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EXPERT CONSENSUS

Joint Position Paper of the Working Group of Pacing and Electrophysiology of the French Society of Cardiology and the French Society of Diagnostic and Interventional Cardiac and Vascular Imaging on magnetic resonance imaging in patients with cardiac electronic implantable devices

Position conjointe du groupe de rythmologie et de stimulation cardiaque de la Société Française de Cardiologie et de la Société Française d'Imagerie Cardiaque et Vasculaire Diagnostique et Interventionnelle sur la pratique des examens par résonnance magnétique chez les patients porteurs de dispositifs cardiaques électroniques implantables

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Abbreviations: CEID, cardiac electronic implantable device; ICD, implantable cardioverter defibrillator; MR, magnetic resonance; MRI, magnetic resonance imaging.

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KEYWORDS
Magnetic resonance imaging;
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Pacemaker;
Defibrillator;
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Summary Magnetic resonance imaging (MRI) has become the reference imaging technique for the management of a large number of diseases. The number of MRI examinations increases every year, simultaneously with the number of patients receiving a cardiac electronic implantable device (CEID). The presence of a CEID was considered an absolute contraindication for MRI for many years. The progressive replacement of conventional pacemakers and defibrillators by ''magnetic resonance (MR)-conditional'' CEIDs and recent data on the safety of MRI in patients with ''MR-non-conditional'' CEIDs have gradually 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''. 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 French Society of Diagnostic and Interventional Cardiac and Vascular Imaging describes the effect of and risks associated with MRI in CEID carriers. We propose recommendations for patient workflow and monitoring and CEID programming in MR-conditional, ''MR-conditional non-guaranteed'' and MR-non-conditional devices.

MOTS CLÉS
Imagerie par résonance magnétique ;Dispositif électronique cardiaque implantable ; Stimulateur cardiaque ; Défibrillateur ; Société Française de Cardiologie

Résumé L'imagerie par résonance magnétique (IRM) est devenue l'imagerie de référence pour le diagnostic d'un grand nombre de pathologies. Le nombre d'examens IRM est en augmentation constante, parallèlement au nombre de patients implantés avec un dispositif électronique cardiaque implantable (DECI). L'IRM était considérée comme une contre-indication absolue à l'IRM jusqu'à il y a quelques années. Le remplacement progressif des stimulateurs et des défibrillateurs conventionnels par des dispositifs « IRM compatibles sous conditions » ainsi que les données récentes sur la sécurité des examens IRM chez les patients porteurs de dispositifs « non-IRM compatible » ont considérablement accru la demande d'examens IRM chez les patients porteurs de DECI. Cependant, les IRM peuvent être associés à certains risques chez les porteurs de DECI, y compris ceux « IRM compatibles sous conditions ». La programmation spécifique de l'appareil en mode « IRM » et la surveillance des patients pendant l'examen restent obligatoires pour tous les patients porteurs de DECI. Une prise en charge standardisée s'appuyant sur un protocole institutionnel est recommandée dans chaque établissement effectuant de tels examens. Ce document conjoint du Groupe Rythmologie et Stimulation Cardiaque de la Société Française de Cardiologie et de la Société Française d'Imagerie Cardiaque et Vasculaire Diagnostique et Interventionnelle décrit les effets et les risques associés à l'IRM chez des porteurs de DECI. Nous proposons des recommandations pour la prise en charge de ces patients, leur surveillance, ainsi que la programmation des dispositifs qu'ils soient « IRM compatibles sous conditions », « IRM compatibles sous conditions hors garantie constructeur » ou « non-IRM compatibles ».

Background

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 approximately 70,000 pacemakers and 15,000 ICDs implanted in 2018 (International Health Market Trends data). At least one in 50 people aged $\geq$ 75 years will have a permanent pacemaker implanted [2]. At the same time, magnetic resonance imaging (MRI) has become the reference imaging technique for the management of a large number of diseases, and the number of examinations performed increases every year (+12%), with approximately 7 million MRI examinations in France in 2017 [3].

For many years, the presence of a CEID, such as a pacemaker or an ICD, was considered an absolute contraindication for MRI. Two major developments have changed this paradigm in recent years. First, manufacturers have progressively marketed new ''MR-conditional'' systems. However, these MR-conditional materials are not ''MR safe'', and therefore require specific device programming and patient monitoring. Second, several large observational studies have shown that MRI can also be performed in patients carrying an ''MR-non-conditional'' CEID with a low risk of complications, which shifts the presence of an MRI non-conditional 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-non-conditional 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 an MR-conditional or MR-non-conditional device, any MRI should be integrated into a standardized workflow, defined in an institutional protocol involving both MRI specialists 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 a patient 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 MRI specialists 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 (Société Française de Cardiologie; SFC) and the French Society of Diagnostic and Interventional Cardiac and Vascular Imaging (Société Française d'Imagerie Cardiaque et Vasculaire Diagnostique et Interventionnelle; SFICV) on the technical conditions for MRI in patients with MR-conditional and MR-non-conditional CEIDs, which 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, 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 combining leads and generators from the same manufacturer have been specifically tested to be safe and are guaranteed by the manufacturer as MR conditional. Specific MR-mode programming is always required during the MRI to limit the effect of the magnetic and radiofrequency fields on the functioning of the device. All MR-conditional systems exclude epicardial devices, abandoned or fractured leads and lead extensions/adapters.

MR-conditional non-guaranteed CEIDs are defined as systems consisting of MR-conditional generators and leads issued by different manufacturers. MR-non-conditional CEIDs are all other devices.

An updated list of MR-conditional CEIDs is provided at www.irm-compatibilite.com; the list was 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 < 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 CEIDs

During MRI, three magnetic fields are involved: a static field called B0 (1.5—3 T in current magnet technology, but higher fields are now commercially available); a three-dimensional gradient magnetic field (Gx, Gy, Gz); 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 is present in conventional leads), but movement of the generator is unlikely [9]. The mechanical switch of MR-non-conditional generators can be activated by MRI, thereby resulting in asynchronous pacing in pacemakers or deactivation of tachycardia detection in ICDs [10]. All magnetic fields can cause electrical reset of MR-non-conditional generators, leading to backup 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 lead to induced myocardial capture. The gradient and B1 (radiofrequency) magnetic fields can generate oversensing that can lead to pacing inhibition or inappropriate therapies [13]. MR-non-conditional 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 to be particularly great with abandoned leads.

Some risks are associated with the temporary MR mode, and are common to MR-conditional and MR-non-conditional devices. During MRI, an asynchronous mode (VOO/DOO) or a deactivation of 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 caused by 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 hydroelectrolyte disturbances and in patients who are not pacing dependent [19]. For ICDs, the deactivation of tachycardia detection carries the risk that a ventricular arrhythmia cannot be treated during this time. In patients who are not pacing dependent and 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 have been some concerns about the risk of thoracic and cardiac MRI in patients with CEIDs because of the close proximity of the device. However, most studies have shown a similar safety profile between cardiac/thoracic and extrathoracic MRI [20—22]. CEIDs, especially ICDs [20] and CEIDs positioned at the left side [21,23], can cause artefacts. Cardiac artefacts 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 artefacts [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 MRI specialists and device specialists. This workflow should include the benefit/risk ratio of the MRI (particularly in patients with MR-non-conditional devices), evaluation of a possible alternative imaging modality (frequently computed tomography) and the exclusion of patient- or device-related contraindications (Table 2). The risk from MRI in a patient with an implant is considerably lower than that from 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 they are pacing dependent, as well as the history of ventricular arrhythmias in ICD carriers. A transmission form including all information needed before the MRI examination is proposed in Fig. 1 and Fig. A.1.

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

Table 1 Risks associated with magnetic resonance imaging in patients with magnetic resonance-non-conditional and magnetic resonance-conditional cardiac electronic implantable devices.

MR-non-conditional CEIDs	Acute bradycardia in ODO/OOO mode
	Inactivation of ICD therapy: absence of VT/VF treatment
	Oversensing → pacing inhibition/inappropriate ICD therapy
	Ventricular arrhythmia induced by asynchronous pacing mode (VOO/DOO)
	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)
MR-conditional CEIDs under specific conditions	Acute bradycardia in ODO/OOO mode
	Inactivation of ICD therapy: absence of VT/VF treatment
	Oversensing → pacing inhibition/inappropriate ICD therapy
	Ventricular arrhythmia induced by asynchronous pacing mode (VOO/DOO)

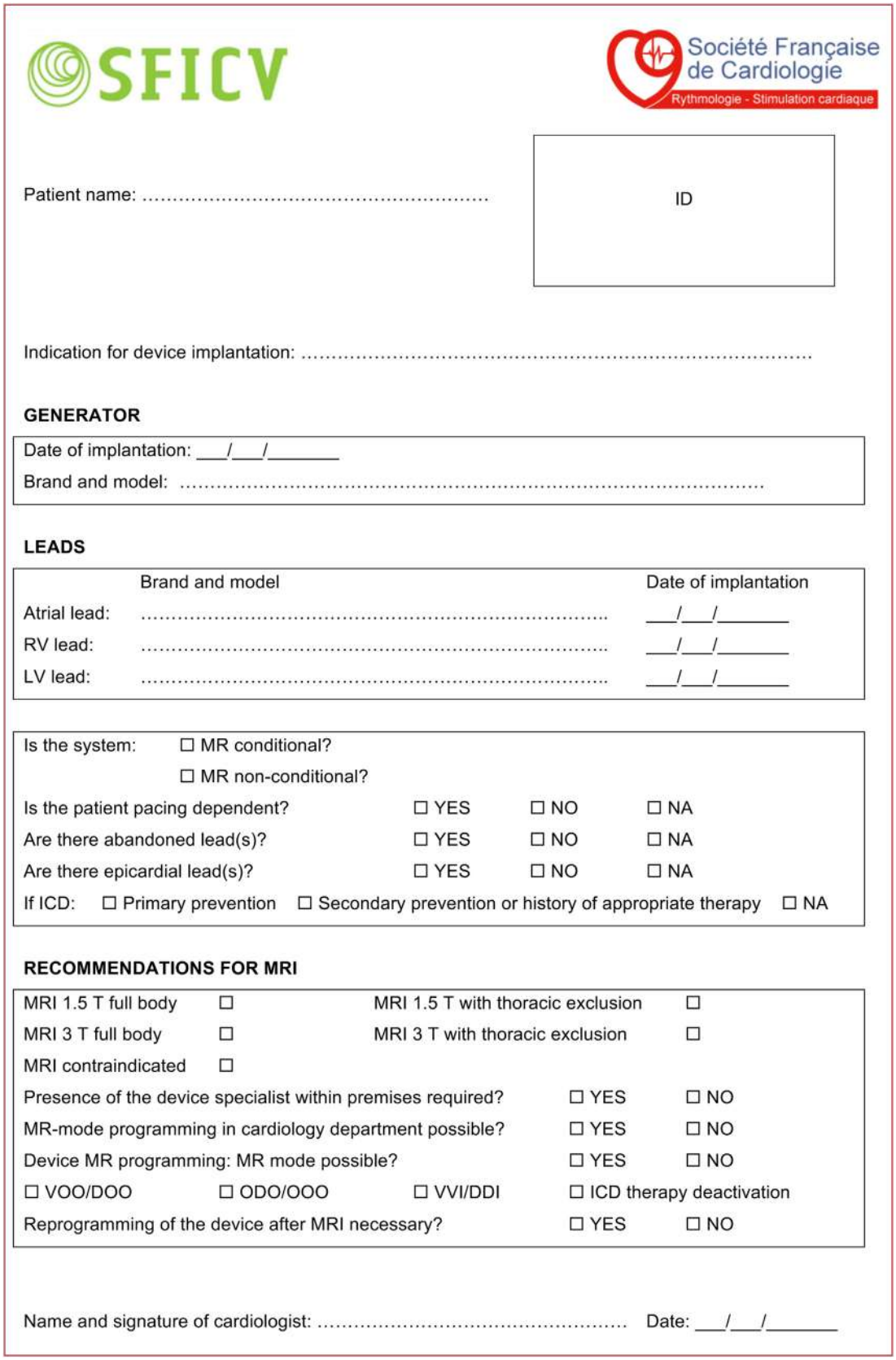
CEID: cardiac electronic implantable device; ICD: implantable cardiac defibrillator; MR: magnetic resonance; ODO/OOO: atrium and ventricle being sensed (ODO)/deactivation of CEID (OOO); VF: ventricular fibrillation; VOO/DOO: ventricular pacing (VOO) or dual chamber pacing (atrium and ventricle) (DOO)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

Table 2 Common workflow for magnetic resonance imaging in patients with magnetic resonance-conditional and magnetic resonance-non-conditional cardiac electronic implantable devices.

Before MRI scan	Validate the clinical benefit of the MRI scan (consider 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 MR-non-conditional system?
	Medical indication of the device, pacing dependency, history of ventricular arrhythmias
	Exclude contraindications: epicardial, fractured and abandoned leads as well as adapters and lead extensions (with X-ray if necessary); high capture thresholds > 2 V/0.4 ms; out-of-range impedance values < 200 or > 1500 ohms; elective replacement indicator or end of service
	Set specific MR pacing programme according to the underlying rhythm, deactivate tachycardia detection (ICDs)
During MRI scan	Monitoring (cardiac frequency by pulse oximetry + electrocardiogram monitoring if possible + visual monitoring) by physician or qualified personnel
	Presence of a defibrillator and emergency material
	Physicians with the skill to perform resuscitation available immediately
	Physicians with the skill to programme devices available on call or immediately, depending on the device and patient dependency (Fig. 2 and Fig. 3)
After MRI scan	Device control (battery, sensing, impedance, pacing threshold) and reprogramming of baseline settings, reactivation of tachycardia detection (ICDs)

ICD: implantable cardiac defibrillator; MR: magnetic resonance; MRI: magnetic resonance imaging.

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,



SFICV

Société Française de Cardiologie
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: ☐ MR conditional?
☐ MR non-conditional?

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 ☐ NA

RECOMMENDATIONS FOR MRI

MRI 1.5 T full body	☐	MRI 1.5 T with thoracic exclusion	☐
MRI 3 T full body	☐	MRI 3 T with thoracic exclusion	☐
MRI contraindicated	☐		

Presence of the device specialist within premises required?	☐ YES	☐ NO
MR-mode programming in cardiology department possible?	☐ YES	☐ NO
Device MR programming: MR 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. ICD: implantable cardioverter defibrillator; ID: identification; LV: left ventricular; MR: magnetic resonance; MRI: magnetic resonance imaging; NA: not available; ODO/OOO: atrium and ventricle being sensed, no pacing (ODO)/deactivation of sensing and pacing (OOO); RV: right ventricular; SFICV: Société Française d'Imagerie Cardiaque et Vasculaire Diagnostique et

sensing and battery status); MRI is contraindicated in case of an elective replacement indicator.

During the MRI examination, we recommend that all patients with MR-conditional or MR-non-conditional devices be at least monitored with cardiac frequency from pulse oximetry. If possible, electrocardiogram monitoring and visual/voice contact with a physician or qualified staff member are advised. Because MR sequences can cause electrocardiogram artefacts, monitoring of cardiac frequency with pulse oximetry is mandatory for all patients. Although electrocardiogram monitoring is advised in addition to pulse oximetry, it is not mandatory if cardiac frequency can be efficiently monitored with pulse oximetry. An external defibrillator and emergency materials 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 device programming skills should be available on an emergency standby basis, depending on the conditions defined by the institutional protocol (Fig. 2 and Fig. 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: EnRhythm SureScan® and Advisa® pacemakers and Evera® ICD (Medtronic Inc., Minneapolis, MN, USA); Entovis ProMRI® and Evia® pacemakers and Iforia® ICD (Biotronik Inc., Lake Oswego, OR, USA); and Kora® pacemaker (Microport, Shanghai, China) [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 modelling that enables a large number of conditions to be tested [36]. On the basis of these tests, each manufacturer provides specific guidelines and conditions under 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 whereas others allow full-body MRI. Hence, these specific conditions and guidelines can vary between 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 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 reprogramming of the device before an MRI depend mainly 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 programme is active. In patients who are not pacing dependent, programming the device in an inhibited pacing mode (VVI/DDI) seems safe, although this programming is off manufacturer guarantee. Inhibited mode in patients who are not pacing dependent decreases the risk of a non-treated paroxysmal bradycardia and the risk associated with asynchronous pacing [22,37]. Inhibited modes may be preferred with paroxysmal atrioventricular block/sinus node dysfunction (off manufacturer guarantee) [22].

The reprogramming of devices before and after MRI could reasonably be performed on the same day as the MRI, on site, but at a different place from the MRI scan (cardiology outpatient clinic) (Fig. 2). We recommend that the time for which 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 reprogramming of devices before and after MRI could reasonably be performed just before and after the MRI in high-risk patients with an 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 the MRI scan 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 prespecified MR programme. 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 the scan.

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://irm-compatibilite.com).

Workflow for MR-conditional non-guaranteed CEIDs

A current issue is to determine in which category to include the MR-conditional non-guaranteed CEIDs, which are defined by MR-conditional materials (leads and generators), but from different manufacturers. By definition,

Interventionnelle (French Society of Diagnostic and Interventional Cardiac and Vascular Imaging); VOO/DOO: ventricular pacing (VOO) or dual chamber pacing (atrium and ventricle) (DOO), no sensing (asynchronous mode); 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).

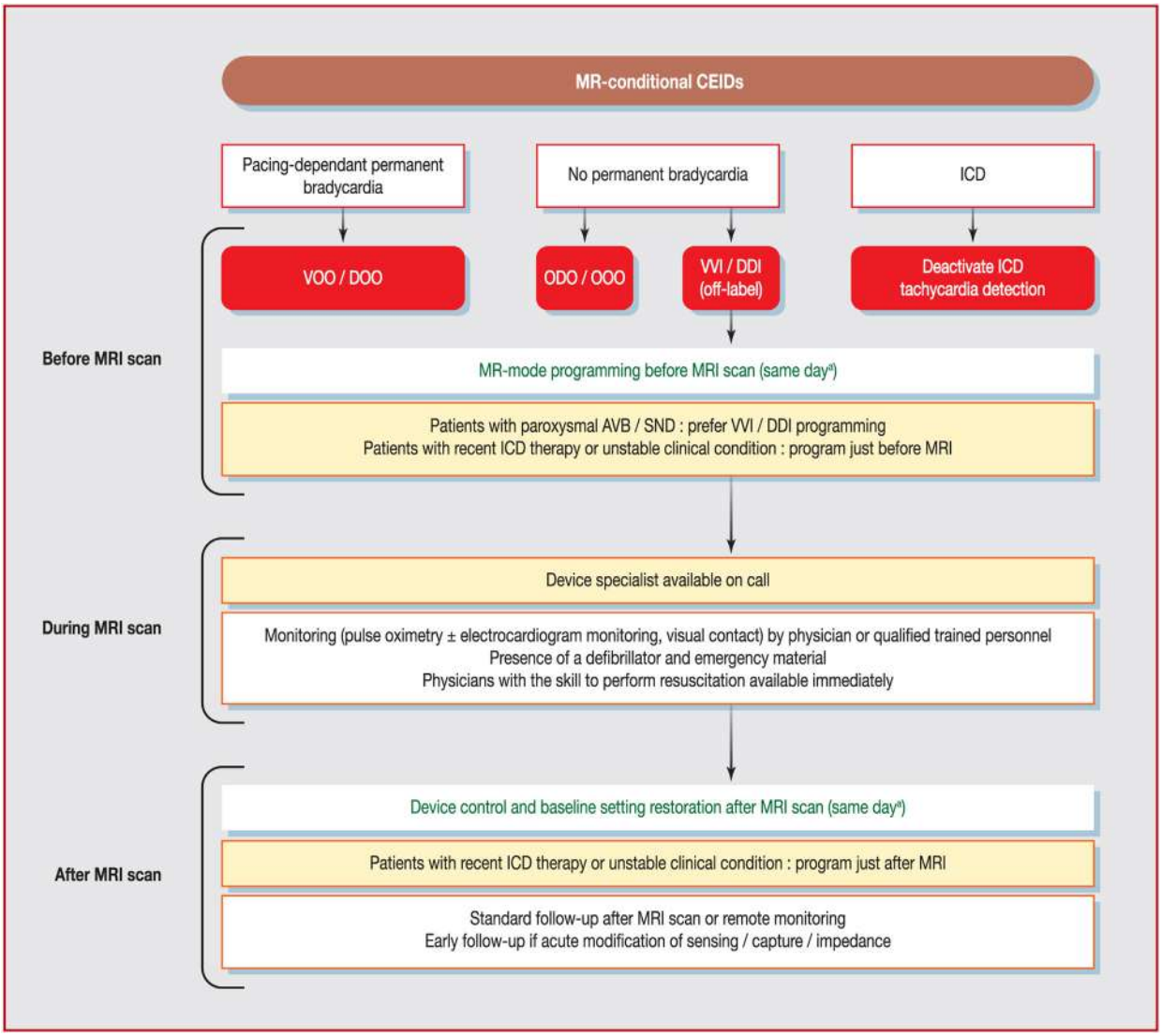


Figure 2. Workflow for magnetic resonance (MR)-conditional guaranteed and non-guaranteed cardiac electronic implantable devices (CEIDs). AVB: atrioventricular block; ICD: implantable cardioverter defibrillator; MRI: magnetic resonance imaging; ODO/OOO: atrium and ventricle being sensed, no pacing (ODO)/deactivation of sensing and pacing (OOO); SND: sinus node dysfunction; VOO/DOO: ventricular pacing (VOO) or dual chamber pacing (atrium and ventricle) (DOO), no sensing (asynchronous mode); 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).[a] Except for devices with automatic detection of MR field.

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 to these devices (Fig. 2). A national registry should be developed for these patients to validate the safety of this workflow applied to MR-conditional non-guaranteed CEIDs.

Workflow for MR-non-conditional CEIDs

Recent clinical observational retrospective and prospective data have demonstrated the relative safety of MRI in patients with MR-non-conditional material. In the MagnaSafe registry, including extrathoracic MRI performed with 1000 MR-non-conditional 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—4% of cases, 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.

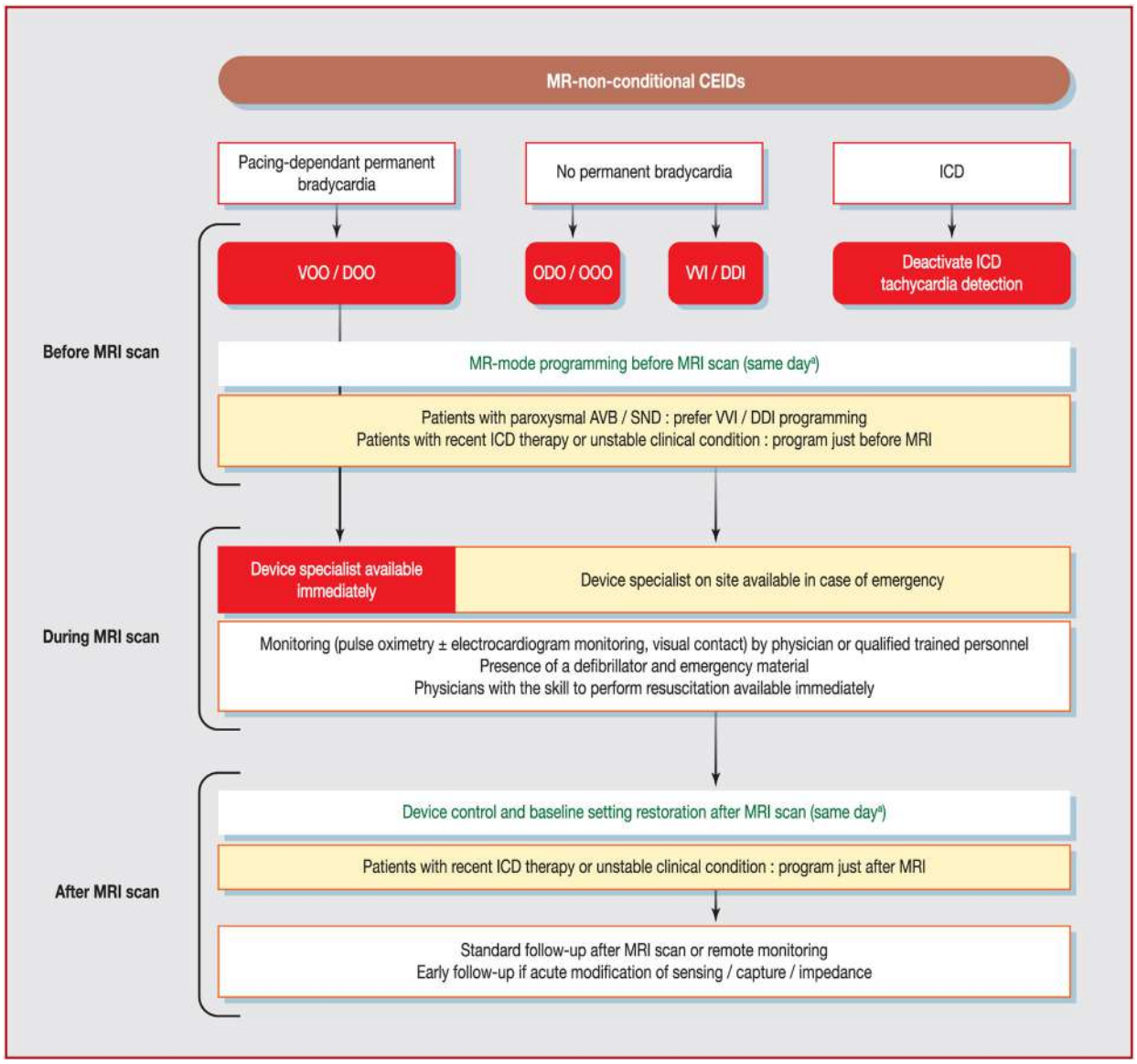


Figure 3. Workflow for magnetic resonance (MR)-non-conditional cardiac electronic implantable devices (CEIDs). AVB: atrioventricular block; ICD: implantable cardioverter defibrillator; MRI: magnetic resonance imaging; ODO/OOO: atrium and ventricle being sensed, no pacing (ODO)/deactivation of sensing and pacing (OOO); SND: sinus node dysfunction; VOO/DOO: ventricular pacing (VOO) or dual chamber pacing (atrium and ventricle) (DOO), no sensing (asynchronous mode); 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).[a] In pacing-dependent patient, control device as soon as possible.

Allowing for extrathoracic MRI in patients with MR-non-conditional 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-non-conditional devices should be assessed in a standardized institutional protocol following the general recommendations specified above. We recommend monitoring (cardiac frequency by pulse oximetry ± electrocardiogram monitoring, visual contact) of all patients with MR-non-conditional 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 patients who are not pacing dependent, a device specialist should be available immediately on the premises, as defined by the institutional protocol. The reprogramming of devices before and after MRI could reasonably be performed on the same day as the MRI, on site, but at a different place from the MRI scan (cardiology outpatient clinic) (Fig. 3). We recommend that the time for which the patient remains on MR mode should be as short as possible, to limit the risks associated with absence of pacing/therapy or asynchronous pacing.

The reprogramming of devices before and after MRI could reasonably be performed on the premises just before and

after the MRI examination in high-risk patients with an unstable clinical cardiac condition or with recent (< 15 days) ICD therapy (Fig. 3).

Because of very low evidence of MR safety for MRI scanning > 1.5 T, we recommend limiting the MR field strength to 1.5 T for non-conditional 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 to a minimum. A specific absorption rate < 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 specific absorption rate 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 significant modification of lead 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 MRI scan 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-non-conditional CEIDs, the indication for cardiac MRI should be discussed between the referring cardiologist, the device specialist and the MRI specialist. Cardiac MRI should be restricted to indications for which alternative methods are inaccurate and only performed in experienced centres. Cardiac CT may be used as an alternative, when suitable.

Epicardial and abandoned leads

We have little data on MR 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 patients who are not pacing dependent after careful consideration of the benefit/risk ratio and multidisciplinary discussion.

Implantable loop recorders

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

Subcutaneous ICDs and leadless pacemakers

The first-generation subcutaneous ICD (SQ-RX™; Boston Scientific, Marlborough, MA, USA) was not labelled as MR conditional, but the second- and third-generation subcutaneous ICDs (EMBLEM™ models A209 and A219; Boston Scientific) are guaranteed to be MR conditional (3 T, full body) [44]. The leadless pacemaker available on the market (Micra™; Medtronic) is also guaranteed to be MR conditional (3 T, full body) [45]. The same workflow as for conventional MR-conditional material should be applied to these devices. However, cardiac imaging can be affected by subcutaneous ICDs and leadless pacemakers, mostly because metallic artefacts on the left ventricle can prevent accurate tissue characterization [44].

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None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.acvd.2020.03.015.

Disclosure of interest

The authors declare that they have no competing interest.

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