

RECOMMENDATIONS

Joint Position Paper of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology (SFC) and the Société française d'imagerie cardiaque et vasculaire diagnostique et interventionnelle (SFICV) on magnetic resonance imaging in patients with cardiac electronic implantable devices



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KEYWORDS

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Defibrillators;
Pacemaker

Abstract Magnetic resonance imaging (MRI) has become the reference imaging for the management of a large number of diseases. The number of MR examinations increases every year, simultaneously with the number of patients receiving a cardiac electronic implantable device (CEID). A CEID was considered an absolute contraindication for MRI for years. The progressive replacement of conventional pacemakers and defibrillators by MR-conditional CEIDs and recent data on the safety of MRI in patients with “MR-nonconditional” CEIDs have progressively increased the demand for MRI in patients with a CEID. However, some risks are associated with MRI in CEID carriers, even with “MR-conditional” devices because these devices are not “MR-safe”. A specific programming of the device in “MR-mode” and monitoring patients during MRI remain mandatory for all patients with a CEID. A standardized patient workflow based on an institutional protocol should be established in each institution performing such examinations. This joint position paper of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology and the Société française d’imagerie cardiaque et vasculaire diagnostique et interventionnelle (SFICV) describes the effect and risks associated with MRI in CEID carriers. We propose recommendations for patient workflow and monitoring and CEID programming in MR-conditional, “MR-conditional nonguaranteed” and MR-nonconditional devices.

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Abbreviations

CEID	cardiac electronic implantable device	DOO	dual chamber (atrium and ventricle) pacing (so-called “asynchronous” mode)
ICD	implantable cardiac defibrillator	ODO	atrium and ventricle being sensed (no pacing)
S-ICD	subcutaneous implantable cardiac defibrillator	OOO	deactivation of CEID
MRI	magnetic resonance imaging	VVI	ventricular pacing and ventricular sensing; inhibition of a sensed beat
VOO	ventricular pacing (asynchronous mode)	DDI	dual chamber pacing and dual chamber sensing; inhibition of a sensed beat (DDI)
		ILR	implantable loop recorders

Introduction

The rate of cardiac electronic implantable device (CEID) implantation is increasing every year. An estimated 4 million patients carry a CEID worldwide. Each year, more than 500,000 pacemakers and 85,000 implantable cardioverter-defibrillators (ICDs) are implanted in Europeans (European Heart Rhythm Association data, [1]). In France, about 400,000 patients carry a CEID, with ~70,000 pacemaker and ~15,000 ICDs implanted in 2018 (International Health Market Trends data). At least 1 in 50 of people ≥ 75 -year-old will have a permanent pacemaker implanted [2]. At the same time, magnetic resonance imaging (MRI) has become the reference imaging for the management of a large number of diseases, and the number of examinations performed increases every year (+12%), with ~7 million MRI examinations performed in France in 2017 [3].

For a long time, the presence of a CEID such as a pacemaker or ICD has been considered an absolute contraindication for MRI. Two major evolutions have changed this paradigm in the last years. First, manufacturers have progressively marketed new "MRI-conditional" systems. However, these MRI-conditional materials are not "MRI-safe" and therefore require specific device programming and patient monitoring. Second, several large observational studies have shown that MRI could be also performed in patients carrying an "MRI-nonconditional" CEID with a low risk of complications, which shifts the presence of an MRI-nonconditional CEID from an absolute to a relative contraindication. As a class IIb, level B recommendation, the 2013 European Society of Cardiology guidelines on pacing and resynchronization therapy allow for MRI with a conventional MR-nonconditional CEID if appropriate precautions are taken [4]. In 2017, the Heart Rhythm Society expert consensus statement on MRI and radiation exposure in patients with CIEDs issued a class IIa, level B recommendation for this indication [5]. However, for all patients carrying a MRI-conditional or nonconditional device, any MR imaging should be integrated into a standardized workflow defined in an institutional protocol involving both radiologists and device specialists [6].

Despite these recommendations, MRI remains underused in patients carrying a CEID. A patient with an ICD is 50 times less likely to benefit from MRI than patients without implantation [7]. The reasons are multiple: issues related to local organization, the difficulty of establishing a concerted institutional workflow, the availability of device specialists, legal/responsibility issues between radiologists and cardiologists, the unjustified fear of some patients or treating physicians because of lack of knowledge of the recent recommendations and the lack of financial recognition of the complexity of MRI in CEID carriers.

This position paper gives the common position of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology (SFC) and the Société française d'imagerie cardiaque et vasculaire diagnostique et interventionnelle (SFICV) on the technical conditions of MRI in patients with MR-conditional and -nonconditional CEID that could serve as a basis for institutional MRI protocols in patients with a CEID. This consensus was based on an extensive analysis of the current literature followed by exchanges

between CEID and MRI specialists representing both societies.

Definitions

An MR-conditional CEID is defined as a whole system consisting of a generator, an MR protection mode software and leads that has been tested and approved by manufacturers for MRI under specific conditions of use. Modifications have been made to the material to limit the effect of the magnetic and radiofrequency fields on the device and the patient. Only systems associating leads and generators from the same manufacturer have been specifically tested to be safe and are guaranteed by the manufacturer as MR-conditional. A specific MR-mode programming is always required during the MRI to limit the effect of the magnetic and radiofrequency fields on the device functioning. All MR-conditional systems exclude epicardial devices, abandoned or fractured leads and lead extensions/adapters. MR-conditional nonguaranteed CEIDs are defined as systems consisting of MR-conditional generators and leads issued from different manufacturers. MR-nonconditional CEIDs are all other devices. The updated list of MR-conditional CEIDs is provided at <http://www.irm-compatibilite.com/> that has been created with the support of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology.

Pacing-dependent patients are defined as those with an inadequate or even absent intrinsic rhythm (i.e., asystole longer than 5 s or spontaneous frequency of less than 30/min) [8]. Patients with permanent bradycardia are defined as those with permanent spontaneous cardiac frequency < 50/min. "On site" means within the same hospital. "On the premises" means within the same building.

Effect of MRI on CEID

During MRI, three magnetic fields are involved (a static one called B0 [1.5- to 3-T in current magnet technology but higher fields are now commercially available]), a 3-D gradient magnetic field (G x, y, z) and a radiofrequency (B1) field; all three fields can interfere with the functioning of the device. The different risks associated with MRI are shown in Table 1. The static magnetic field B0 can theoretically induce force and torque to the ferromagnetic components that are present within the generator (none are present in conventional leads), but movement of the generator is unlikely [9]. The mechanical switch of MR-nonconditional generators can be activated by MR, thereby resulting in asynchronous pacing in pacemakers or deactivation of tachycardia detection in ICDs [10]. All magnetic fields can cause electrical reset of MR-nonconditional generators leading to back-up in emergency mode with VVI pacing and reactivation of therapies that could cause pacing inhibition or inappropriate shocks [11–13].

Rapid depletion of the battery can also occur [14]. A gradient magnetic field can induce a current within the conductive wire of the lead that can induce myocardial capture. The gradient and B1 (radiofrequency) magnetic fields can generate oversensing that can lead to pacing inhibition or

Table 1 Risks associated with MRI in patients with MR-nonconditional and conditional devices.

MR-nonconditional devices	MR-conditional devices under specific conditions
Acute bradycardia in ODO/OOO mode	Acute bradycardia in ODO/OOO mode
Inactivation of ICD therapy: absence of VT/VF treatment	Inactivation of ICD therapy: absence of VT/VF treatment
Oversensing → pacing inhibition/inappropriate ICD therapy	Oversensing → pacing inhibition/inappropriate ICD therapy
Ventricular arrhythmia induced by asynchronous pacing mode (DOO/VOO)	Ventricular arrhythmia induced by asynchronous pacing mode (DOO, VOO)
Power on reset mode and emergency mode (usually VVI with risk of pacing inhibition by pulsed MR fields and risk of reactivation of ICD therapies)	
Reed switch → asynchronous pacing/inhibition of tachycardia detection	
Transmission of radiofrequency field: tissue heating and damage, arrhythmias, change in capture or sensing thresholds	
Battery depletion	
Gradient magnetic field induced electrical current → oversensing, myocardial rapid capture, arrhythmias	
Magnetic-induced force and torque (generator)	

ICD: implantable cardiac defibrillator; MR: magnetic resonance; VT: ventricular tachycardia; VF: ventricular fibrillation; VOO/DOO: ventricular pacing (VOO) or dual chamber (atrium and ventricle, DOO) pacing (asynchronous mode); ODO/OOO: atrium and ventricle being sensed (ODO)/deactivation of CEID (OOO); VVI/DDI: ventricular pacing and ventricular sensing; inhibition of a sensed beat (VVI); Dual chamber pacing and dual chamber sensing; inhibition of a sensed beat (DDI).

inappropriate therapies [13]. MR-nonconditional leads can receive the B1 (radiofrequency) field as an antenna and transmit the energy to the myocardium, thereby generating arrhythmias, tissue heating and damage around the lead leading to increased capture threshold or decreased sensing [15–17]. This risk appears particularly great with abandoned leads.

Some risks are associated with the temporary MR-mode. These risks are common to MR-conditional and -nonconditional devices. During MRI, an asynchronous mode (DOO/VOO) or deactivation of the pacing mode (ODO/OOO) according to the underlying rhythm of the patient and deactivation of therapy detection in ICDs should be programmed to avoid oversensing leading to pacing inhibition or inappropriate therapies. In asynchronous mode, there is a very low risk (< 1/10,000) of induced ventricular arrhythmia due to inappropriate pacing in a ventricular vulnerable period [18]. This complication has been mainly described in patients with low left ventricular ejection fraction, acute coronary syndrome or hydro-electrolyte disturbances and nonpacing-dependent patients [19]. For ICDs, the deactivation of tachycardia detection carries the risk that a ventricular arrhythmia could not be treated during this time. In nondependent patients who are programmed in ODO/OOO, there is a risk of acute bradycardia. Although all the mentioned risks seem very low, they remain difficult to assess and are unpredictable at the patient level.

There were some concerns about the risk of thoracic and cardiac MRI in patients with CEID because of the close proximity with the device. However, most studies have shown a similar safety profile between cardiac/thoracic and

extra-thoracic MRI [20–22]. CEIDs, especially ICDs [21] and CEIDs positioned at left side [22,23], can cause artifacts. Cardiac artifacts caused by the device can be a concern, but specific techniques (frequency-scout acquisitions, spoiled gradient-echo, reduced echo time, fast spin echo) may reduce the artifacts [24].

General conditions for MRI in patients with a CEID

As stated above, CEIDs are not MR-safe but are rather MR-conditional materials. Thus, a standardized patient workflow needs to be established by each institution based on an institutional protocol decided with consensus between radiologists and device specialists. This workflow should include the benefit/risk ratio of the MRI (particularly in patients with MR-nonconditional devices), evaluation of a possible alternative imaging modality (frequently, CT) and the exclusion of patient- or device-related contraindications (Table 2). The risk of MRI in a patient with an implant is considerably lower than that of device removal before MRI [25]. For all patients, one should check the precise characteristics of the material (manufacturer and models of generators and all leads), the medical indication of the device, the underlying rhythm of the patient and whether the patient is pacing-dependent, as well as the history of ventricular arrhythmias in ICD carriers. A transmission form including all information needed before MRI examination is proposed in Fig. 1.

Table 2 Common workflow for MRI in patients with MR-conditional and nonconditional CEIDs.

<p>Before MRI scan</p> <ul style="list-style-type: none"> Validate the clinical benefit of the MRI examination (consider a possible alternative imaging) Verify integrity of the system (battery, leads) Characteristics of the device (date of implantation, manufacturer and model of generator and leads): MR-conditional or -nonconditional system? Medical indication of the device, pacing-dependency, history of ventricular arrhythmias Exclude contraindications <ul style="list-style-type: none"> Epicardial, fractured and abandoned leads as well as adapters and lead extensions (use X-ray is necessary) High capture thresholds > 2V/0.4 ms Out-of-range impedance values < 200 or > 1500 Ohms Elective replacement indicator or end of service Set specific MR-pacing program according to the underlying rhythm, deactivate tachycardia detection (ICDs) <p>During MRI scan</p> <ul style="list-style-type: none"> Monitoring (cardiac frequency by pulse oximetry + if possible ECG monitoring + visual monitoring) by physician or qualified personal Presence of a defibrillator and emergency material Physicians with the skill to perform resuscitation available immediately Physicians with the skill to program devices available on call or immediately depending on the device and patient dependency (Figs. 2 and 3) <p>After MRI scan</p> <ul style="list-style-type: none"> Device control (battery, sensing, impedance, pacing threshold) and reprogramming of baseline settings, reactivation of tachycardia detection (ICDs)

CEIDs: cardiac electronic implantable devices; ICDs: implantable cardiac defibrillators.


Despite some evidence that MRI within the first weeks of implantation is safe [26,27], we recommend in the absence of an emergency to respect a 6-week delay after CEID implantation. Epicardial, fractured or abandoned leads as well as adapters and lead extensions are classical contraindications for MRI and in some cases, a chest radiograph can be performed to exclude them. For all devices, one should verify the integrity of the device (generator and leads) before the MRI: lead impedance, capture voltage threshold, sensing and battery status with MRI is contraindicated in case of an elective replacement indicator.


During the MRI examination, we recommend that all patients with MR-conditional or -nonconditional devices be at least monitored with cardiac frequency and pulse oximetry. If possible, electrocardiography (ECG) monitoring and visual/voice contact with a physician or qualified staff member are advised. Because MR sequences can cause ECG artifacts, monitoring of the cardiac frequency with pulse oximetry is mandatory for all patients. Although ECG monitoring is advised in addition to pulse oximetry, it is not mandatory if the cardiac frequency can be efficiently monitored with pulse oximetry. An external defibrillator and emergency material should be present on site. Physicians with the ability to perform resuscitation and advanced cardiac life support should be available immediately on an emergency standby basis, as defined by the institutional protocol. Physicians with the skill of programming devices should be available on an emergency standby basis depending on conditions defined by the institutional protocol (Figs. 2 and 3).

Workflow for MR-conditional CEIDs

MR-conditional CEIDs have been tested and approved (CE-certification) for MRI under specific conditions. MR-conditional generators and leads have been modified by manufacturers to limit the influence of magnetic and radiofrequency fields on the system. The safety of MRI has been validated in clinical trials for some systems: Enrythm Surescan®, Advisa® and Evera® from Medtronic; Entovis ProMRI® and Evia® pacemakers; Iforia® ICDs from Biotronik; Kora® for Microport [28–35]. Because clinical validation is limited by practical/logistical issues and does not allow for validating thousands of variables that could affect ICD or pacemaker systems during MRI, MR-conditional materials are now validated by computer modeling that allows for testing a large number of conditions [36]. On the basis of these tests, each manufacturer provides specific guidelines and conditions in which the safety of the MRI is guaranteed. Some systems have been validated for only 1.5 T, others for 3 T, some include a thoracic exclusion zone, and others allow full-body MRI. Hence, these specific conditions and guidelines can vary among manufacturers and can only be applied to a whole validated system (i.e., generator plus leads). The specific manufacturer recommendations for each system are available at each manufacturer's website or at <http://www.irm-compatibilite.com/>.

Before the MRI, the system should be validated as MR-conditional by the physician. The workflow for MR-conditional devices should be assessed in a standardized institutional protocol following the general recommendations specified above. The time and location of the pre-MRI





Rythmologie - Stimulation cardiaque

Patient Name:

ID

Indication for device implantation:

GENERATOR

Date of implantation: __/__/____

Brand and model:

LEADS

Brand and model:	Date of implantation
Atrial lead:	__/__/____
RV lead:	__/__/____
LV lead:	__/__/____

Is the system MRI-conditional
 MRI-nonconditional

Is the patient pacing-dependent? YES NO NA

Are there abandoned lead(s)? YES NO NA

Are there epicardial lead(s)? YES NO NA

If ICD : Primary prevention Secondary prevention or history of appropriate therapy

Recommendations for MRI

MRI 1.5T full body MRI 1.5T with thoracic exclusion

MRI 3T full body MRI 3T with thoracic exclusion

MRI contra-indicated

Presence of the device specialist within premises required YES NO

MR-mode programing in cardiology department possible YES NO

Device MR-programming: MRI mode possible YES NO

VOO/DOO ODO/OOO VVI/DDI ICD therapy deactivation

Reprogramming of the device after MRI necessary: YES NO

Name and signature of cardiologist: Date: __/__/____

Figure 1. Transmission form.

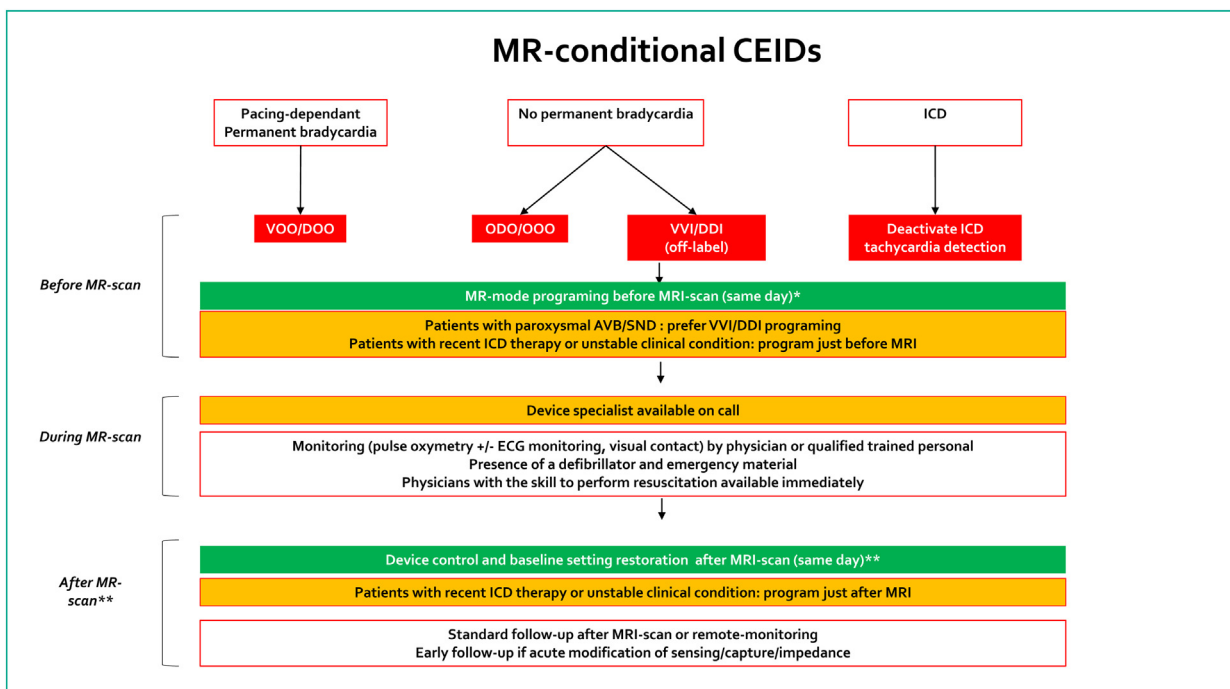


Figure 2. Workflow for MR-conditional guaranteed and nonguaranteed CEIDs. * except for devices with automatic detection of MR field. AVB: atrioventricular block; SND: sinus node dysfunction; VOO/DOO: ventricular pacing (VOO) or dual chamber (atrium and ventricle, DOO) pacing (asynchronous mode); ODO/OOO: atrium and ventricle being sensed (ODO)/deactivation of CEID (OOO); VVI/DDI: ventricular pacing and ventricular sensing; inhibition of a sensed beat (VVI); dual chamber pacing and dual chamber sensing; inhibition of a sensed beat (DDI).

reprogramming of the device mainly depend on the potential impact of the temporary MR-mode on patient safety: lack of pacing of acute bradycardia in ODO/OOO mode, triggered ventricular arrhythmia with asynchronous pacing, or lack of treatment of ventricular arrhythmias with ICDs. This risk increases with time when the temporary program is active. In nondependent patients, programming the device in inhibited pacing (VVI/DDI) modes seems safe, although this programming is off-manufacturer guarantee. Inhibited-mode in nondependent patients decreases the risk of a nontreated paroxysmal bradycardia and the risk associated with asynchronous pacing [20,37]. Inhibited modes may be preferred with paroxysmal atrioventricular block/sinus node dysfunction (off-manufacturer guarantee) [20].

The pre- and post-MRI reprogramming of devices could reasonably be performed during the same day of the MRI on site but at a different place than the MR equipment (cardiology outpatient clinic) (Fig. 2). We recommend that the time when the patient remains on MR-mode should be as short as possible to limit the risks associated with lack of pacing/therapy or asynchronous pacing. The pre- and post-MRI reprogramming could reasonably be performed just before and after the MRI in high-risk patients with unstable clinical cardiac condition or with recent (< 15 days) ICD therapy (Fig. 2).

Because several studies have shown that MRI is safe for MR-conditional devices, the presence of the device specialist during MR examination is not mandatory. However, a device specialist should be available on call as

specified in the institutional protocol. Some devices have a specific algorithm allowing for the automatic detection of an MR field leading to the automatic activation of the temporary pre-specified MR-program. In these cases, the temporary MR-mode will be activated only during the MRI, and baseline settings will be restored automatically at the end of the examination. For these devices, the control and programming of the device by the device specialist can be performed several days before MRI examination. The maximum MR field and exclusion zone conditions should be applied according to the manufacturer's recommendations (available at each manufacturer's website or at <http://www.irm-compatibilite.com/>).

Workflow for MR-conditional nonguaranteed CEIDs

A current issue is to determine in which category the MR-conditional nonguaranteed CEIDs should be included, which are defined by MR-conditional material (leads and generators) but from different manufacturers. By definition, MR-conditional generators have been validated only in combination with the MR-conditional leads from the same manufacturer. No published data have specifically addressed this issue. However, from expert experience, the MR-conditional CEID workflow could reasonably be applied for these devices. A national registry should be developed for these patients to validate the safety of this workflow applied to MR-conditional nonguaranteed CEIDs.

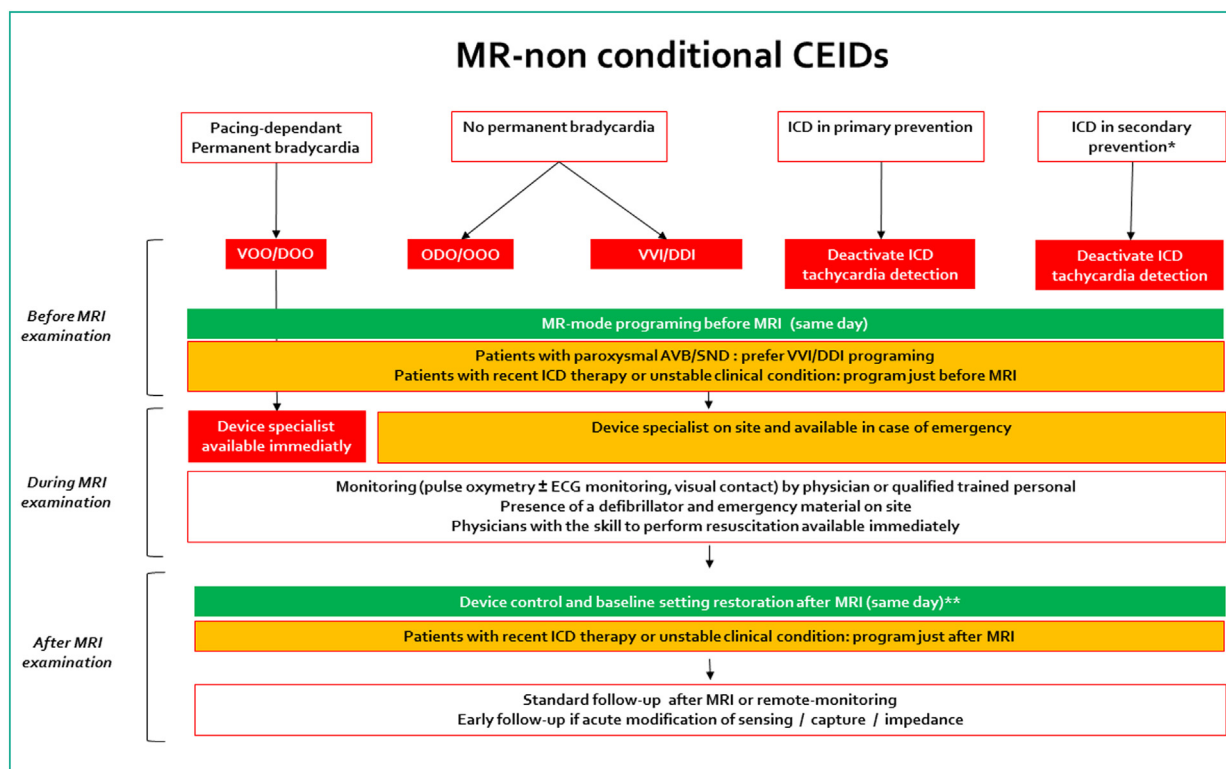


Figure 3. Workflow for MR-nonconditional CEIDs. * in pacing-dependent patient, control device as soon as possible. AVB: atrioventricular block; SND: sinus node dysfunction. VOO/DOO: ventricular pacing (VOO) or dual chamber (atrium and ventricle, DOO) pacing (asynchronous mode); ODO/OOO: atrium and ventricle being sensed (ODO)/deactivation of CEID (OOO); VVI/DDI: ventricular pacing and ventricular sensing; inhibition of a sensed beat (VVI); dual chamber pacing and dual chamber sensing; inhibition of a sensed beat (DDI).

Workflow for MR-nonconditional CEIDs

Recent clinical observational retrospective and prospective data have demonstrated the relative safety of MRI in patients with MR-nonconditional material. In the MagnaSafe registry, including extra-thoracic MRI performed with 1000 MR-nonconditional pacemakers and 500 ICDs, six cases of electrical reset, one case of generator heating and six cases of atrial arrhythmias were observed [27]. No ventricular arrhythmia occurred. One patient without adequate MR programming presented ICD generator dysfunction requiring immediate replacement. Minor increases in voltage capture threshold or lead impedances, decreased sensing or battery depletions have been observed in 0.4% to 4%, but none led to the loss of capture, programming changes or generator/lead replacement. Pacing-dependent patients with ICDs, epicardial or abandoned leads or generators with an elective replacement indicator were excluded. Although the risk of complications appears low, it seems unpredictable and could have substantial consequences for pacing-dependent patients.

Allowing for extra-thoracic MRI in patients with MR-nonconditional CEIDs seems reasonable if MRI is the more accurate test for the patient's condition. MRI indications should be evaluated on a risk/benefit balance basis for each patient, especially pacing-dependent patients. Information on the risk associated with the MRI should be provided to

the patient. The workflow for MR-nonconditional devices should be assessed in a standardized institutional protocol following the general recommendations specified above. We recommend monitoring (cardiac frequency by pulse oximetry \pm ECG monitoring, visual contact) of all patients with MR-nonconditional devices during MRI in the presence of a physician or qualified and trained staff member. For pacing-dependent patients, physicians with skills in programming devices should be present or available immediately on an emergency standby basis during the MRI examination. For pacing-nondependent patients, a device specialist should be available immediately on the premises as defined by the institutional protocol. The pre- and post-MRI reprogramming of devices could reasonably be performed within the same day of the MRI on site but at a different place than the MRI scan (cardiology outpatient clinic) (Fig. 3). We recommend that the time in which the patient remains on MR-mode be as short as possible to limit the risks associated with absence of pacing/therapy or asynchronous pacing. The pre- and post-MRI reprogramming could reasonably be performed on the premises just before and after the MRI examination in high-risk patients with unstable clinical cardiac condition or with recent (< 15 days) ICD therapy (Fig. 3).

Because of very low evidence of MRI safety for MRI scanning > 1.5 T, we recommend limiting the MRI field strength to 1.5 T for nonconditional devices [38]. To limit the risk of

conducting radiofrequency pulses to the myocardium within the conductive lead, we recommend limiting the whole-body specific absorption rate (SAR) to a minimum. An SAR < 3.2 W/Kg for head examinations and 2 W/Kg for body examinations are commonly advised. We advise scanning in standard mode and avoiding SAR levels 1 and 2. We also recommend limiting the time of exposure and number of sequences to those absolutely necessary.

Control of the device and restoration of the baseline settings should be performed as soon as possible after the end of the MRI scan. If a significant modification of leads parameters is observed (increase of capture threshold voltage > 0.5 V/0.4 ms, decrease of sensing > 50%, modification of impedance > 100 Ohms or high-voltage lead impedance > 10 Ohms), remote monitoring or early follow-up within 2 weeks after the MR examination is recommended.

Cardiac MRI may be associated with increased risk of interference because of the location of device inside the radiofrequency field. However, with MR-nonconditional CEIDs, the indication for cardiac MRI should be discussed between the referring cardiologist, the device specialist and the radiologist. Cardiac MRI should be restricted to indications for which alternative methods are inaccurate and only performed in experienced centers. Cardiac CT may be used as an alternative, when suitable.

Epicardial and abandoned leads

We have little data on MRI safety in patients carrying epicardial, fractured or abandoned leads because these patients were excluded from observational studies. In small case-series, no complication of MRI was observed in these patients [39–43]. However, we think that these data are insufficient to recommend MRI in these cases and that the presence of epicardial, fractured, or abandoned leads should remain a contraindication for MRI. In individual cases with a life-threatening emergency, non-thoracic MRI can be discussed in nonpacing-dependent patients after careful consideration of the benefit/risk ratio and multidisciplinary discussion.

Implantable loop recorders (ILRs)

ILRs are MR-safe material. No specific MR-mode programming is necessary before MRI and no monitoring of the patient is advised. MRI can cause artifacts that can be recorded by the device and overload the memory. The patient should notify his/her treating device specialist of any MRI that occurred during follow-up. However, to avoid any problems in the radiology departments, any MRI requested for a patient with an ILR should mention the device and its full compatibility with MRI.

Subcutaneous ICDs (S-ICDs) and leadless pacemakers

The first-generation S-ICDs (SQ-RX) are not labeled as MR-conditional, but the second- and third-generation (A 209

and A219, Boston) S-ICDs are guaranteed MR-conditional (3 T, full-body) [44]. The leadless pacemaker available on the French market (Micra®, Medtronic) is also guaranteed as MR-conditional (3 T, full-body) [45]. The same workflow as for conventional MR-conditional material should be applied for these devices. However, cardiac imaging can be affected by S-ICDs and leadless pacemakers, mostly because metallic artifacts on the left ventricle can prevent accurate tissue characterization [44].

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Disclosure of interest

The authors declare that they have no competing interest.

References

- [1] Raatikainen MJP, Arnar DO, Zeppenfeld K, Merino JL, Levya F, Hindriks G, et al. Statistics on the use of cardiac electronic devices and electrophysiological procedures in the European Society of Cardiology countries: 2014 report from the European Heart Rhythm Association. *Europace* 2015;17: i1–75.
- [2] Bradshaw PJ, Stobie P, Knuiman MW, Briffa TG, Hobbs MST. Trends in the incidence and prevalence of cardiac pacemaker insertions in an ageing population. *Open Heart* 2014;1:e000177.
- [3] OECD. Magnetic resonance imaging (MRI) exams (indicator); 2019 [n.d.].
- [4] European Society of Cardiology (ESC), European Heart Rhythm Association (EHRA), Brignole M, Auricchio A, Baron-Esquivias G, Bordachar P, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the task force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). *Europace* 2013;15:1070–118.
- [5] Indik JH, Gimbel JR, Abe H, Alkmim-Teixeira R, Birgersdotter-Green U, Clarke GD, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. *Heart Rhythm* 2017;14:e97–153.
- [6] Cruypheninck Y, Dubourg B, Michelin P, Godin B, Savoye-Collet C, Gérardin E, et al. Pacemakers and MRI: a protocol in line with international guidelines and approved by the SFICV (French Society of Cardiovascular Imaging). *Diagn Interv Imaging* 2017;98:203–15.
- [7] Nazarian S, Reynolds MR, Ryan MP, Wolff SD, Mollenkopf SA, Turakhia MP. Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. *J Magn Reson Imaging* 2016;43:115–27.
- [8] Korantzopoulos P, Letsas KP, Grekas G, Goudevenos JA. Pacemaker dependency after implantation of electrophysiological devices. *Europace* 2009;11:1151–5.
- [9] Luechinger R, Duru F, Scheidegger MB, Boesiger P, Candinas R. Force and torque effects of a 1.5-Tesla MRI scanner on cardiac pacemakers and ICDs. *Pacing Clin Electrophysiol* 2001;24:199–205.

- [10] Luechinger R, Duru F, Zeijlemaker VA, Scheidegger MB, Boesiger P, Candinas R. Pacemaker reed switch behavior in 0.5, 1.5, and 3.0 Tesla magnetic resonance imaging units: are reed switches always closed in strong magnetic fields? *Pacing Clin Electrophysiol* 2002;25:1419–23.
- [11] Higgins JV, Sheldon SH, Watson RE, Dalzell C, Acker N, Cha Y-M, et al. "Power-on resets" in cardiac implantable electronic devices during magnetic resonance imaging. *Heart Rhythm* 2015;12:540–4.
- [12] Gimbel JR. Unexpected asystole during 3 T magnetic resonance imaging of a pacemaker-dependent patient with a "modern" pacemaker. *Europace* 2009;11:1241–2.
- [13] Maffè S, Paffoni P, Perucca A, Signorotti F, Dellavesa P, Parravicini U. Pseudo "end of life" indication after electromagnetic field exposure: an unusual effect of magnetic resonance imaging on implanted cardioverter defibrillator. *Int J Cardiol* 2012;156:e36–9.
- [14] Zaremba T, Jakobsen AR, Thøgersen AM, Oddershede L, Riahi S. The effect of radiotherapy beam energy on modern cardiac devices: an in vitro study. *Europace* 2014;16:612–6.
- [15] Luechinger R, Zeijlemaker VA, Pedersen EM, Mortensen P, Falk E, Duru F, et al. In vivo heating of pacemaker leads during magnetic resonance imaging. *Eur Heart J* 2005;26:376–83.
- [16] Horwood L, Attili A, Luba F, Ibrahim E-SH, Parmar H, Stojanovska J, et al. Magnetic resonance imaging in patients with cardiac implanted electronic devices: focus on contraindications to magnetic resonance imaging protocols. *Europace* 2017;19:812–7.
- [17] Fontaine JM, Mohamed FB, Gottlieb C, Callans DJ, Marchlinski FE. Rapid ventricular pacing in a pacemaker patient undergoing magnetic resonance imaging. *Pacing Clin Electrophysiol* 1998;21:1336–9.
- [18] Nowak B. Ist die asynchrone ventrikuläre Schrittmacherstimulation gefährlich? *Dtsch med Wochenschr* 2005;130:997–1001.
- [19] Irnich W, Irnich B, Bartsch C, Stertmann WA, Gufler H, Weiler G. Do we need pacemakers resistant to magnetic resonance imaging? *Europace* 2005;7:353–65.
- [20] Nazarian S, Hansford R, Rahsepar AA, Welton V, McVeigh D, Gucuk Ipek E, et al. Safety of magnetic resonance imaging in patients with cardiac devices. *N Engl J Med* 2017;377:2555–64.
- [21] Buendía F, Cano Ó, Sánchez-Gómez JM, Igual B, Osca J, Sancho-Tello MJ, et al. Cardiac magnetic resonance imaging at 1.5 T in patients with cardiac rhythm devices. *Europace* 2011;13:533–8.
- [22] Naehle CP, Kreuz J, Strach K, Schwab JO, Pingel S, Luechinger R, et al. Safety, feasibility, and diagnostic value of cardiac magnetic resonance imaging in patients with cardiac pacemakers and implantable cardioverters/defibrillators at 1.5 T. *Am Heart J* 2011;161:1096–105.
- [23] Sasaki T, Hansford R, Zviman MM, Kollandavelu A, Bluemke DA, Berger RD, et al. Quantitative assessment of artifacts on cardiac magnetic resonance imaging of patients with pacemakers and implantable cardioverter-defibrillators. *Circ Cardiovasc Imaging* 2011;4:662–70.
- [24] Hilbert S, Jahnke C, Loebe S, Oebel S, Weber A, Spampinato R, et al. Cardiovascular magnetic resonance imaging in patients with cardiac implantable electronic devices: a device-dependent imaging strategy for improved image quality. *Eur Heart J Cardiovasc Imaging* 2018;19:1051–61.
- [25] Bongiorno MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA, et al. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) registry of transvenous lead extraction outcomes. *Eur Heart J* 2017;38:2995–3005.
- [26] Friedman HL, Acker N, Dalzell C, Shen WK, Asirvatham SJ, Cha YM, et al. Magnetic resonance imaging in patients with recently implanted pacemakers. *Pacing Clin Electrophysiol* 2013;36:1090–5.
- [27] Russo RJ, Costa HS, Silva PD, Anderson JL, Arshad A, Biederman RWW, et al. Assessing the risks associated with MRI in patients with a pacemaker or defibrillator. *N Engl J Med* 2017;376:755–64.
- [28] Awad K, Griffin J, Crawford TC, Lane Cox S, Ferrick K, Mazur A, et al. Clinical safety of the Iforia implantable cardioverter-defibrillator system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions. *Heart Rhythm* 2015;12:2155–61.
- [29] Savouré A, Mechulan A, Burban M, Olivier A, Lazarus A. The Kora pacemaker is safe and effective for magnetic resonance imaging. *Clin Med Insights Cardiol* 2015;9:85–90.
- [30] Shenthar J, Milasinovic G, Al Fagih A, Götte M, Engel G, Wolff S, et al. MRI scanning in patients with new and existing CapSureFix Novus 5076 pacemaker leads: randomized trial results. *Heart Rhythm* 2015;12:759–65.
- [31] Gimbel JR, Bello D, Schmitt M, Merkely B, Schwitter J, Hayes DL, et al. Randomized trial of pacemaker and lead system for safe scanning at 1.5 Tesla. *Heart Rhythm* 2013;10:685–91.
- [32] Wilkoff BL, Bello D, Taborsky M, Vymazal J, Kanal E, Heuer H, et al. Magnetic resonance imaging in patients with a pacemaker system designed for the magnetic resonance environment. *Heart Rhythm* 2011;8:65–73.
- [33] Gold MR, Sommer T, Schwitter J, Al Fagih A, Albert T, Merkely B, et al. Full-body MRI in patients with an implantable cardioverter-defibrillator: primary results of a randomized study. *J Am Coll Cardiol* 2015;65:2581–8.
- [34] Bailey WM, Rosenthal L, Fananapazir L, Gleva M, Mazur A, Rinaldi CA, et al. Clinical safety of the ProMRI pacemaker system in patients subjected to head and lower lumbar 1.5-T magnetic resonance imaging scanning conditions. *Heart Rhythm* 2015;12:1183–91.
- [35] Bailey WM, Mazur A, McCotter C, Woodard PK, Rosenthal L, Johnson W, et al. Clinical safety of the ProMRI pacemaker system in patients subjected to thoracic spine and cardiac 1.5-T magnetic resonance imaging scanning conditions. *Heart Rhythm* 2016;13:464–71.
- [36] Wilkoff BL, Albert T, Lazebnik M, Park S-M, Edmonson J, Herberg B, et al. Safe magnetic resonance imaging scanning of patients with cardiac rhythm devices: a role for computer modeling. *Heart Rhythm* 2013;10:1815–21.
- [37] Sommer T, Bauer W, Fischbach K, Kolb C, Luechinger R, Wiegand U, et al. MR imaging in patients with cardiac pacemakers and implantable cardioverter defibrillators. *Rofo* 2017;189:204–17.
- [38] Naehle CP, Meyer C, Thomas D, Remerie S, Krautmacher C, Litt H, et al. Safety of brain 3-T MR imaging with transmit-receive head coil in patients with cardiac pacemakers: pilot prospective study with 51 examinations. *Radiology* 2008;249:991–1001.
- [39] Langman DA, Goldberg IB, Finn JP, Ennis DB. Pacemaker lead tip heating in abandoned and pacemaker-attached leads at 1.5 Tesla MRI. *J Magn Reson Imaging* 2011;33:426–31.
- [40] Strach K, Naehle CP, Mühlsteffen A, Hinz M, Bernstein A, Thomas D, et al. Low-field magnetic resonance imaging: increased safety for pacemaker patients? *Europace* 2010;12:952–60.
- [41] Kanal E. Safety of MR imaging in patients with retained epicardial pacer wires. *AJR Am J Roentgenol* 1998;170:213–4.
- [42] Pulver AF, Puchalski MD, Bradley DJ, Minich LL, Su JT, Saarel EV, et al. Safety and imaging quality of MRI in pediatric and adult congenital heart disease patients with pacemakers. *Pacing Clin Electrophysiol* 2009;32:450–6.
- [43] Higgins JV, Gard JJ, Sheldon SH, Espinosa RE, Wood CP, Felmler JP, et al. Safety and outcomes of magnetic resonance imaging

- in patients with abandoned pacemaker and defibrillator leads. *Pacing Clin Electrophysiol* 2014;37:1284–90.
- [44] Keller J, Neužil P, Vymazal J, Janotka M, Brada J, Žáček R, et al. Magnetic resonance imaging in patients with a subcutaneous implantable cardioverter-defibrillator. *Europace* 2015;17:761–6.
- [45] Blessberger H, Kiblboeck D, Reiter C, Lambert T, Kellermair J, Schmit P, et al. Monocenter Investigation Micra® MRI study (MIMICRY): feasibility study of the magnetic resonance imaging compatibility of a leadless pacemaker system. *Europace* 2019;21:137–41.