REVIEW ARTICLE

MRI in Patients With Pacemakers

Overview and Procedural Management

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SUMMARY

Background: Magnetic resonance imaging (MRI) is generally contraindicated for patients with a pacemaker (PM) or implantable cardiac defibrillator (ICD), because of the risk of life-threatening interference with the device. Nevertheless, the question whether to perform MRI despite the presence of these devices can still arise when MRI is vitally indicated. In some hospitals, special precautionary measures are taken so that MRI can be performed in such cases.

Methods: This review is based on the authors' experience in 42 patients who underwent MRI at our university hospital, on the pertinent literature, and on the recommendations of medical societies.

Results: Because of its excellent image quality, MRI is often an indispensable diagnostic tool. Structured multidisciplinary management enables it to be performed safely even in patients with a PM or ICD. Pre- and post-MRI checks of the device are recommended, as well as extensive monitoring and the availability of the necessary personnel to deal with an emergency. In general, the pacing and defibrillator functions should be deactivated; for pacemaker-dependent patients, the asynchronous pacing mode should be activated. No serious incidents have occurred when these precautions have been observed, either among our own patients or in the literature. Newer PM systems have been approved for MRI scanning under certain conditions.

Conclusion: In patients with a PM or ICD, the benefit of MRI may far outweigh its risks if the indication has been established for the particular patient as an interdisciplinary decision and if the appropriate precautions are observed during scanning. Now that newer PM systems have been approved for MRI scanning, the problem seems close to being solved.

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The continuing technical advances in cardiac devices, particularly pacemakers (PMs) and implantable cardiac defibrillators (ICDs), and the broadening of the spectrum of potential indications for their use have led to a further increase in the number of systems implanted in Germany (70 928 PM in 2009) (e1, e2). At the same time, the number of diagnostic radiology examinations has risen sharply, with an especially high increase in magnetic resonance imaging (MRI). For example, there was a 38% increase in MRI examinations among holders of statutory health insurance between 2004 and 2009 (e3). The principal reason for this is the efficacy of MRI in the diagnostic imaging of the central nervous system, the locomotor apparatus, and cardiovascular system. The likelihood that MRI will be indicated at least once in a given person with a PM is estimated at around 50% (e4). Traditionally MRI has been contraindicated in patients with a PM or ICD because of the potentially life-threatening interactions between the magnetic fields or the high-frequency (HF) pulses and the respective device. A total of 10 deaths associated with MRI examinations were reported at the end of the 1980s. These events were poorly characterized, however, and no ECG records exist (1). In Germany, 6 deaths in the period 1992 to 2001 were investigated by public prosecutors and autopsies were conducted. All of these patients had been examined by radiologists working in their own offices, not in the hospital, with no monitoring of any kind. None was PM dependent. The cause of death in these cases can only be guessed at, but the most probable reason seems to be induction of ventricular fibrillation by inadequate asynchronous pacing on activation of magnetic function (2). In the past 10 years there have been no reports of deaths among properly monitored patients. Despite the known risks, some centers conduct MRI in strictly selected individual cases, observing appropriate precautions. Our intention in this review is first to present the technical and theoretical principles and potential risks of MRI in patients with a PM or ICD, and second to recommend a “strategy” for the performance of the examination in individual cases. Moreover, we will discuss how new MRI-compatible PM systems may solve the basic problem.

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Basic principles of MRI

Magnetic resonance imaging is based on the excitation and resonance of hydrogen nuclei in the tissues. Because of their charge and intrinsic rotation they possess their own magnetic moment. In the MR scanner, the protons are predominantly aligned in parallel (longitudinal magnetization) by a strong static external magnetic field (B_0). Bombardment by high-frequency pulses from transmitting antennas—so-called coils—leads to displacement (transverse magnetization) of the protons proportional to the intensity and duration of the pulse; at the end of each pulse they return to their previous longitudinal orientation. In doing so, they re-release the transmitted energy in proportion to the strength of B_0 , which is modulated by additional weak, varying magnetic fields (gradients) in order to enable assignment to planes (spatial encoding) along the longitudinal axis. The duration and intensity of the resonance signals depend on the properties of the tissues. Three factors are relevant for the problematic interactions with PMs/ICDs and their electrodes: the static magnetic field (mechanical effects), the transmitted HF pulse (thermal effects), and the changing magnetic gradients in spatial encoding (induction effects) (Figure).

Effects of MRI on PM/ICD devices

Mechanical effects

Most modern clinical MR scanners display magnetic field intensity of between 1 and 3 tesla (T) (for comparison, the Earth's magnetic field at the equator is only around 30 μ T). The effect on ferromagnetic materials has been dramatically shown by incidents in which objects have been hurled across the room. The proportion of magnetic metals in devices and electrodes is now limited, however, so the resulting forces are not great enough to cause displacement of either device or electrode (e5). In one of the largest studies on this topic, no paresthesias caused by mechanical effects of MRI were found in 115 PM patients (3).

Thermal effects (induction)

Another crucial factor is the warming of electrode tips induced by the incoming HF pulses. The electrode leads function as an antenna, in which energy generated by variable magnetic fields is conducted to the adjacent tissue in the form of heat. This results in warming of the endo-/myocardium that may lead to edema formation or even scarring, which in turn can result in alteration of the pacing thresholds (3). The strength of the current generated in the electrodes, and thus the resulting warming, depends on the so-called specific absorption rate (SAR), a measure of the energy arising from the MRI examination sequence used (e6), and on the type and position of the electrode (4). In an in-vivo study of dogs with implanted ICDs, electrode tip warming of 0.2°C was measured with a maximum SAR of 3.5 W/kg (e6). Histological processing of the tissue adjacent to the tip of the electrode revealed no significant increase in focal cell necrosis compared with the

Diagram showing the three components of an MRI system that potentially influence a pacemaker: Apart from the permanent static magnetic field (usually 1 to 3 T), additional rapidly changing (magnetic field) gradients may also affect PM/ICD devices. Moreover, the high-frequency (HF) pulses (radio waves) may interact with these devices.

MRI, magnetic resonance imaging; PM, pacemaker; ICD, implantable cardiac defibrillator; T, tesla

control group of animals with ICDs that did not undergo MRI. In contrast, an in-vivo study in pigs showed a maximum increase of 20.4°C in electrode tip heat with an SAR of 3.8 W/kg. Such an increase in temperature approaches those used in thermoablative procedures, so the potential for harm is considerable (5); this can be expressed, for instance, in alterations of the pacing threshold (6). However, this investigation also showed no changes in the myocardial tissue surrounding the electrodes.

Electromagnetic interference

The device may be directly affected by electromagnetic interference. One factor is the activity of the reed switch. This depends on the position of the PM relative to the static magnetic field, and is thus unpredictable, but generally leads to asynchronous pacing at a predetermined frequency (3, 7). In some devices, however, the PM's reaction to activation of the reed switch can be programmed so that the asynchronous pacing is activated for only 10 cycles or not at all. A few devices also perform an automatic pacing threshold test. In ICDs, activation of the reed switch generally leads to deactivation of treatment delivery. The gradient field can affect the sensing algorithms such that the so-called

TABLE 1

Classification of patients according to the risk involved in performing MRI, when no other diagnostic procedure is indicated (modified from [8])

Risk groups		
Group 1: extremely high risk	PM-dependent patients	Alternative means of cardiac stimulation (transcutaneous electrodes, temporary sensors) should be to hand
Group 2: high risk	ICD patients (non-PM-dependent)	External defibrillation apparatus should be available
Group 3: low risk	Non-PM-dependent patients	External defibrillation apparatus should be available

PM, pacemaker; ICD, implantable cardiac defibrillator ; MRI, magnetic resonance imaging

interference mode is activated; stimulation by the PM is again asynchronous at a predetermined frequency (2). More dangerous, however, is inhibition of the atrial and/or ventricular pacing, as has been observed under particular examination conditions (2, 8). Rapid ventricular pacing at the upper limit of frequency by induction of energy beyond the sensing threshold of the atrial sensor has also been reported (e7, e8).

There have been a few reports of a PM reset, leading to activation of the device's standard configuration (3, 6, 9). The latter is generally a VVI mode (ventricular pacing, ventricular sensing, and inhibition of a sensed ventricular event); therefore, PM-dependent patients may be at risk of asystole from inhibition of pacing owing to misinterpretation of artifacts induced by the gradient fields (8, 10). Furthermore, the standard parameters may not always suffice for effective stimulation in patients who need high initial energy. The main dangers are thus asystole from inhibition of pacing and induction of tachycardia by inadequate asynchronous pacing.

The problems with ICDs are basically the same as with PMs, but with the addition of the theoretically possible misidentification of HF pulses as ventricular tachycardia, potentially resulting in delivery of inadequate treatment. However, theoretical considerations make inappropriate shock delivery appear unlikely, as charging of the capacitor is not possible in a static magnetic field (1). This problem may nevertheless lead to a permanent defect of the device owing to battery depletion or deactivation following repeated unsuccessful charging of the capacitor (1). Resetting the device may reactivate the previously deactivated treatment delivery.

The principal published studies, complemented by our own data, yield a total of 1043 patients with a PM or ICD who have undergone MRI (3, 4, 11–20). No life-threatening complications have been observed. In 11 cases (1%) electrical resetting of the device was necessary, and a significant increase in pacing threshold (>1.0 mV) was seen in 16 cases (1.5%). The study conditions varied widely, of course, with differences in localization, field strength of the MR scanner, device, sensors, etc., so it is difficult to draw any watertight conclusions. However, this survey gives an impression of how frequently—or infrequently—complications can be expected.

Indications and procedure

Before examining a patient with a PM or ICD, it is particularly important to ponder how urgently MRI is indicated and whether there are feasible diagnostic alternatives. Other imaging procedures such as computed tomography, sonography, or nuclear medicine should be considered and, if appropriate, preferred. The position paper of the European Society of Cardiology (ESC), published in 2008 (1), proposes classification of PM and ICD into three categories for purposes of MRI: non-PM-dependent patients (low risk), ICD patients (high risk), and PM-dependent patients (extremely high

TABLE 2

Recommendations for procedural management (modified from [1])

Procedural management of MRI in patients with a PM or ICD		
MRI protocols and examination procedure	PM/ICD settings and measures	Planning and conduct of procedure
<ul style="list-style-type: none"> – Restrict scanner field strength to ≤ 1.5 T – Keep SAR of sequences used as low as possible; no SAR > 2 W/kg – Plan examination precisely in advance with as few sequences as possible – If possible, do not use surface coils 	<ul style="list-style-type: none"> – Perform MRI no less than 4–8 weeks after implantation – Inspect device thoroughly before and after MRI – Continue monitoring after MRI until completion of reprogramming and testing (threshold values of sensing and pacing) – Switch PM to "Off" during MRI (sensing only) or to "Output" below the pacing threshold – ICD treatment off – Non-PM-dependent patients on asynchronous mode – Check ICD/PM parameters (pacing threshold etc.) after 1 month and 3 months 	<ul style="list-style-type: none"> – Perform the examination at a well-equipped center with experienced staff – Obtain cardiological assessment of PM (non)dependence; if patient is PM dependent, consider re-evaluating the indications – Radiologist and cardiologist should be present during the examination, with continuous monitoring (ECG, blood pressure, pulse oximetry) – Programming of the PM/ICD in the MRI suite should be possible – A defibrillator with PM capability should be available in the MRI suite

T, tesla; MRI, magnetic resonance imaging; SAR, specific absorption rate; W, watt; PM, pacemaker; ICD, implantable cardiac defibrillator; kg, kilogram

risk) (Table 1). Urgent indications for which there are few diagnostic alternatives include intraspinal cerebral processes of degenerative, inflammatory, or neoplastic origin (e.g., spinal canal stenoses, spondylodiscitis, abscesses, metastases, and myelopathies) with existing or threatened neurological symptoms where MRI can point to the appropriate treatment. The incidence of inflammatory processes of the spinal canal, for instance, is increasing worldwide (e9). Without antibiotic treatment the prognosis for patients with spondylodiscitis is poor, and even with administration of antibiotics the hospital mortality is 2% to 17% (e10). Other malignant or inflammatory processes in various parts of the body may also render MRI indispensable.

Recommendations for MRI in patients with a PM or ICD

The procedural management of MRI comprises three basic components:

- The technical requirements for the MR scanner and the selection and planning of examination sequences
- The technical handling of the PM/ICD device before, during, and after examination
- The basic planning and execution of the examination, taking all appropriate (emergency) precautions to minimize the risk for the patient.

MRI of PM/ICD wearers places high demands on both personnel and apparatus, and should thus preferably be performed at well-equipped centers with experienced staff. Our procedural recommendations, based on the ESC position paper, are outlined in Table 2. Basically, it must be borne in mind that the metal components of the devices and sensors can cause image artifacts that may limit the diagnostic power of the examination (especially in the thorax area), although successful cardiac MRI in PM patients has been reported (21). The ESC position paper (1) recommends always restricting field strength to 1.5 T, but non-complicated examinations on 3-T systems have been described (17, 22). Patients with sensors left over from previous devices represent a particular risk group, as they may become hotter than sensors connected to a pacemaker (23).

MRI-compatible PMs

The manufacturers of PMs have recognized the increasing problems posed by the necessity of MRI in PM wearers and have developed devices that are compatible with MRI under certain conditions. Medtronic marketed an MRI-compatible system at the end of 2008. The sensors were modified to minimize warming of their tips. Moreover, the composition of the device

was changed (less ferromagnetic material, protection for the internal circuits to prevent interruption of the power supply, replacement of the reed switch by a Hall sensor with predictable properties in a static magnetic field). In addition, dedicated program functions for activation of an MRI mode were built in. This system is licensed for MRI at 1.5 T field strength with maximum SAR of 2 W/kg per sequence and maximum gradient slew rate of 200 T/m/s. In the Enrhythm MRI SureScan Pacing System Study, 464 patients with a Medtronic system underwent MRI without complications (24). Similar systems are now available from other manufacturers, e.g., Biotronik and St. Jude Medical. The new devices and sensors allow safe performance of MR scanning under the defined conditions. However, it must be remembered that the devices have to be reprogrammed and checked both before and after the examination.

Discussion

According to the current guidelines of the US Food and Drug Administration (FDA) and the manufacturers' own recommendations, normal PMs and ICDs should still be considered non-compatible with MRI (e11), and patients wearing such devices should therefore be kept away from MR scanners. However, the literature contains numerous reports, encompassing a total of 1043 patients (3, 4, 11–20), describing essentially complication-free performance of MRI examinations. A recent publication even reported on 10 patients who each underwent 3 cardiac MR scans within a year, all without complications (25).

In our opinion, however, the data do not permit the conclusion that MRI in PM or ICD patients is largely safe; it cannot be considered a "routine examination of slightly increased complexity." In the face of the variety of devices and sensors and the broad spectrum of anatomic and (patho-)physiological conditions that can be encountered, together with the range of different MR scanners and sequences, the decision whether or not to perform MRI must always be taken on an individual basis. In view of the above-mentioned—albeit incompletely explained—deaths and the experimentally proven effects of MRI on sensors and devices and the consequences thereof, the considerations and precautions we have outlined regarding indications and procedural management seem not just sensible, but vital. Close cooperation between the physician who establishes the indication for MRI, the cardiologist, and the radiologist is indispensable in each and every case. We have been carrying out MRI examinations of patients with PMs or ICDs for a number of years, following the procedure described here, and have never encountered complications. Altogether we have examined 42 patients with an implanted PM (n = 33) or ICD (n = 9) without problems. We believe that with proper indications and observance of the appropriate precautions, MRI can also be performed in device wearers. Moreover, it is safe to assume that the problem will be largely solved in the foreseeable future by the increasing availability of MRI-compatible PM systems.

KEY MESSAGES

- Patients with a PM or ICD should be subjected to MRI only when there is no alternative.
- Interactions of devices and sensors with the magnetic fields and HF pulses of the MR scanner can have life-threatening consequences (disturbances of cardiac rhythm, asystole, warming).
- Controlled studies at recognized centers and the authors' own experience document that with comprehensive precautions and appropriate modification of the MRI protocols, examinations can be carried out without serious complications.
- In individual cases, with careful establishment of the indications and optimization of the procedure, the benefit of MRI may clearly outweigh the potential risk, providing comprehensive precautions are observed.
- The first licensed MRI-compatible PM systems are available and the basic problem seems close to being solved.

Conflict of interest statement

Prof. Liebig has acted as consultant for ev3, Sequent med and Concentric. He has received lecture fees and reimbursement of attendance fees and travel costs from ev3 and Concentric.

Dr. Zobel has received reimbursement of congress fees and travel costs from Medtronic.

The remaining authors declare that no conflict of interest exists.

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