MRI in Patients with Cardiac Implantable Electronic Devices

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Indications for MRI have grown considerably in recent years. However, many patients with cardiac implantable electronic devices are denied imaging due to physician misinterpretation of the risks associated with MRI. This review discusses the theoretical basis for the perceived risk by exploring preclinical literature. It then presents a detailed examination of the true rates of adverse events in clinical studies across both MR nonconditional (legacy) and MR conditional devices. Indeed, many of these adverse events are rare, nonexistent, and/or clinically insignificant in the wealth of published data. The authors then address image quality and the constituents of a safety checklist that institutions should consider when performing MRI in patients with a cardiac implantable electronic device. Lastly, the authors conclude with an overview of future directions for advancement in the field.

Online supplemental material is available for this article.

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Learning Objectives:

After reading the article and taking the test, the reader will be able to:

- Identify the potential complications of MRI in patients with a cardiac implantable electronic device (CIED)
- Recognize factors that impart a higher risk for patients with CIED undergoing MRI
- Describe the important components of a safe protocol for subjecting patients with CIED to MRI

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MRI is the standard imaging modality for an increasing number of medical conditions owing to its excellent spatial resolution, tissue characterization, and lack of ionizing radiation. However, MRI in the presence of a cardiac implantable electronic device (CIED) still causes trepidation owing to concerns regarding the interaction between electromagnetic fields and the CIED. Denial of MRI services is particularly consequential as 50%–75% of patients with a CIED are estimated to require an MRI during their lifetime (1).

Early reports of deaths associated with MRI in patients with permanent pacemakers (PPMs) and implantable cardioverter defibrillators (ICDs) resulted in an inflexible classification of absolute contraindication to CIED for MRI among clinicians, institutions, and professional associations (2,3). However, these deaths occurred during unmonitored MRI examinations and were thus inconclusive regarding etiology. In at least three cases, the deaths were presumed related to spontaneous fatal arrhythmia (3).

The American Society for Testing and Materials uses three specific terms to delineate the safety of products in an MRI environment: MR safe, MR conditional, and MR unsafe (Table 1) (4). No PPMs or ICDs have been declared MR safe by the Food and Drug Administration (FDA). *MR nonconditional* is a term used in the 2017 Heart Rhythm Society guidelines, which refers to objects that have not been declared MR conditional or safe (5). *MR unsafe* refers to objects known to pose a risk in all MRI environments. *MR conditional* denotes an item that poses no hazards in a specified MRI environment with specified conditions of use. The first MR conditional CIED system was approved by the FDA in 2011 (6).

The 2017 Heart Rhythm Society guidelines provide the most up-to-date recommendations for performance of MRI in CIED (5). They make a class I (strong) recommendation for MRI with MR conditional systems only in the context of a standardized institutional workflow. For MR nonconditional systems, they make a class IIa (moderate) recommendation that it is reasonable to perform MRI in the absence of fractured, epicardial, or abandoned leads. However, research suggests persistent reluctance among clinicians and institutions to perform MRI

Abbreviations

CIED = cardiac implantable electronic device, FDA = Food and Drug Administration, ICD = implantable cardioverter defibrillator, POR = power-on reset, PPM = permanent pacemaker, SAR = specific absorption rate

Summary

This review details the current evidence regarding the performance of MRI in patients with cardiac implantable electronic devices.

Essentials

- The presence of a pacemaker or implantable cardioverter defibrillator has traditionally been a contraindication for MRI.
- In the past 10 years, evidence has proven concern for serious adverse events to be overstated, with large studies showing limited and manageable side effects.
- Newer MR conditional devices are now commonly implanted, but patients with older MR nonconditional devices can usually undergo MRI safely with proper precautions.
- Future work will focus on MR safe devices that have no conditions on their use and on further exploration of the safety of leadless device designs.

in patients with MR nonconditional CIEDs (7,8). Experience and technology have advanced rapidly, and these perspectives need to be modified accordingly (9,10).

This review provides a brief summary of the basis for MRI interaction with CIEDs followed by a discussion of the current clinical evidence regarding both MR conditional and MR nonconditional products (11,12). Finally, we discuss the elements of an institutional checklist and outline evolving areas in the field.

Interaction between MRI Units and Implantable Devices

MRI utilizes a static magnetic field that orients hydrogen protons along the axis of the imager–this field is described in tesla and ranges from 0.5 to 10.5 T, about 140 000 times the strength of the Earth's magnetic field (for 7-T imagers). Separate gradient coils vary the magnetic field locally across different sections of the body. Once the atoms align, energy in the form of a specific radiofrequency pulse causes the magnetic vector to deflect. When the radiofrequency pulse is removed, the magnetic vector returns to its resting state, which causes a signal to be produced. For a full explanation of MRI technology, readers are referred to one of many high-quality review articles (13).

The MR imager produces three electromagnetic fields, which can interfere with CIED: the static magnetic field (measured in tesla), the radiofrequency field (measured by specific absorption rate [SAR] in watts per kilogram), and the pulsed gradient field (measured in tesla per meter per second). The hypothetical consequences of these fields interacting with CIED are discussed below and summarized in Table 2.

Mechanical Displacement

Concern about CIEDs in MRI was initially driven by the concern of mechanical displacement of the device due to the static magnetic field acting on the ferromagnetic components of CIEDs (14). Ferromagnetic components are present in the batteries and reed switches (a magnetically activated switch that places the device in "magnet mode") of CIEDs. The effect of the magnetic field on ferromagnetic components has been assessed both in vitro and through symptoms of pulling or movement in patients. However, concern regarding displacement has proven unjustified for PPMs made after 1995, because the ferromagnetic content of these devices is so low that they only experience forces within the range of gravity (15,16). ICDs have a higher ferromagnetic content and consequently generate forces that are marginally higher than gravity, yet, these are still unlikely to be clinically significant (15). It is important to note that CIED lead tips are unaffected by static magnetic fields as they have no ferromagnetic materials. This negates the possibility of the lead becoming dislodged and failing to capture (17).

Device Reprogramming

MRI can reprogram CIEDs in two main ways. First, the static magnetic field can activate the reed switch. The reed switch is normally used to reset the pacemaker into an asynchronous pacing mode and disable antitachyarrhythmia function in response to a magnet being placed on the patient's skin (magnet mode). Activation of the reed switch prevents interference with CIED function during electrocautery surgery. Additionally, pacemakers can undergo power-on reset (POR). PORs are electrical resets designed for safety in the event of battery depletion or circuit malfunction. PORs typically reset the device to inhibited pacing (pacing mode VVI). POR and reed switch activation are detected by interrogating the pacemaker after the MRI and/or noticing changes in the patient's vital signs during imaging.

Reed Switch Closure

A reed switch "closes" in a magnetic field causing current to flow through it. PPMs contain reed switches that, when closed, set the pacemaker to a preprogrammed function. This is typically asynchronous (pacing mode VOO) pacing. In asynchronous pacing, the device paces the ventricle at a preprogrammed rate continuously. In addition, the reed switch suspends antitachyarrhythmia therapies for ICDs. The static magnetic field is capable of closing reed switches. In asynchronous mode with antitachyarrhythmia therapies off, devices will not detect a ventricular arrhythmia, spontaneous or MRI induced, and will not treat the arrhythmia (18). There is also a theoretical danger of competitive pacing between the heart's intrinsic rhythm and the preprogrammed asynchronous pacing. This can lead to proarrhythmia due to R-on-T phenomena in patients who have a high heart rate. Reed switches are unpredictable in the static field strengths produced by clinical MRI, with half of them initially closing and then reopening later during the imaging (19–21). For this reason, most protocols disable the magnet response when reprogramming the CIED prior to MRI so that the static field does not activate the reed switch (22).

Power-On Reset

A POR is a specific type of reprogramming that reverts the device to factory default settings when battery voltage falls below a critical level or damage to the circuits is detected. This is a failsafe feature. The settings to which the device reverts vary by

Table 1: Definitions Related to Cardiac Implantable Electronic Devices and MRI

Term	Definition
MR safe	Objects that pose no known hazards in all MRI environments
MR conditional	Objects that pose no hazards in a specified MRI environment with specified conditions of use
MR unsafe	Objects known to pose a risk in all MRI environments
MR nonconditional	A term used in the 2017 Heart Rhythm Society guidelines that refers to objects that have not been declared MR conditional or MR safe
Asynchronous pacing	A pacing mode where the device delivers stimuli at preset intervals independent of intrinsic cardiac signals
Inhibition pacing	A pacing mode where the device only delivers stimuli when no intrinsic cardiac signals are sensed
Antitachyarrhythmia therapies	Therapies delivered by a device that can terminate arrhythmias. Types of therapy include antitachycardia pacing and defibrillation
Pacing capture threshold	The minimum electrical stimulus needed to consistently depolarize or "capture" the myocardium. This is measured in volts (V)
Lead impedance	A measure of the opposition to current flow through the device's leads. Decreased lead impedance increases the drain on the battery. This is measured in ohms (Ω)
Sensing amplitude	A measure of a device's ability to detect cardiac signals. This is measured in millivolts (mV)

manufacturer. Many devices reset to inhibition pacing, with antitachyarrhythmia therapy on, where the device will initiate therapies for life-threatening arrhythmias. This is problematic when electrical induction in the leads causes inappropriate sensing of induction as intrinsic cardiac activity and results in inhibition of required pacing. Additionally, in patients needing high intrinsic heart rates (such as children), the factory default may not provide the required cardiac output. However, devices are usually easy to reprogram after the MRI following a POR event.

Induction of Currents and Changes in the Electrocardiogram

The gradient magnetic and radiofrequency fields can electromagnetically couple with leads to induce electric currents through the "antenna effect." These currents can alter the recorded electrogram, stimulate dangerous arrhythmias, and permanently interfere with ICD function (23,24). Induced currents can result in inhibition of pacing due to the device perceiving an intrinsic underlying rhythm on the electrogram (25). Furthermore, the induced artifactual current can be interpreted as ventricular arrhythmia with subsequent attempts to initiate antitachyarrhythmia therapy in ICDs (26). However, ICD therapy usually fails as the capacitor cannot charge due to "saturation" in the static magnetic field (27). Thus, the ICD may drain its battery while continuously attempting to charge a saturated capacitor.

There is a potential for induced currents to be substantial enough to cause life-threatening arrhythmia through rapid pacing. This potential was demonstrated in vitro by Erlebacher et al, who showed atrial pacing rates of 800 ppm due to the radiofrequency field detected on pacemaker interrogation (25). This was later replicated in a swine study, where a stable tachycardia of 200 beats per minute was induced for 10 seconds during 1.5-T MRI (28). Again, due to ICD therapy being impaired by the static magnetic field, an MRI-induced arrhythmia may not be treated by the ICD and result in battery drainage. Thus, most protocols call for the disabling of antitachyarrhythmia sensing and therapies to circumvent the problem of unnecessary shock or battery depletion.

Heating Effects

Another consequence of the radiofrequency field is deposition of heat energy, particularly at the lead tips, which can result in myocardial tissue damage. At an SAR of 4.0 W/kg–below most clinical scans, tissue heating in the absence of foreign materials (such as CIEDs) does not exceed 0.7°C (29). However, energy absorption changes in the presence of conducting materials. This makes temperatures difficult to predict. Consequences of myocardial tissue damage include changes in pacing threshold with subsequent loss of capture (where the pacing signal no longer depolarizes the myocardium), re-entrant arrhythmia induction, and myocardial perforation. Thus, these consequences are typically investigated in vitro by measuring temperature directly and in vivo by interrogating the pacemaker and measuring serum biomarkers of myocardial damage such as troponin. There are many variables in determining the degree of heating, including lead location and design, presence of abandoned leads, position in the imager, power and duration of the radiofrequency field, and rate of blood flow (28,30–32). In vitro phantom studies using "worst-possible" conditions have demonstrated severe heating at lead tips, with a maximal temperature of 88.8°C, though this was in a temporary pacing lead (33,34). Most in vitro studies demonstrate much milder heating in the range of 0.5°C or less (35). In a swine model, direct lead tip temperature measurements increased by up to 20.4°C (28). These temperatures were associated with changes in lead impedance. Despite this, there were no elevations in troponin or evidence of thermal injury at histologic examination. The absence of thermal injury around the lead tip has been demonstrated in other animal studies (36). In humans, there have been negligible effects on post-MRI troponin levels, with very few subjects experiencing increases in troponin above the normal limit (20,37). However, pacing capture thresholds before and after imaging undergo minor alterations, presumably due to MRI-induced thermal injury (38). Importantly, threshold changes are rarely clinically significant, and those that occur are usually temporary and do not require pacemaker reprogramming.

Table 2: Electromagnetic Fields Used in MRI, the Most Commonly Studied Field Strengths, Potential Effects on CIEDs, and Event Rates from In-Human Clinical Studies

Electromagnetic Field Type	Commonly Studied Strength	Effect on CIEDs	In-Human Event Rates*
Static magnetic field	1.5 T	Mechanical displacement; Device reprogramming	0 to 0.2% experience symptoms (31,32); 100% "magnet-mode" activation in reed-switch devices (25). 0 to 10.4% power-on reset rate (12,36)
Radiofrequency and gradient magnetic field	2.0 W/kg and 200 T/m/sec	Tissue heating; Induction of current	Up to 37% of leads with minor parameter changes. Almost none clinically significant (27); 13.5% have ventricular ectopy during scan. No sustained ventricular arrhythmias (45). 0 to 7% of devices record artifact as arrhythmia during scan (31,47)

Note.—CIED = cardiac implantable electronic devices.

* These event rates are derived from studies in experienced centers with appropriate protocols.

Clinical Studies of MR Nonconditional Devices

Pacemakers

Early clinical studies of MR nonconditional devices that were not specifically designed for the MRI environment (also known as legacy devices) began in the mid-1990s with single-digit sample sizes (39). These studies used low static field strengths (0.5 T) and limited imaging to nonthoracic regions (34,39,40). Additionally, these studies excluded pacemaker-dependent patients, those with recent (less than 3 months) implants, and those with abandoned or surgical epicardial leads. The early results were reassuring, with most events being reed-switch activation (magnet-response) and minor changes in lead parameters or battery voltage. Importantly, no major complications such as induced arrhythmias or inappropriate pacing inhibition were seen.

After these early reassurances, researchers in the mid-2000s conducted studies with larger numbers of patients. They also included thoracic and cardiac MR examinations, higher magnetic field strengths, and cardiac resynchronization devices (38,41). Again, the most common complications observed were clinically insignificant lead parameter and battery voltage changes, occasional symptoms around the implant site (such as vibration), activation of reed switches, and, uncommonly, PORs (Table 3) (20,38,41).

The MagnaSafe registry of 1500 MRI examinations and the Nazarian et al cohort of 2103 MRI examinations in patients with CIED constitute the largest studies to date with MR nonconditional devices (9,10). MagnaSafe demonstrated a remarkable lack of adverse events in its 1000 PPM MRI examinations, with no deaths, generator failures, lead failures, or loss of myocardial capture. The only complications seen in the pacemaker cohort were low rates of minor lead parameter changes (ranging from 0.8% to 16.4% depending on the parameter), spontaneously reverting atrial fibrillation, and PORs. It is notable that the MagnaSafe registry excluded thoracic MRI examinations, where energy absorption by the CIED is thought to be the greatest. However, low rates of adverse effects were observed in the Nazarian et al cohort that contained 257 thoracic scans (10,37). In Nazarian et al cohort of 880 patients with PPMs, one examination was terminated due to inappropriate inhibition in response to electromagnetic interference resulting in temporary bradycardia (10). There were no clinical consequences. Sommer et al attempted to relate change in lead impedance after MRI to myocardial injury by measuring troponin I levels. They found no overall increase in troponin levels after MRI (20). A lack of troponin increase after MRI has subsequently been observed by other investigators (26,37,42–45). Cohen et al were the first, to our knowledge, to include a control group that did not undergo MRI (46). They found that device parameter changes occur even without exposure to electromagnetic fields. The results of Cohen et al suggest baseline variation in CIED parameters, as opposed to myocardial injury, as a possible explanation for observed pre- and post-MRI differences (46). Thus, CIED parameter changes, while not unusual, should not be considered a clinically significant adverse event of MRI in CIED patients.

Symptoms of pulling, heating, vibration, and palpitations have been reported during MRI in patients with CIED. Very few correlate with clinical events, although the MRI examination may be stopped due to apprehension. In the MagnaSafe and Nazarian cohorts combined, only five instances of symptoms were experienced out of 3603 examinations (0.1%) (9,10). One of these patients experienced a pulling sensation associated with POR of the device and thus, the MRI was aborted. However, this patient had an old ICD implant from 1999. These devices are more prone to displacement due to their higher ferromagnetic content. The majority of literature has shown low or no symptom rates during MRI (20,44,47–49).

Reed switch activation is a largely accepted fact of MRI in devices that are not fitted with newer magnetic field–resistant Hall sensors. As discussed above, reed switch activation creates problems as the device will pace at a preprogrammed rate and fail to deliver therapies for potentially life-threatening arrhythmias. Thus, most protocols call for disabling of magnet response, which means that activation of a reed switch will have no effect. The inevitability of reed switch activation is reflected in the literature with an almost 100% occurrence and resultant pacing at the preprogrammed magnet-response rate if this setting cannot be disabled (10,20,40,50). One case series by Heatlie et al

Table 3: Summary of Major Studies of MRI Effects in MR Nonconditional Cardiac Implantable Electronic Devices

A: Pacemaker Studies with > 40 Patients

Year	First Author	No. of Patients with Pacemakers	Safety Findings
2000	Sommer (34)	44	Reed switch closure and minor battery voltage changes
2004	Martin (38)	54	Vibration and palpitations, reed switch closure and 37% with PCT change but only 9.4% with > 1 V change
2006	Nazarian (41)	31	Reed switch closure
2006	Sommer (20)	82	Reed switch closure, 8.5% with POR, 3.1% had PCT increase > 1 V, minor decrease in impedance and minor decrease in battery voltage
2008	Naehle (42)	44	Minor decreases in battery voltage and 16% with POR
2009	Mollerus (54)	52	Minor decrease in sensing amplitude and 7 patients with significant ectopy
2009	Naehle (59)	47	Minor decrease in PCT (0% > 1 V), minor impedance changes and a minor decrease in battery voltage
2010	Mollerus (47)	105	1 POR and a minor decrease in sensing amplitude
2010	Strach (85)	114	Reed switch closure
2012	Cohen (46)	109 with ICD or PPM	Reed switch closure
2013	Friedman (61)	171	Minor change in PCT, sensing amplitude and frequent ventricular ectopy during scans
2014	Kaasaleinen (86)	62	Reed switch closure and minor change in lead impedance
2014	Muehling (45)	356	Reed switch closure and 10.4% with POR
2015	Higgins (51)	196	3.5% with POR
2015	Sheldon (26)	40	2.5% with POR, 1 patient with artifact sensed as VF
2015	Shenthar (65)	177	Minor PCT changes and minor lead impedance changes
2016	Bertelson (83)	137	None
2016	Camacho (56)	74	3 patients with symptoms but no sequelae, electromagnetic noise in 7.1%
2017	Russo (9)	818	5 patients with spontaneously reverting AF, 6 patients with POR
2017	Nazarian (10)	880	8 PORs, reed switch closure, inhibition of pacing in pacing dependent patient, lead parameter changes not requiring revision/reprogramming, battery drainage

B: ICD Studies with > 20 Patients

Year	Author	No. of Patients with ICDs	Safety Findings
2006	Nazarian (41)	24	Reed switch closure
2010	Mollerus (47)	22	1 POR, 1 ICD arrhythmia log erased and minor decrease in sensing amplitude
2012	Cohen (46)	109 with ICD or PPM	Reed switch closure
2016	Camacho (56)	39	3 patients with symptoms but no sequelae, electromagnetic noise in 7.1%
2016	Dandamudi (64)	29	1 patient with chest pain
2017	Russo (9)	428	1 generator failure requiring replacement, 1 induced AF
2017	Nazarian (10)	629	1 POR, lead parameter changes, 1 pulling sensation in chest, reed switch closure, battery drainage

Note.—PCT = pacing capture threshold, POR = power-on reset, VF = ventricular fibrillation, ICD = implantable cardioverter defibrillator, AF = atrial fibrillation.

reported a patient inappropriately pacing at maximum voltage output at a rate of 100 ppm during cardiac MRI (48).

POR is a more sinister reprogramming complication of CIED during MRI. The reported rates of POR range from 0% to 16% (10,20,26,38,42,43,45,51,52). POR seems to be associated with older devices manufactured before 2002 (43,51). In most of these cases, the devices are reset to an inhibition mode (usually VVI). In VVI mode, the devices pace at the manufacturer's default rate, rarely causing clinical incident. However, the potential for lethal events does exist in pacing-dependent patients who experience POR and have pacing inhibited by inappropriate sensing of electromagnetic interference. In 2009, Gimbel et al described unexpected asystole in a pacemaker-dependent patient undergoing 3-T MRI of the head (53). Pacing resumed when the gradient field was removed, and the patient survived. This occurred in a pacemaker released in 2005, which is against the

trend that only devices older than 2002 are affected by POR. Thus, it is recommended that continuous electrocardiography, if available, and pulse oximetry should always be performed for pacemaker-dependent patients undergoing MRI. This allows identification of cases of inappropriate inhibition of pacemaker function.

There are no records of MRI-induced ventricular arrhythmia aside from ventricular ectopy (54). All of the sustained arrhythmias have been atrial fibrillation and/or flutter, with the MagnaSafe registry reporting six episodes of 1500 MR examinations (9). Furthermore, only one patient did not have a prior history of atrial fibrillation/flutter and it spontaneously resolved within 48 hours.

Implantable Cardioverter Defibrillators

There was initially greater concern in introducing ICDs to the MRI environment owing to their larger size and higher ferromagnetic content. However, after the early successes of MR nonconditional PPMs, testing began in 2004 with small cohorts of patients (55). ICDs were suspected to be associated with more displacement, greater battery voltage change, and the potential for inappropriate tachyarrhythmia sensing and therapies than PPMs. To reduce this, tachyarrhythmia sensing and therapies were disabled before the MRI examination (37,41).

Regarding ICD displacement, there have been no major lead or implant complications in ICD studies to date. Minor symptoms over the implant site have been reported at a rate similar to that of PPMs (10,56).

Inappropriate sensing of electromagnetic noise by the ICD as a shockable rhythm (usually ventricular fibrillation) is well documented. In one example, Burke et al found that nine of 14 patients with ICDs undergoing MRI recorded electromagnetic noise as fast ventricular tachycardia or ventricular fibrillation (57). None of these patients had clinical sequelae because the ICD therapies were programmed off. Burke et al found no difference in the energy required to terminate ventricular fibrillation before and after MRI, suggesting no interference with shock delivery. Other studies have found much lower rates of noise misinterpretation and, in the cases that do occur, they are clinically insignificant owing to appropriate pre-MRI programming (26,58,59). The importance of appropriate programming is highlighted by a case from the MagnaSafe registry (9). In that case, tachycardia therapy was not disabled during pre-MRI reprogramming. After MRI, the ICD could no longer be interrogated or reprogrammed and thus required immediate generator replacement. Retrospective evaluation determined that the device had interpreted MRI signals as ventricular fibrillation and had made repeated failed attempts to charge the capacitor, though no shocks were delivered due to capacitor saturation. Thus, after correct programming the risk of inappropriate sensing and therapy is extremely low.

Battery depletion has also proved to be a low-risk event. Most studies observe transient changes from before to after MRI, with a full recovery in many during follow-up (59,60). In the MagnaSafe registry, 7.2% of ICDs had an immediate battery voltage decrease of 0.04 V or greater; however, only 4.2% had persistent changes at 3–6-month follow-up, with a similar pattern observed in the Nazarian cohort (10). For perspective, at beginning of life a CIED battery will usually have 2.8 V of output. At approximately 2.0–2.4 V, the elective replacement indicator will be triggered, which leaves 6 months before the generator will begin to malfunction.

Contraindications to Imaging

Prior studies of patients with CIEDs have had strict exclusion criteria that developed from the theoretical risks as previously discussed. Previously discussed contraindications include patients with recent implants, epicardial and abandoned leads, high SARs, serial MRI examinations, pacemaker dependency, and thoracic imaging. Next, we examine current evidence in relationship to previously described contraindications.

Recent Implants

Time after implantation has been considered an exclusion criterion. Recent implantation of a CIED ranges from 6 weeks to 3 months (37,59). The purpose of a waiting period after implantation was to allow the lead tips to establish a fibrous sheath in the myocardium, thereby reducing the likelihood of lead dislodgement. Friedman et al prospectively compared outcomes in eight examinations of early pacemaker implants (< 6 weeks; range, 7–36 days) versus 211 examinations of older implants (mean, 1150 days) (61). They observed no major complications or troponin increase in any of the patients, nor any difference in lead parameters at 104 days follow-up. Comparable results were seen in 80 newly implanted leads in the MagnaSafe registry. These results are reassuring for those patients requiring urgent MRI after device implantation (9).

Epicardial and Abandoned Leads

Epicardial and abandoned leads were traditionally excluded from studies due to preclinical research demonstrating unpredictable heating in vivo. However, Higgins et al performed a retrospective review of 35 examinations in patients with abandoned leads undergoing head or spine MRI (62). Within 7 days of follow-up, they observed no symptoms or arrhythmias in these patients. In 10 of the patients who had their generators reconnected for clinical reasons, the largest capture threshold increase was 0.7 V in a ventricular lead. The authors concluded that there were no clinically significant sequelae from the MRI on the abandoned leads. Horwood et al found similar results in a cohort of 12 abandoned leads, which included three epicardial leads (63). Despite this observational data indicating limited risk, most studies still preclude patients with abandoned leads (56,64).

There is limited experience and literature regarding permanent surgical epicardial leads and thus, it is not possible to determine their safety. Temporary postsurgical epicardial leads that have been partially removed are not considered abandoned leads and are not considered contraindications to MRI (5).

High SARs

Most large prospective studies have placed limits on the radiofrequency field (measured in SAR). This was due to preclinical work that suggested a correlation between SAR and potential complications (29). Mollerus et al investigated this in a prospective study of 127 examinations with no SAR restrictions (me-

Table 4: MR Conditional Devices Approved by the U.S. Food and Drug Administration

Manufacturer	Pacemakers	Defibrillators/CRT	Leads
Biotronik (ProMRI)	Eluna 8 (DR-T and SR-T) Entovis (DR-T and SR-T) Edora 8 (DR-T and SR-T)	Iforia (VR-T DX and DR-T) Iperia (VR-T DX, DR-T and HF-T) Inventra (VR-T DX and HF-T) Intica (DX and CRT DX) Ilivia (VR-T, DR-T and HF-T)	Setrox S (53,60) Solia S (45,53,60) Corox OTW Sentus ProMRI Protego (ICD) Linoxsmart (ICD) Plexa ProMRI (ICD)
Boston Scientific (ImageReady)	Accolade MRI Essentio MRI Vitalio MRI Proponent MRI Advantio Formio Ingenio	Emblem MR imaging *S*-ICD Resonate HF/X4/EL Perciva and Perciva HF Vigilant ×4/EL Autogen Mini/EL/X4 Dynagen EL/Mini/X4 Inogen Mini/EL/X4 Origen Mini/EL/X4 Charisma ×4	Ingevity MR imaging Endotak Reliance DF4 (ICD) Fineline II Acuity ×4
Medtronic (SureScan)	Advisa MRI (DR and SR) Revo MRI Micra Transcatheter Pacer	Visia AF MRI VR Evera MRI XT DR Evera MRI S DR and VR Amplia MRI Quad CRT-D Amplia MRI CRT-D Complia MRI Quad CRT-D	5086 MRI 5076 6947M (ICD) 6935M (ICD) 4196 (CRT) 4296 (CRT) 4396 (CRT) 4298 (CRT) 4398 (CRT) 4598 (CRT)
Sorin	None available in United States	None available in United States	None available in Unites States
St Jude Medical/Abbott	Assurity MRI	Ellipse MRI	Tendril MRI LPA1200M Durata 7120Q and 7122Q (ICD) Optisure LDA220Q and LDA210Q (ICD)

Note.—Data received from representatives of each company and by examining their online materials. ICD = implantable cardioverter defibrillator, CRT = cardiac resynchronization therapy.

dian SAR, 2.5 W/kg; interquartile range, 1.3–3.2 W/kg) in both PPMs and ICDs (47). They found that SAR poorly predicted safety outcomes for these patients. At present, many studies continue to impose SAR limits, usually to less than 2.0 W/kg, to limit heating and electromagnetic induction (45,65). However, the recently published Nazarian et al cohort removed SAR restrictions during recruitment owing to a lack of evidence for harm beyond normal SAR limits in non-CIED patients (10).

Serial MRI Examinations

Little was known about the effect of serial MRI examinations on CIED function. The underlying concern was an assumption that cumulative minor effects could become clinically significant. Naehle et al performed a retrospective review of 47 patients with PPM who had undergone at least two examinations (including thoracic examinations) at 1.5 T (59). The study included three patients who underwent more than 10 examinations. They found that changes in capture thresholds, impedance, and battery voltage were not clinically significant even after 10-plus examinations. Junttilla et al furthered this by examining serial cardiac MRI examinations in ICD patients with a follow up of 370 days (60). They observed no meaningful change in lead parameters. Similar results were found by Nazarian et al, where there was an association with changes in lead impedance and capture thresholds, but no other variables (10).

Pacemaker Dependency

Pacemaker dependency comes with a higher risk during MRI due to potential inappropriate inhibition of pacemaker activity with resultant asystole. For this reason, many studies excluded pacemaker-dependent patients. One study reported a decrease in pacing rate from 90 ppm to 50 ppm, resulting in hypotension in a pacemaker-dependent patient who underwent POR. This patient had an ICD system that was on advisory–a notification from the device company that there is an increased risk to patient safety from the device (63). While there is now much experience with pacemaker-dependent patients, careful monitoring is mandated during MRI to avoid potential catastrophe in the form of inappropriately inhibited pacing after a POR.

Thoracic and Cardiac MRI

Experience with thoracic and cardiac imaging has been restricted based on a belief that greater energy deposition would result in worse outcomes. There are minor differences in long-

term battery voltage when imaging the thorax or heart (50). However, most studies including thoracic and cardiac MRI examinations have had a safety profile equivalent to that of extrathoracic MRI (10,37,38,49). The main issue with thoracic and cardiac imaging is the MRI artifact over the area of interest. This is particularly evident on balanced steady-state free precession sequences, as discussed below (44).

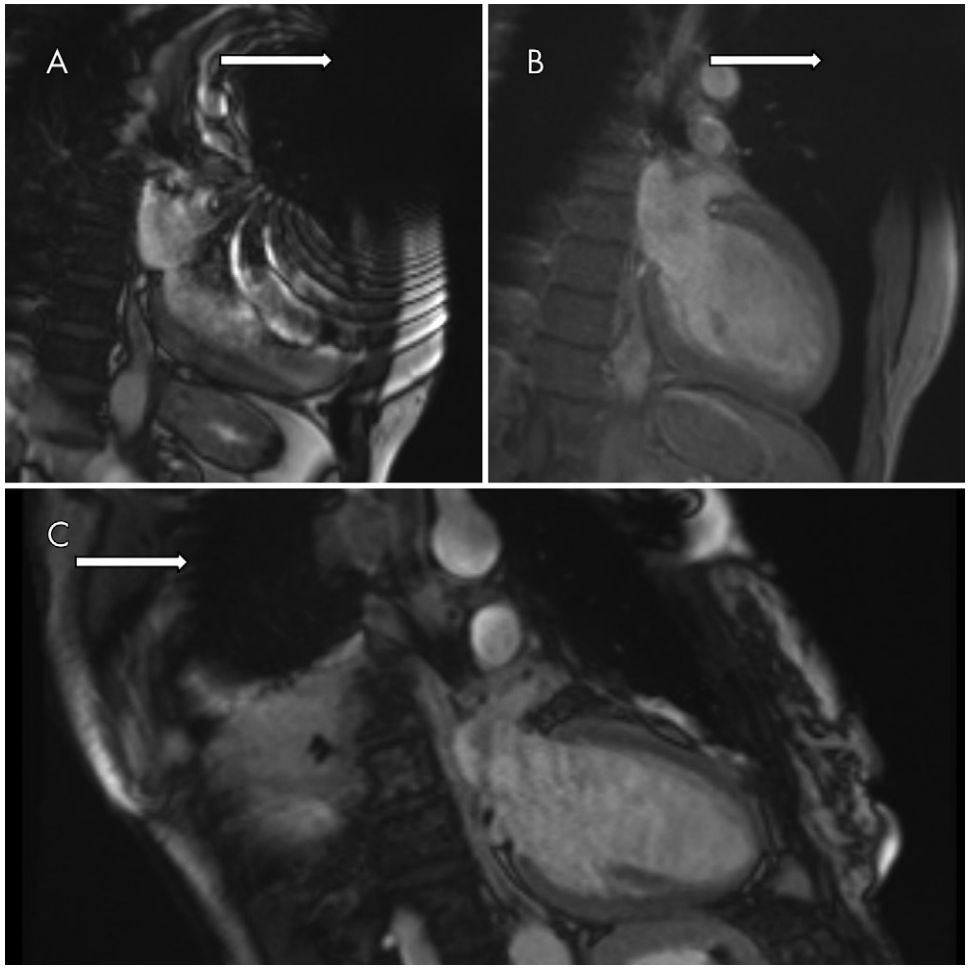

Figure 1: *A, B,* Images in a 61-year-old man with a Medtronic Evera MRI XT single-chamber implantable cardiac defibrillator. *C,* Image in a 55-year-old woman with a Medtronic Revo MRI Surescan dual-chamber pacemaker. Images obtained with a Siemens Magnetom Aera 1.5-T unit. Arrows = artifacts caused by an implantable cardiac defibrillator in a two-chamber plane of the left ventricle: *A,* balanced steady-state free precession sequence with signal loss and banding artifacts, *B,* gradient-echo sequence (same patient as in *A*), and, *C,* balanced steady-state free precession sequence in a right-sided implant, with the generator farther away from the heart.

Clinical Studies of MR Conditional Devices

MR conditional devices are those that have been designed and approved for use in the MRI environment under specific conditions. A list of all FDA-approved MR conditional PPMs and ICDs is shown in Table 4. Typical MRI examination conditions include static field strength, SAR, and imaging field of view. To achieve a designation as MR conditional, the generator must be paired as a unit with leads that have been tested for MRI safety. MR conditional PPMs and ICDs have been available since the FDA approval of the first system in 2011 (6).

CIEDs undergo multiple alterations to be MR conditional devices. These include lead modification to reduce lead tip heating, circuitry shielding to prevent POR, reduction of ferromagnetic materials, changing the reed switch to a "Hall sensor" (which has predictable behavior in a magnetic field), and updated software. Newer software aids reprogramming and, in some instances, automatically changes to MRI mode when a strong magnetic field is detected.

The first MR conditional PPM to undergo clinical testing was the Medtronic SureScan system (Medtronic, Minneapolis, Minn) consisting of the EnRhythm generator paired with CapSureFix 5086 MRI leads. In a prospective randomized controlled trial of 464 patients, Wilkoff et al showed no significant difference between the group undergoing MRI and the control group (66). This pattern has continued for all other clinically tested MR conditional PPMs and ICDs, including studies that removed restrictions on thoracic imaging (67–74). Notably, there was initial concern regarding the safety of the specially designed Medtronic CapSureFix 5086 MRI leads. These leads demonstrated unusually high rates of pericarditis, perforation, and tamponade compared with other modern active fixation leads. This was most likely due to their rigid design (75,76). Shortly after this, the older and safer Medtronic 5076 leads were retrospectively declared MR conditional due to their demonstrated safety in a randomized trial (65). None of the other MR conditional leads have displayed the safety concerns seen with the CapSureFix 5086 leads since (67,70).

Image Quality

The most important factor that affects image quality is the anatomic region being imaged. Nonthoracic imaging (imaging with a field of view above C7 and below T12) results in virtually no artifact from CIEDs (34,41,50,52,77). If a thoracic or cardiac imaging is being performed, artifacts will be present from the CIED.

ICDs show larger areas of MRI artifact than do PPMs due to their bulkier design and greater use of ferromagnetic components (49,63,64). Some studies have shown distortion up to 12

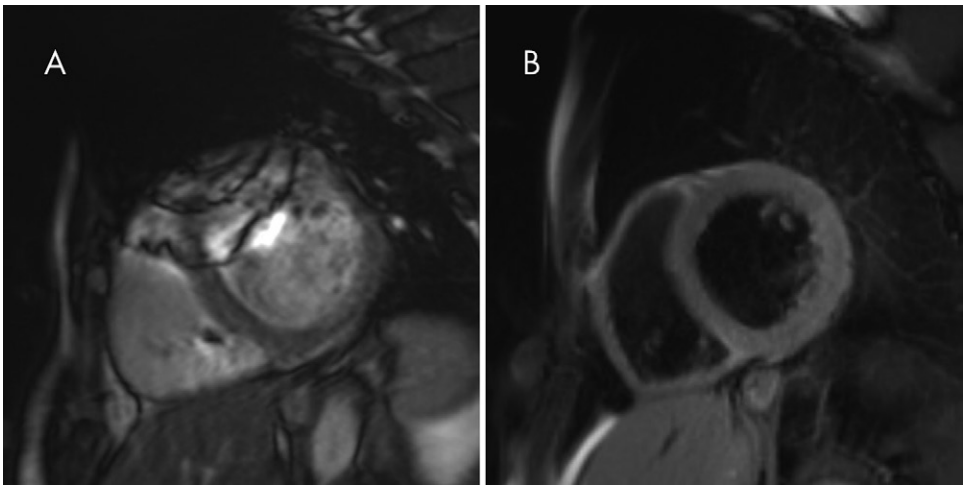

Figure 2: Images in a 61-year-old man with a Medtronic Evera MRI XT single-chamber implantable cardiac defibrillator imaged with a Siemens Magnetom Aera 1.5-T unit. Basal short-axis images acquired with, *A,* balanced steady-state free precession sequence and, *B,* spin-echo sequence (in this case T2 weighted), which is less sensitive to susceptibility artifacts.

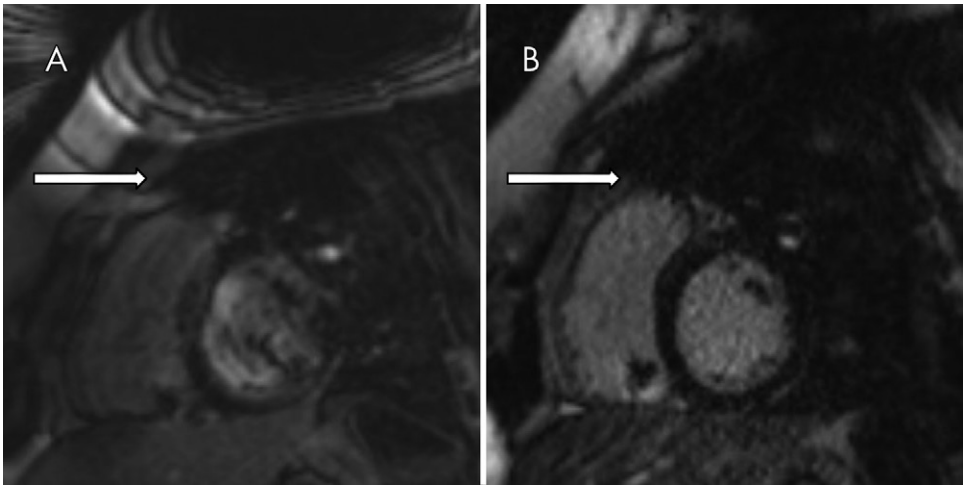

Figure 3: Images in a 28-year-old woman with a Medtronic Evera MRI XT single-chamber implantable cardiac defibrillator imaged with a Siemens Magnetom Aera 1.5-T unit. Short-axis delayed enhancement images with artifacts (arrow) acquired with, *A,* balanced steady-state free precession sequence and, *B,* gradient-echo sequence.

cm away from the generator (78). Leads have a small amount of artifact and do not usually obscure diagnostic quality, even for cardiac MRI (44).

The position of the device also affects the image quality (Fig 1). For cardiac MRI, left-sided devices create more artifact and lead to reduced diagnostic accuracy. In a study of 32 patients, 100% of studies with right-sided devices had diagnostic quality but only 35% of studies with left-sided devices were diagnostic (44,79). In general, right ventricular studies are of higher quality than those of the left ventricle (80).

For cardiac and thoracic MRI, balanced steady-state free precession images exhibit more artifact than do gradient-echo sequences (Figs 2, 3). Therefore, gradient echo should be used to maximize image quality (49,78). For balanced steady-state free precession sequences, frequency-scout acquisition may help to reduce image artifact by adjustment of the receiver center frequency (72). In the presence of artifact, imaging in perpendicular image planes to the generator and using reduced echo time and fast spin-echo sequences may improve image interpretation.

Overall, about 90% of thoracic and cardiac MRI examinations are described as diagnostic (49,56,63). Under worst-case conditions (left-sided ICD and balanced steady-state free precession acquisition) about 50% of studies are reported to have acceptable image quality (78).

Guidelines and Protocols

The 2017 Heart Rhythm Society consensus statement on MRI in CIED is the most up-to-date guideline document available (5). MRI in pacemaker-dependent patients is allowed with the proviso of temporary pacing facilities and a CIED-trained physician in place. The guidelines recommend against the performance of MRI in systems with fractured, epicardial, or abandoned leads. Recently implanted devices are considered reasonable if clinically warranted. A simplified flowchart adapted from the Heart Rhythm Society guidelines is shown in Figure 4.

For MR conditional devices, the FDA provides the conditions required to meet the conditional requirements. This information can be found on the individual manufacturer's website and varies depending on the model of CIED being imaged. Additionally, information regarding the latest FDA approvals can be found on the FDA website under "Device Approvals, Denials and Clearances" (81).

It is the opinion of the authors that every center performing MRI in CIED patients should have a checklist in place with associated adverse event monitoring. The use of a checklist is supported by a class I (strong) recommendation from the Heart Rhythm Society guidelines (5). A copy of the sample checklist provided in the Heart Rhythm Society guidelines is provided in Figure E1 (online). A standard checklist minimizes the potential for harm and improves safe access to a vital modality. Common elements of a standardized checklist include a system for referral and screening of CIED

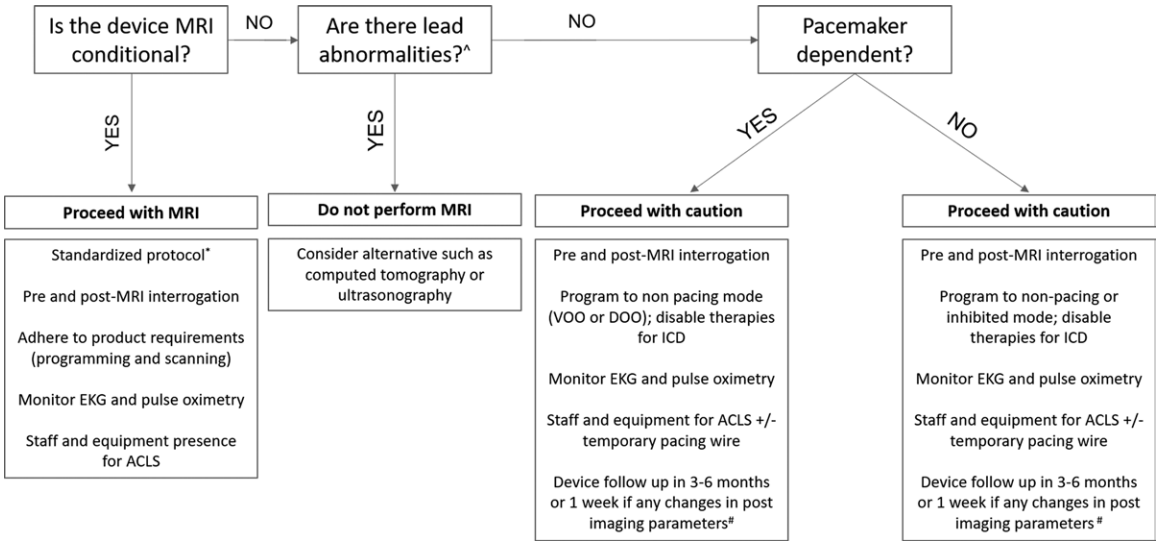

Figure 4: Checklist for treatment of patients referred for MRI with implantable electrical device. Adapted from the Heart Rhythm Society 2017 guidelines see for detailed information (5). ^Fractured, abandoned, or epicardial leads. *All departments should have standardized prebooking checklists and liaison with cardiology electrophysiology departments for patient suitability and device evaluation if possible. #Capture threshold increase more than 1.0 V, sensing drop more than 50%, pacing dependence change more than 50 Ω, shock impedance change more than 5 Ω. ACLS = advanced cardiac life support, EKG = electrocardiography, ICD = implantable cardiac defibrillator.

patients needing MRI, assessment and programming of the CIED before and after the imaging, requirements for monitoring during the imaging, and follow-up at regular intervals to ensure long-term safety (Fig 5). In centers where electrophysiology support staff are not available, device company representatives may be available to help with reprogramming MR conditional devices. In the case of MR nonconditional devices, electrophysiological consultation should be obtained prior to the MRI examination (5).

Future Directions

New MR conditional devices are frequently released with improved designs to limit the interference of MRI. Additionally, there are encouraging early experiences with leadless pacemakers and limited monitoring of patients during MRI.

Leadless pacemakers are new devices that contain the entire pacing system in a small bullet-shaped case that sits in the ventricle. This allows pacing without the use of a generator and pacing leads that run from the generator to the endocardium. Reassuring preclinical data and early case reports of patients with the Micra (Medtronic) leadless pacemaker have emerged leading to a retrospective FDA classification of MR conditional at 1.5 T and 3 T (82). Preclinical data have demonstrated less torque and heating of the Micra compared with a standard pacemaker. A case series of 15 patients with the Micra system undergoing MRI showed no adverse events (82). The Nanostim (St Jude Medical, St Paul, Minn) leadless pacemaker has received CE mark approval in Europe for MR conditional labeling but awaits FDA approval. Larger prospective datasets may validate these systems as being safer than conventional PPMs.

New research has also attempted to lessen the burden of performing MRI in CIED patients. Bertelsen et al, in a study of 207 patients, challenged the need for monitoring in nonpacemaker-dependent patients (83). In that study, they used no additional monitoring of vital signs or symptoms and observed no adverse events in patients undergoing MRI. It is

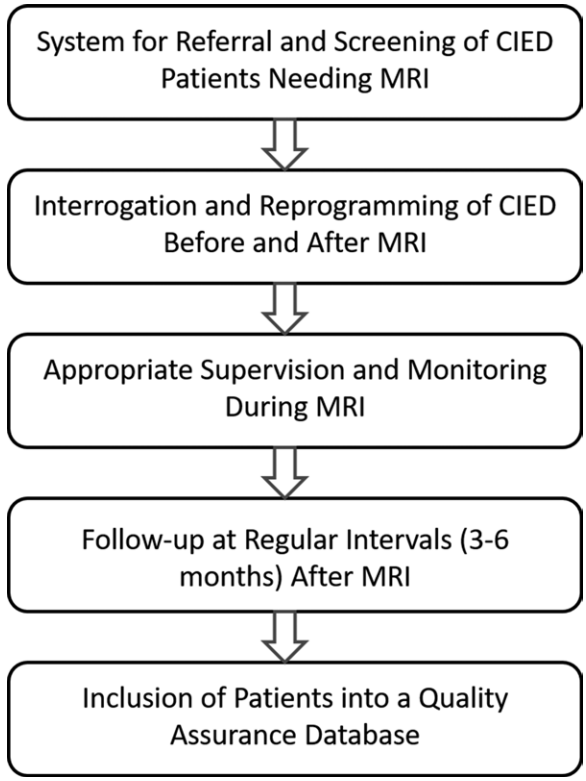

Figure 5: Flowchart shows the essential considerations for an institution when designing a checklist for MRI of implantable cardiac device. *As described in text, dependent on the patient's device and dependence on device. CIED = cardiac implantable electronic device.

important to note that vital sign monitoring is still required in pacemaker-dependent patients to detect asystole caused by POR and subsequent inappropriate inhibition due to electromagnetic interference (53).

With increasing use of 3-T and 7-T MRI systems, data are also required regarding the safety of CIED at these field strengths as most of the contemporary data relate to 1.5-T units. Furthermore, we await the improvement of pacing methods that do not rely on conductive materials, such as optogenetics (84). These are in early stages of development but may one day provide an MR-safe method of pacing and defibrillation.

Conclusion

Significant clinical data have been accumulated to show MRI can be safely performed in the presence of CIEDs, when monitored appropriately. Clinicians should be aware of the risks and safety measures needed to minimize potential harm. Due to the rapidly expanding body of research, committee guidelines must be updated regularly to reflect the current knowledge and prevent patients being denied a potentially vital diagnostic tool. Lastly, institutions should be making efforts to enact a safe checklist and monitor adverse events for contribution to the worldwide understanding of the MRI risk profile.

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