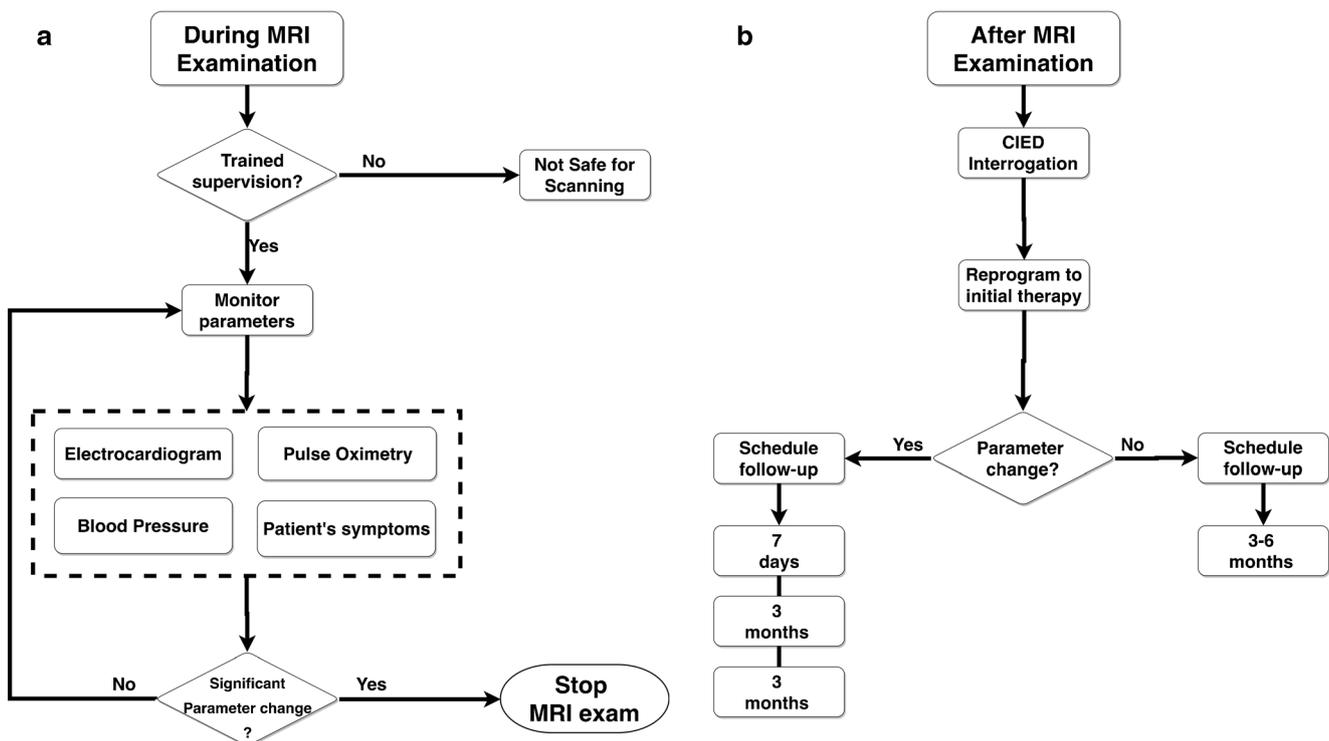


Fig. 4 Workflow to follow during (a) and after (b) an MRI examination for patients with CIEDs

MR unsafe CIEDs before and after an MRI examination without landmark or SAR restrictions. Similarly, a retrospective study analyzed troponin levels for patients with abandoned leads undergoing an MRI examination with a SAR limit of 1.5 W/kg [37]. Neither study showed a significant elevation of troponin, and both concluded that RF-induced heating was not sufficient to cause significant tissue damage. In practice, the measurement of blood biomarkers of myocardial damage is not performed. Adding this step in the MRI exam protocol is unlikely to benefit clinical management of these patients.

Current Issues

Summarizing previous studies [24••, 27, 28••, 29], the body regions most frequently scanned for patients with both MR conditional and MR unsafe CIEDs are shown in Table 3. Centers in need of a CIED MRI exam protocol should be aware and prioritize protocol evaluation accordingly, thereby ensuring, for example, that neuro and spine MRI protocols are available for patients with CIEDs. In the majority of the protocols, whole-body SAR was limited to ≤ 2 W/kg. One exception was the MagnaSafe study, wherein this restriction was not followed after the first 55 patients. The authors explained that SAR is not associated with device malfunction. Thus, restricting SAR to a certain limit does not appear to affect the safety of the

exam. Previous studies suggested that a change in pacing threshold was related to LTH [38]. From 61 CIEDs that underwent an MRI examination (107 leads), it was observed that regardless of the whole-body SAR reported, only ~ 10% of the leads had a significant change in pacing threshold (increase or decrease > 1 V). It is well known that whole-body SAR is not a good estimate of LTH.

As previously mentioned, RF-induced heating depends on several device- and patient-specific parameters that are not accounted for in the estimation of whole-body SAR. Energy being deposited at the device/tissue interface (i.e., local SAR) may still occur at a restricted whole-body SAR value [39]. Thus, a better estimate to assess tissue damage is needed in evaluating the safety of MRI examinations.

Table 3 List of the most common MRI referrals for patients with both MRI unsafe and MRI conditional CIEDs during the device lifetime

Incidence	Range [%]	Body region
1	52–34	Brain
2	40–22	Spinal*
3	27–4	Abdomen
4	16–12	Chest
5	9	Extremities**

*Includes cervical, thoracic, and lumbar spine

**Refers to hand, legs, and feet

Conclusion

In a period of 30 years, CIEDs have moved from being a complete contraindication in the MRI environment to not presenting significant risks for MR conditional CIEDs in controlled situations. Substantial device design engineering to improve CIED components to limit interactions with the MRI magnetic fields has enabled this step forward. Clinical evidence shows that MRI examinations for patients with CIEDs can be obtained with no reported significant adverse events. Nevertheless, research continues to reduce the risks and simplify the MRI exam procedures for patients with CIEDs. While the risks associated with the main (B_0) magnetic field have largely been diminished, it is still necessary to better understand and limit the interactions between the CIED and the time-varying gradient and RF magnetic fields.

Compliance with Ethical Standards

Conflict of Interest Jessica A. Martinez and Daniel B. Ennis declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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