

RECOMMENDATIONS / Professional Information

Pacemakers and MRI: A protocol in line with international guidelines and approved by the SFICV (French Society of Cardiovascular Imaging)



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The rate of pacemaker implantation is increasing each year. It has been estimated that about 1 person in 1000 in the Western world has received a pacemaker worldwide [1]. Despite major advances in pacemaker technology, notably with the advent of “magnetic resonance imaging (MR)-compatible” pacemakers, it should be borne in mind that these medical devices still contain ferromagnetic material and remain a relative contraindication for MRI. Nonetheless, when the risk–benefit ratio is favorable, imaging may be performed under specific safety conditions. In all cases, MRI in a patient with a pacemaker must be closely supervised by cardiology (cardiac rhythm disorder specialists) and radiology teams [2]. To ensure such conditions are fulfilled, this kind of imaging should only be performed in hospitals that have implemented efficient interdepartmental protocols and collaboration procedures.

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At the same time, the use and scope of MRI has expanded greatly with, for example, 5.3 million MRI scans performed in France in 2012 [3]. To continue considering pacemakers as an absolute contraindication for MRI when this modality's indications are steadily expanding, could result in missed opportunities for these patients. A Japanese study demonstrated that 17% of pacemaker patients were likely to require MRI in the year following implantation [4]. Similarly, Roguin et al. estimated that the likelihood of pacemaker patients requiring MRI during the lifespan of the device ranged from 50% to 75% [5]. Finally, a two-fold increase in the likelihood of needing MRI is observed in patients aged over 65.

The indications for MRI keep expanding. For the pacemaker patient age group, the main indications are for neurological disorders (stroke, dementia, Parkinson's disease, etc.) and neurosurgery (tumors, hematoma, abscess, etc.), although MRI examinations for cancer and cardiovascular disorders are also steadily increasing [6,7].

The aim of the present article is to suggest rules of good practice when performing MRIs in pacemaker patients regardless the device's compatibility. This recommendation was endorsed by the SFICV (French Society of Cardiovascular Imaging).

Pacemakers, implantable automatic defibrillators: basic principles

Schematically, pacemaker insertion is indicated for patients with atrioventricular conduction abnormalities. An international three-letter code describes the pacing mode and settings. The first letter indicates which chamber(s) are stimulated [A atrium, V ventricle, D (dual) atrium and ventricle, O none], the second which chamber(s) are detected (A, V, D, O), and the third the mode of response of the pacemaker (I inhibited, T triggered, D inhibited and triggered, O none). For example, a pacemaker programmed to the VOO mode performs simple asynchronous ventricular pacing.

An implantable automatic defibrillator is a pacemaker that can deliver shocks. Such pacemakers are indicated for patients at risk for ventricular rhythm disorders, certain patients with cardiomyopathy or cardiac failure with a reduced ejection fraction of less than 30–35%.

The new “MRI-compatible” pacemakers

These recently marketed devices consist in a pacing box and leads that are immediately recognizable on X-ray examinations due to the radiopaque markers they contain. In 2010, a study on the first commercially released device confirmed that MRI could be performed without harm to the patients or damage to the device [8]. The study included 464 patients with this pacemaker from 41 different sites. Two hundred and forty-four of these patients underwent non-cardiac MRI 9 to 12 weeks after pacemaker implantation. The control group included 206 patients. No immediate or delayed complications attributable to MRI were observed. No differences were found between the threshold parameters measured for the pacemakers having undergone MRI and control pacemakers.

MRI-compatible pacemakers are not non-magnetic; therefore, they are categorized as “MR conditional” by the Foods and Drugs Administration, not “MR Safe”. This implies maintaining a high safety standard. All pacemaker manufacturers provide their own recommendations for MRI on their websites (Table 1).

In practice, MRI teams should implement the same safety conditions, whether the patient has a MRI-compatible pacemaker or not. The main differences are in fact the indications for MRI and the applicable legal framework. The manufacturer's warranty guaranteeing the absence of incidents means that the indications for MRI can be extended. For example, a patient with a MRI-compatible pacemaker with dementia, brain metastases, extrapyramidal symptoms or meniscus injury may benefit from MRI, even if the procedure is not vital for patient care. However, MRI would most likely be contraindicated in the same clinical setting if the pacemaker is not MRI-compatible.

Contraindications for implantable defibrillators are more stringent than for pacemakers, except for the new “MRI-conditional” models. Still, imaging may be performed in the same rigorous safety conditions as for pacemakers, if the expected benefit exceeds by far the potential risk.

Potential risks

The risk of harm to the patient or device during a MRI scan is not negligible. Multiple interactions occur when a patient with a pacemaker is placed within a MRI machine. A large number of patient, pacemaker and MRI parameters need to be taken into account to minimize the risks associated with MRI scans. Each additional sequence, each additional minute that the scan lasts represents a new risk, hence the need to keep the procedure to the bare minimum.

Potentially interfering factors are: B0 static field and gradient intensities, the spatial magnetic field gradient, the radiofrequency used (pulse type), the specific absorption rate (SAR), the anatomical region investigated, the position inside the magnet, the implanted material (leads and pacing box), the patient's dependence on the pacemaker, lead length, loops and direction, and the duration of the scan.

Risks for the pacemaker

Placing a pacemaker in a MRI system may result in damage to the pacing box or leads. Potential risks include premature deterioration of the battery, heating of stimulation leads with possible endocardial burns, device switch to asynchronous mode, stimulator deprogramming or inhibition, permanent device failure, and stimulator or lead migration.

Risks for the patient

The potential risks for the patient are variable, depending on how much the patient relies on his/her pacemaker. Although the risks are different, both dependent and non-dependent patients are subject to potentially dangerous incidents, and

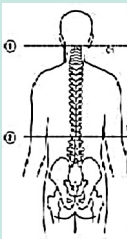
Table 1 MRI-compatible pacemakers.

	Models	Field	Patient position	Exclusion zone		SAR	Slew rate	Spatial gradient	Total exposure duration allowed	Leads
BIOTRONIK	Evia SR-DR	1.5 T or 3 T (for some combination pace-maker/leads)	Strict supine position	Isocenter of the reel excluded between the level of eyes and top of hips		Full body $\leq 2 \text{ W/kg}$	Slew rate $\leq 216 \text{ T/m/s}$ per axis Up to the serial number 66237094 included, maximum slew rate of 125 T/m/s per axis Slew rate $\leq 200 \text{ T/m/s}$ per axis	Not specified	30 min total active imaging by session	Safio S 53, S60 Siello S 53, S 60, S45 Solia S 45, S & T 53, S & T 60 Setrox S 53, S60
	Entovis SR-DR									
	Estella SR-DR Ecuro SR-DR			Over exclusion zone from the serial number 66237095 Full body		Head $< 3.2 \text{ W/kg}$			10 hours for the life of the system	
BOSTON SCIENTIFIC	Eluna 8 Epyra 6 et 8 Etrinsa 6 et 8	1.5 T	Prone or supine position	Full body		Full body $\leq 4 \text{ W/kg}$ if INGEVITY leads otherwise 2 W/kg Head $< 3.2 \text{ W/kg}$ Full body $\leq 2 \text{ W/kg}$ Head $< 3.2 \text{ W/kg}$	Slew rate $\leq 200 \text{ T/m/s}$ per axis	Not specified	Not specified	INGEVITY MRI, FINELINE II Sterox, FINELINE II Sterox EZ
	Accolade MRI Essensio MRI Proponent MRI Advantio MRI Formio MRI Ingenio MRI Vitalio MRI									

Table 1 (Continued)

	Models	Field	Patient position	Exclusion zone	SAR	Slew rate	Spatial gradient	Total exposure duration allowed	Leads
St JUDE MEDICAL	Assurity MRI Accent MRI Endurity MRI	1.5 T	Strict supine position	Consult SJM web site Full body or Isocenter of the reel excluded between the eyes (or 10 cms above) and the vertebra L4 depends on the PM/leads association	Full body ≤ 2 W/kg or ≤ 4 W/kg based on PM/leads association Head < 3.2 W/kg	Slew rate ≤ 200 T/m/s per axis	Not specified	30 min of active imaging by session. 30 min of wait between the sessions	Tendril MRI, Tendril STS, IsoFlex Optim
	Endurity Endurit Core Nanostim leadless	1.5 T	Prone or supine position	Full body				Full body ≤ 4 W/kg Head ≤ 3.2 W/kg	≤ 19 T/m or 1900 gauss/cm None
SORIN	Kora 100	1.5 T	Prone or supine position	Isocenter of the reel excluded between the level of eyes and top of hips					
	Full body ≤ 2 W/kg Head < 3.2 W/kg	Slew rate ≤ 200 T/m/s per axis	Not specified	40 min of active imaging except thorax by session. 20 min thoracic region	Beflex 52 cm RF45D – 58 cm RF46D				

Table 1 (Continued)

	Models	Field	Patient position	Exclusion zone	SAR	Slew rate	Spatial gradient	Total exposure duration allowed	Leads
	Kora 250			Full body	Full body ≤ 2 W/kg (1 W/kg in thoracic region if body mass index < 23) Head < 3.2 W/kg				
MEDTRONIC	Revo	1.5 T	Prone or supine position	Isocenter of the reel excluded between C1 et T12		Slew rate ≤ 200 T/m/s per axis	≤ 20 T/m or 2000 gauss/cm		
	Not specified	CapSureFix Novus MRI™ SureScan® 5076 (models 5076-35, 5076-45, 5076-52, 5076-58, 5076-65, 5076-85)							
	Enrythm Advisa Ensura Micra	1.5 or 3 T		No restrictions					
					Full body ≤ 4 W/kg Head < 3.2 W/kg		≤ 25 T/m or 2500 gauss/cm		None

MRI: magnetic resonance imaging. These recommendations are for illustration only and do not exclude to check accurately the recommendations given by the manufacturers.

non-dependent patients are not apparently at less risk than dependent patients [9].

For dependent patients, the risk is over-detection resulting in inhibition of stimulation (bradycardia, cardiac arrest). Indeed, the pacemaker can wrongly detect radiofrequency waves as a signal mimicking cardiac activity and stop stimulating the patient's ventricles. The clinical outcome is bradycardia, or even cardiac arrest.

For non-dependent patients, the risk is inappropriate asynchronous stimulation that can result in tachycardia or ventricular fibrillation. This basically means that the stimulator no longer receives external input and stimulates the heart regardless of its real physiological activity.

However, many studies have reported successful MRI scans for patients with standard pacemakers without any harm to either the patient or the device. Martin et al. reported a series of 62 MRI scans for 49 patients without any clinical incidents [10]. In the same way, Nazarian et al. reported that no complications had occurred during the 555 scans they performed on 438 patients with pacemakers. It should be noted nevertheless that devices implanted before 1998 were excluded. In three cases, the pacemakers reverted to transient back-up programming mode without consequences either for the patients or the devices [11]. In the study by Roguin et al., no thermal injury was observed and the levels of magnetic attraction and torsion remained low. However, the authors reported that devices manufactured before 2000 were more subject to damage than more recent models [12].

Devices implanted after 2000 are smaller in size and contain less ferromagnetic components explaining their improved MRI-compatibility. So, the date the device was implanted should also be taken into account when making decisions. The year 2000, a date that is easy to remember, is a key element of the decision tree.

In the same way, the anatomical region that requires investigation and pacemaker manufacturer recommendations should also be taken into account, since the risk is higher if the pacemaker is located in the imaged region.

Any clinical incident (malaise, palpitations or even patient asking to stop the scan), electrical anomaly (especially bradycardia or tachycardia) should result in immediate discontinuation of the MRI scan and removal of the patient from within the magnet as quickly as possible. ECG readout quality should be monitored, in particular during the emission of radiofrequency waves. ECG artifacts can occur and must not be mistaken for heart rhythm problems. We suggest using both external monitoring and the imager's onboard monitoring system (ECG, heart rate monitoring).

French and international guidelines

In 2005, the French Agency for the Safety of Health Products (AFSSAPS now known as ANSM) issued guidelines on the interactions between MRI and active implantable devices (pacemakers, implantable defibrillators, neurostimulators). Some of the contraindications for these devices are the same, such as the minimum time after implantation and the maximum magnetic field intensity. As far as possible, computed tomography (CT) should be preferred over MRI.

All three kinds of devices are considered to be relative contraindications for MRI with a field of not more than 1.5 Tesla.

The decision to go ahead with MRI must be discussed among the physician asking for the scan, the cardiac rhythm specialist and the radiologist. These three clinicians should review the indication and consider alternatives to MRI.

If MRI is to be performed, the following conditions must be fulfilled without fail:

- presence of a clinician at the patient's bedside during the scan;
- quickly available crash cart and external defibrillator;
- permanent ECG monitoring during the scan with a MRI-compatible ECG system;
- correct pacemaker programming prior to entering the MRI environment and pacemaker operation checked before and after the scan by the cardiologist;
- pacemaker implanted at least 6 weeks before the MRI scan;
- if necessary, chest X-ray to verify the absence of damaged, abandoned or epicardial leads;
- immediate discontinuation of the scan upon occurrence of an incident.

In the AFSSAPS guidelines, 3 Teslas MRI scans were strictly contraindicated. However, certain new generation MRI-compatible pacemakers are eligible for 3-Tesla static fields. The American Heart Association (AHA) advises against performing MRI for patients with pacemakers, with a higher-level contraindication for pacemaker-dependent patients, unless the benefit of MRI be significantly higher than the risk [13].

Pacemaker-dependent and non-dependent patients are managed in the same way as regards to MRI (Fig. 1) [14], the only difference is how the pacemaker is programmed.

Pacemakers and MRI: a strictly monitored process

The present protocol for managing pacemaker patients is in line with international guidelines and has been approved by the executive committee of the Société française d'imagerie cardiovasculaire (SFICV, French society for cardiovascular imaging).

MRI scans for patients with pacemakers should only be considered in public or private hospitals for which the imaging department and cardiology department, as well as a cardiac emergency unit, are located on the same campus. MRI-compatible vital signs monitoring equipment, an external defibrillator and an adequately stocked crash cart must be available in the MRI environment to deal with potential emergency situations. MRI staff must be appropriately trained in basic resuscitation techniques.

Given the significant rise in the number of requests for MRI scans for patients with pacemakers and the relative confusion regarding "MRI-compatible" and "non-MRI-compatible" devices, healthcare facilities should define standardized procedures for performing MRI scans in patients with pacemakers, regardless MR compatibility.

Such procedures should describe responsibilities and resource persons, how the patient is prepared before, during and after the scan, and should provide technical

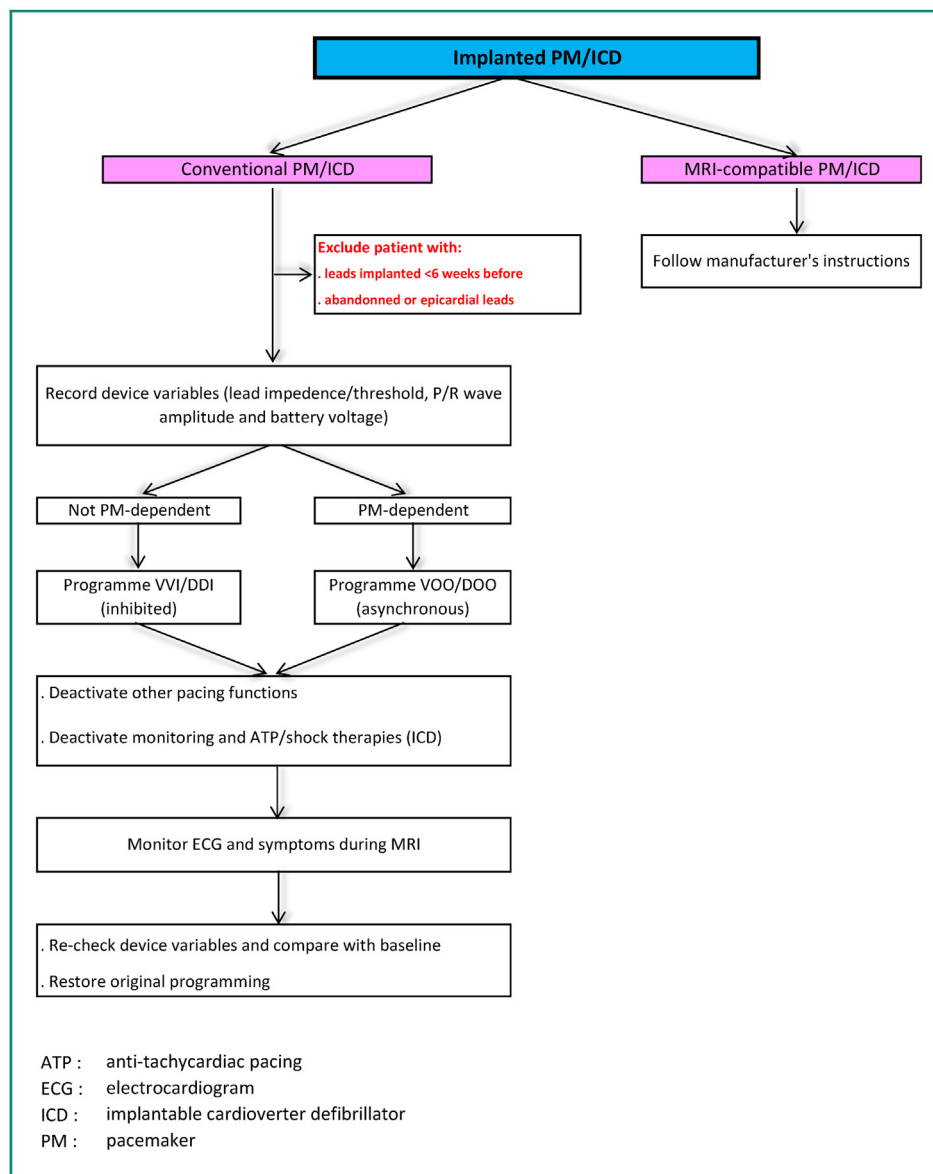


Figure 1. Recommendations regarding the use of magnetic resonance imaging (MRI) for patients with implantable cardiac devices. PM: pacemaker; ICD: implantable cardioverter defibrillator. Adapted from reference [14].

recommendations as regards to how the scan is performed, how the patient is monitored and how MRI is prescribed, as well as information on the patient circuit.

The document can be made available to all staff using a hospital document management system. Drawing up such procedures requires multidisciplinary cooperation. All the information provided in the procedure must be in line with ANSM and AHA guidelines.

In addition to this procedure, we propose a communication sheet to be filled in by the cardiac rhythm specialist (Fig. 2). This sheet is completed when the patient consults prior to MRI and is then sent to the imaging department (Fig. 3). It provides proof that the patient has actually attended the pre-MRI visit. The cardiac rhythm specialist can also provide, via this sheet, specific recommendations as to patient care after the MRI scan and before the post-MRI visit.

In order to differentiate requests for patients with pacemakers from the usual MRI request procedure, a specific pacemaker patient form (Fig. 4) should be used and should be processed separately (Fig. 5). Without a specific process, pacemaker patients may make it to their appointment only to see the scan postponed and rescheduled subsequently.

The specific request form, to be completed by the physician requesting the MRI, will provide specific details as to why MRI is requested and the potential clinical benefit for the patient. It also involves the requesting physician personally in the decision to proceed with MRI. For both cardiac rhythm specialists and radiologists, the form ensures traceability from the very start of the process. It also provides them with the possibility of reviewing the patient record prior to imaging, to discuss the request's relevance and perhaps suggest an alternative method. The request must be



TRANSMISSION FORM - MRI IN A PATIENT WITH PM/ICD

This form to be filled by the cardiologist prior to MRI examination for patients bearing PM or ICD. Please communicate the form to MRI team with the patient.

Patient's ID

Surname :
 First name :
 Date of birth :

Date of MRI examination:

Implanted device:

Pacemaker

Defibrillator (ICD)

Model (specify if "unsafe" or "conditional"):

Implantation date:

Dependent:

Yes

No

1.5 T MR scan authorised by the cardiologist:

Yes

No

PM adjustment for the MRI:

Presence of the cardiologist required during MRI:

Yes

No

Cardiology visit required after MRI:

Yes

No

Patient should be accompanied to comeback to cardiology:

Yes

No

Comments - Instructions for MRI team

Cardiologist Name & Signature
 Phone number or beeper

Figure 2. Magnetic resonance imaging (MRI)-cardiology communication sheet.

validated sequentially first by the radiologist, then by the cardiologist, before MRI can be performed.

To summarize, healthcare facilities with a MRI service should use:

- a specific MR imaging request form;
- a standardized procedure stating all the necessary recommendations on prescribing MRI, the patient circuit, patient care and technical recommendations for scanning;

- a communication sheet to liaise between the cardiology department and the medical imaging department.

The previously described procedure is only feasible as part of a scheduled process (non-emergency). In emergency cases, tripartite dialogue (requesting physician, cardiologist, and radiologist) is required to assess the benefit–risk ratio. If MRI is vital, the cardiologist, radiologist and on-call

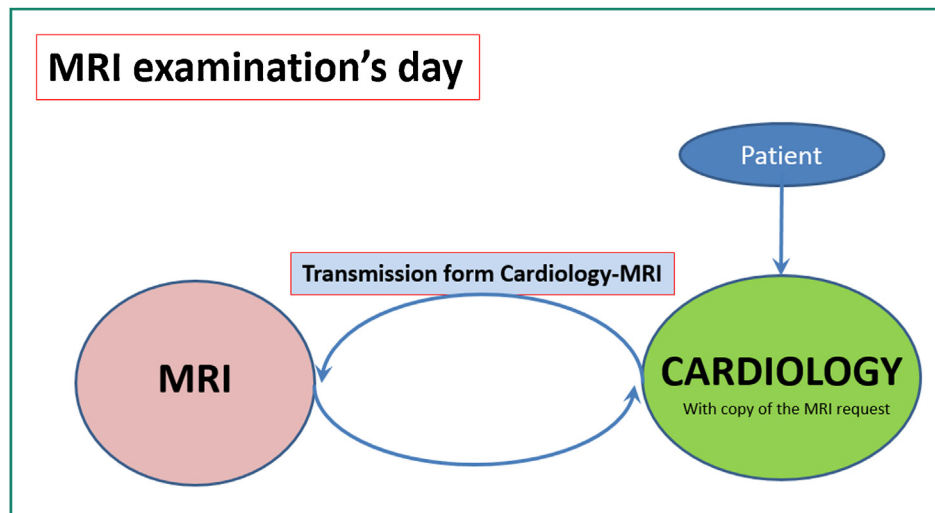


Figure 3. Pacemaker patient circuit on the day of the magnetic resonance imaging (MRI) scan.

MRI operator can proceed with imaging in accordance with our recommendations (see Clinical case).

Role of each staff member

The successful management of patients with pacemakers is conditional upon multidisciplinary collaboration. The multidisciplinary team including prescribing physician, radiologist and cardiologist, assesses the benefit–risk ratio and, if possible, considers using an alternative modality. The cardiologist evaluates the feasibility of imaging based on the patient’s cardiac status. He/she examines the patients during the pre- and post-MRI visits and fills in the MRI-Cardiology communication sheet. If necessary, the cardiologist monitors the patient during MRI. The radiologist ensures that there

are adequate medical grounds for MRI and that it cannot be replaced by another imaging modality. He/she monitors the patient during the scan, limits the acquisition scans to the strict minimum, and ensures the patient’s safety and compliance of the procedure with the pacemaker manufacturer’s recommendations.

The MRI technician reviews the cardiac rhythm specialist’s instructions on the MRI-Cardiology communication sheet and ensures that appropriate medical attention is available throughout the scan. He/she prepares the MRI-compatible monitoring equipment, resuscitation material (crash cart) and external defibrillator. During acquisition, he/she ensures that the SAR is as low as possible (normal operating mode or level 0). After the scan, he/she ensures that the patient returns safely to the cardiology department.



MRI REQUEST – PM / ICD

The physician requesting MRI has to fill the top part of this form. This form and the European card of the patient's pacemaker **MUST** be sent with the MRI request.

Patient's ID

Surname:

First name:

Date of birth:

Anatomical zone to be scanned (Some areas would be excluded with certain PM devices):

Cardiac prosthesis: ☐ Pacemaker ☐ ICD

Attach the copy of the *European card of the patient's pacemaker* or defibrillator

No MRI scanner will be performed in a patient with ICD except in case of vital urgency and absence of any alternative

Potential contribution of MRI:

Radiologist's decision: (name, date)

☐ ACCEPT ☐ REJECT

Alternative proposed by the radiologist:

Cardiologist's decision: (name, date)

☐ ACCEPT ☐ REJECT

Physical presence of cardiologist required during MRI: Yes ☐ No ☐

Figure 4. Request form for magnetic resonance imaging (MRI) for patients with pacemakers or defibrillators.

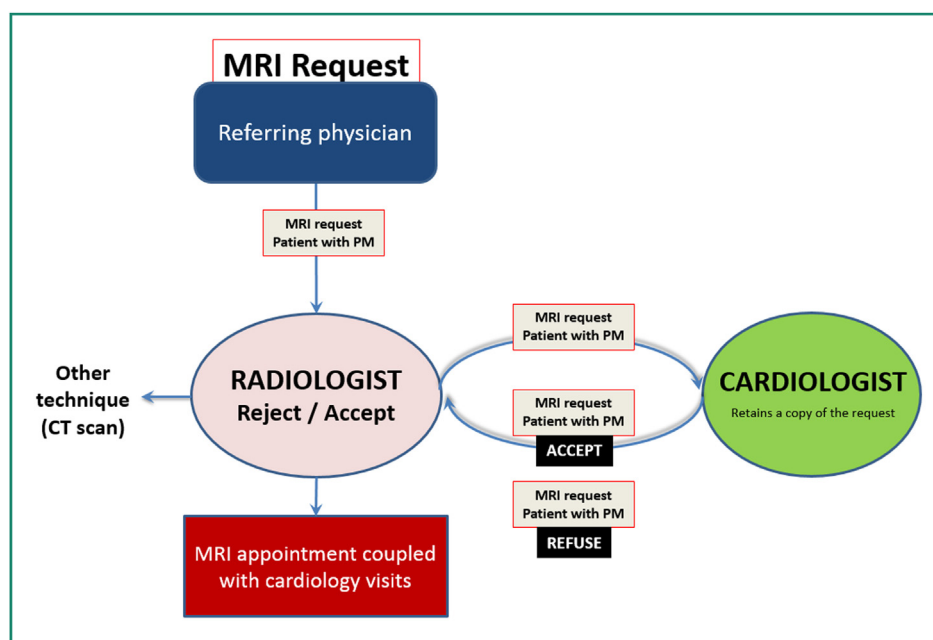


Figure 5. Discussion/approval process for requests for magnetic resonance imaging (MRI) for patients with pacemakers or defibrillators.

Conclusion

Although MRI is still nowadays contraindicated for patients with pacemakers, it may be performed under specific conditions, following multidisciplinary assessment and organization of the scan by a three-member team comprising the radiologist, a cardiac rhythm specialist and the physician requesting the scan. MRI is facilitated in patients with the new “MRI-compatible” pacemakers, provided that the whole device (pacing box and leads) be MRI-compatible. Nevertheless, MRI scans of patients with such new generation pacemakers must still be performed with the same highest level of precaution as for patients with standard pacemakers. Whatever the case, MRI should only be performed in specialized facilities where all the potentially required resources are immediately available. In no instance should MRI of patients with pacemakers be considered as trivial.

Clinical case

This 55-years old man with a non-MRI-compatible pacemaker (Fig. 6) complains of brutal onset neurological deficit following recent implementation of anticoagulation therapy. Clinical examination reveals incomplete paresis of all four limbs and a sensory level C6. After discussion between the prescribing physician, radiologist and cardiologist, MRI of the cervical spine is approved. Close cardiac monitoring is ensured during the scan and the patient’s vital signs are monitored using a MRI-compatible system.

The artifacts caused by the pacing box are clearly visible on the scout image in the axial plane (Fig. 7). T2-weighted images and T1-weighted images of the cervical spine are acquired in the sagittal plane. T1-weighted images reveal

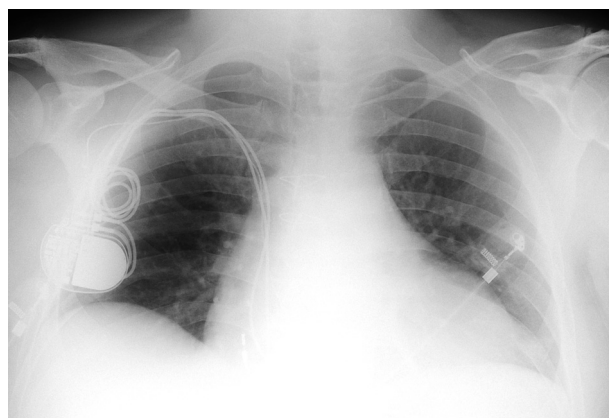


Figure 6. Antero-posterior chest X-ray prior to magnetic resonance imaging (MRI) showing the pacemaker and leads (non-compatible).

epidural injury with central iso-signal intensity and high peripheral signal intensity, and T2-weighted images show widespread high signal intensity from C5 to T2 (Figs. 8 and 9) as well as anterior displacement of the cord with high centromedullar signal intensity. Taken together, these findings suggest subacute compressive epidural hematoma complicated by spinal cord injury.

The patient did not complain about pacemaker heating during the procedure. No rhythm or conduction anomalies were observed. A neurosurgical approach, guided by MRI, was attempted and confirmed diagnosis. Unfortunately, the patient did not recover neurological function. No cardiac complications were observed, either immediately or sometime after MRI, for this patient with a non-MRI-compatible pacemaker.

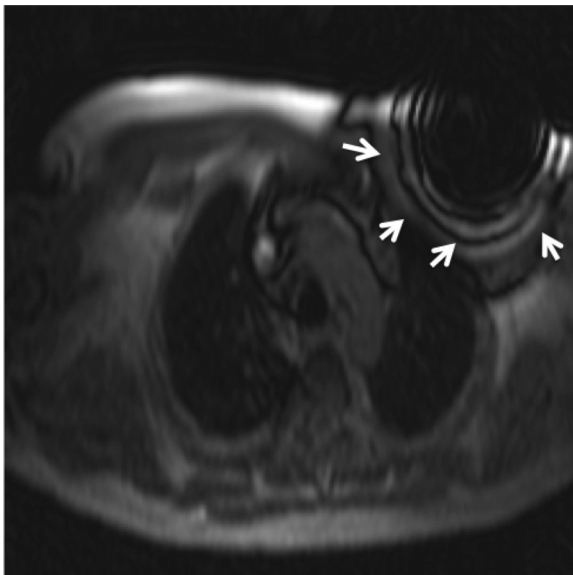


Figure 7. Metal artifacts caused by the pacing box on the scout image (arrows).

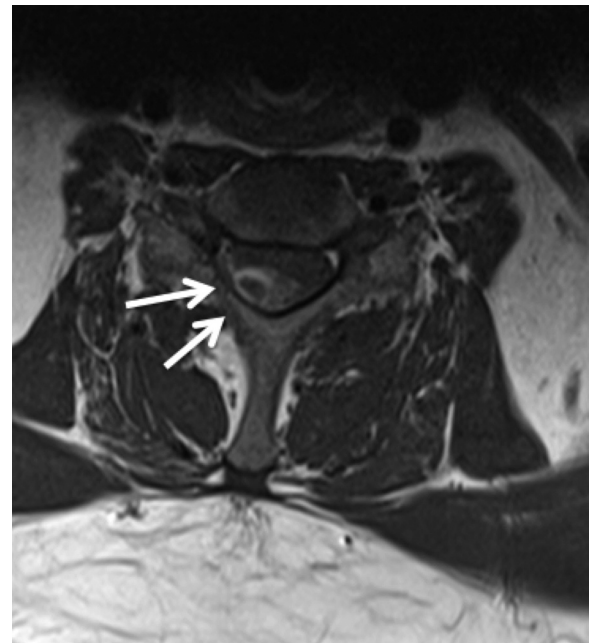


Figure 9. Magnetic resonance imaging (MRI) of spinal cord: T1-weighted image in the axial plane. Right posterior epidural hematoma (arrows) with iso-signal intensity on T1-weighted images except for the peripheral rim that shows high signal intensity.



Figure 8. Magnetic resonance imaging (MRI) of spinal cord: mid-line T2-weighted image in the sagittal plane. Posterior epidural hematoma (arrows).

Disclosure of interest

The authors declare that they have no competing interest.

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