Clinical update

Magnetic resonance imaging safety in pacemaker and implantable cardioverter defibrillator patients: how far have we come?

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Magnetic resonance imaging (MRI) has long been regarded a general contraindication in patients with cardiovascular implanted electronic devices such as cardiac pacemakers or cardioverter defibrillators (ICDs) due to the risk of severe complications and even deaths caused by interactions of the magnetic resonance (MR) surrounding and the electric devices. Over the last decade, a better understanding of the underlying mechanisms responsible for such potentially life-threatening complications as well as technical advances have allowed an increasing number of pacemaker and ICD patients to safely undergo MRI. This review lists the key findings from basic research and clinical trials over the last 20 years, and discusses the impact on current day clinical practice. With ‘MR-conditional’ devices being the new standard of care, MRI in pacemaker and ICD patients has been adopted to clinical routine today. However, specific precautions and specifications of these devices should be carefully followed if possible, to avoid patient risks which might appear with new MR technology and further increasing indications and patient numbers.

Keywords
- Cardiac pacemaker
- Cardiovascular magnetic resonance imaging
- ICD
- Implantable cardioverter defibrillator
- MRI conditional devices
- MRI safety

“A person with a new idea is a crank until the idea succeeds”.

Mark Twain

Introduction

Magnetic resonance imaging (MRI) is the imaging technique of choice in a wide range of diagnostic tasks regarding neurological disorders, muscular and skeletal diseases. Most important, MRI offers better soft tissue contrast than other imaging modalities without the use of ionizing radiation. In the cardiovascular field, MRI is now considered the gold standard in the assessment of global and regional myocardial function, the detection of myocardial damage and viability after myocardial infarction, in congenital heart disease, and for detection of cardiac inflammation or infiltration in rare diseases like e.g. Fabry disease or certain haematological disorders. At the same time, the number of patients with a cardiovascular implanted electronic device (CIED) is rapidly and constantly growing, now comprising several million patients worldwide. As early as in 2005, it was already estimated that ~75% of all patients with pacemaker or implantable cardioverter defibrillator (ICD) systems will have the future need for an MRI investigation due to the high probability of comorbidities such as stroke, lumbar disease, arthritis, or cancer in this patient group. However, one decade ago, MRI in patients with implanted cardiac devices was still denied due to serious safety concerns. It was not before 2011 that the FDA approved the first magnetic resonance (MR) conditional pacemaker system. In the following, we review the development of the devices and clinical trials over the last 10 years that led to the current EMA approval which now allows examining not only pacemaker, but even ICD patients in 1.5 and 3 T MR scanners, given certain prerequisites.

Adverse events

The safety of MRI examinations in patients with implanted rhythm devices was always high on the agenda in both the imaging and...
rhythmology community. Nevertheless, several fatal events occurred worldwide in the 20th century. However, these incidents were generally only poorly documented, because the MRI staff was not aware of the devices, and, therefore, MRI examinations were not well supervised particularly by a specifically trained cardiologist.

Following in vitro and in vivo studies mainly focusing on radio frequency (RF) heating at the tip of cardiac pacemaker leads due to MRI raised safety concerns even further. In a similar well-documented clinical setting, severe and permanent injuries because of RF burns related to implanted electrodes for deep brain stimulation were recorded during MRI. Reports on increased pacing thresholds in some pacemaker patients after MRI also showed that RF heating around the lead tip may jeopardize the patient. Other raised safety issues included higher-grade battery impairment and electronic dysfunction. Experimental studies in a pig model proved the actual potential for induction of ventricular tachycardia during MR imaging of cardiac pacemakers. Therefore, earlier guidelines declared cardiac pacemakers and ICDs as a contraindication for routine MRI.

Technical considerations

When using MRI technique for imaging, different kinds of electromagnetic fields are utilized, which have the potential to interfere with the leads of cardiac pacemakers or ICDs: the static magnetic field, the pulsed gradient fields, and the RF fields. From the large variety of potential risks patients with CIED are exposed in the MRI environment originating from these different electromagnetic fields, three basic effects can be differentiated: mechanical effects, electromagnetic effects, and thermal effects.

Mechanical effects

While mechanical movement—eventually leading to device or lead dislocation—originally was one of the most feared threats, even older pacemaker leads do not contain strong ferromagnetic materials. Therefore, the static magnetic field currently used in routine clinical MRI settings—that is, up to 3 T—shows no or only negligible interference with the leads. This does not hold true for the electronic devices, which contain several ferromagnetic components. Even though these ferromagnetic device components in cardiac rhythm devices continue to decrease, some essential parts such as the battery and transformers for charging capacitors in ICDs remain exceptionally necessary. The threat of mechanical pacemakers or ICDs device movement increases with the magnetic field strength, the amount of ferromagnetic materials within the device, the distance from the bore of the MR scanner, and the stability of the device in the pocket (i.e. older implants have a fibrotic envelope). Further experimental research proved mechanical force and torque effects under current day clinical practice in 1.5 T scanners to be in the order of physiological gravity and acceleration effects.

Electromagnetic effects

In addition to mechanical device dislodgment, the static magnetic field may also have an impact on device function by affecting the reed switch behaviour. In theory, activation of the reed switch by a magnet sets a pacemaker to asynchronous mode, disables tachycardia detection, and/or therapy with subsequent fatal results in case a ventricular tachycardia is induced or occurs spontaneously and is not immediately terminated externally by the attending staff.

The pulsed gradient as well as RF fields of the scanner can induce electric currents in pacemaker leads, which can lead to over- or undersensing in CIED which might prevent necessary cardiac pacing by the device, or trigger anti-tachycardia pacing or shock by the device (Figure 1). However, actual ICD shock delivery in the scanner bore will in most cases not be possible due to the effects of the external magnetic field on the ICD capacitor. This not only might lead to battery depletion but also has to be considered in case an actual tachycardia occurs in the scanner bore. In addition, pulsed gradient fields might be strong enough to electrically stimulate the heart and eventually cause ventricular arrhythmias. In well-monitored patients, this effect seems to be rare in clinical practice. However, theoretical hazards have been experimentally replicated, proving that in the swine model these effects can indeed cause clinically relevant tachycardia. Therefore, arrhythmia induction might be the most probable explanation for the few reported fatal casualties of pacemaker patients in the MRI.

Heating effects

In contrast to the pulsed gradient fields used for local encoding in MRI, which basically show electric interference with CIED, the
repeated RF pulses used for signal induction in MRI induce strong electric fields in the body, leading to RF energy deposition into the tissue. This can result in heating of the body tissue up to several degrees Celsius even in patients without CIED. The amount of actual energy deposition in the surrounding tissue is basically given by the specific absorption rate and also depends on the size and shape of the body and the imaging protocol. The leads of CIED can show strong electromagnetic coupling effects with these RF fields induced in the body. This so-called ‘antenna effect’ is accompanied by the possibility of particularly intense local heating (Figure 2) and subsequent tissue damage due to oedema or necrosis at small device-to-tissue interfaces such as the tip of the lead. These thermal effects might eventually lead to an increase in pacing threshold, capture loss, or arrhythmia induction. Specific absorption rate, lead design, and configuration of the leads in the body are key determinants of local RF energy deposition. Fractured or abandoned leads, or epicardial leads that are not cooled by blood flow may carry an increased risk of severe heating. Also adequate selection of magnetic resonance imaging landmark can significantly reduce potential heating hazards in CIED patients.

Magnetic resonance imaging and cardiovascular implanted electronic device in the early 20th century

One decade ago, the rapid development and use of MRI and CIED in clinical practice, the technical considerations and several clinical reports on the occurrence or absence of adverse events led to a rapidly increasing interest in the topic not only in cardiologists and radiologists but also the cardiovascular device industry. In an editorial to a focused issue on this topic in 2005, it was stressed out that in order to make MR scanning as safe as possible, there would have to be an industry-wide effort from concept to market to design and construct implantable cardiac devices and leads for the MRI environment. In this regard, all components of an implantable system need to be developed, tested, and proven safe for current and evolving MRI technologies. This viewpoint was also shared by the device companies, who accepted the challenge to address this unmet medical need by designing future device systems to be safe by design not by chance.

Clinical trials on magnetic resonance imaging in patients with conventional PMs and implantable cardioverter defibrillators

In 2007, data and observations listed above were summarized in the focused guidelines on safety of MRI in patients with cardiovascular devices endorsed by several key organizations in Cardiology and Radiology, designating MRI scanning of patients with PM and ICD as contraindicated. However, over the last 20 years, an array of mostly smaller clinical studies investigated safety aspects of clinical MRI scans in pacemaker patients. The studies differed in terms of field strength (0.2–3 T), type and body region of MR scan, imaging protocol, limitations of specific absorption rate, and of course the pacemaker type (single or dual chamber) and device manufacturer.

Figure 2. Visualization of pacemaker heating due to radio frequency pulses in magnetic resonance imaging. (A) Experimental setup emulating left thoracic implantation of a conventional one-chamber pacemaker system in a gel-filled torso phantom. Arrows indicate pacemaker lead. The (black) temperature probe is attached to the tip of the pacemaker lead. (B) Heat map assessed by an infrared camera after 2 min of magnetic resonance imaging using a turbo spin echo sequence indicates the temperature increase at the lead tip.
Pacemaker patients
Most early studies focused on examinations in 0.5 T scanners. In a total of 99 patients, no major adverse events were reported. Problems reported were activation of the Reed switch and diminished battery voltage in selected patients. One recent study investigating the effects in a current day low-field MRI scanner was performed at 0.2 T. In 114 patients, no adverse events were detected.

Until then, 14 studies assessed the outcome in 1.5 T MR scanners in a total of 806 patients. There were no major difficulties or adverse events reported. Similar to the trials in the 0.5 T MR tomographs, an impact on the functioning of the devices was seen in several cases, including a decrease in battery voltage, an increase in pacing thresholds, or power-on-resets. The detected changes in lead parameters did not require surgical revision or reprogramming. The largest study also addressed long-term effects. One hundred and fifteen examinations were performed on 82 patients. An increase in pacing thresholds of >1.0 V was noted in 3% of the leads. In seven patients, an electrical reset of their pacemakers requiring new device programming was detected. A Spanish study focusing on 2.0 T MRI reported uneventful scanning of 13 patients.

Recently, the first studies were performed at 3.0 T to evaluate the safety of cardiac electronic implants at higher magnetic field strengths. In a total of 44 patients, all receiving cranial MR scans using a transmit-receive head coil, there were no clinically relevant alterations in device configuration and parameters, no arrhythmias, and no electrical resets. One trial on 14 patients with no scan restriction showed also no adverse events.

The major clinical studies on MRI in patients with cardiac pacemakers are summarized in Table 1. Of note, 15 trials (of 24) did not include pacemaker-dependent patients. This might temper the results with regard to safety of MR scans in these patients.

Implantable cardioverter defibrillator patients
The impact of 1.5 T MR scanning on device function in ICD patients was investigated in 13 studies. Overall, 365 patients were included. The best powered trial with regard to patient numbers to evaluate the safety of MRI in ICD patients was performed in 201 patients. To assess long-term adverse effects, device interrogation was between 3 and 6 months after the MRI procedure. Even though smaller events were reported, there were no clinically significant changes that necessitated device reprogramming or revision of generator or leads. Of note, three of the patients experienced power-on-resets during either cardiac or cranial MR scans. This study subsumed that MRI might be an option in ICD patients with no imaging alternative, provided MRI is carried out in centres with specific expertise and equipment.

The major clinical studies of MRI scans performed in patients with ICDs are summarized in Table 2.

Many trials on MRI in CIED patients also included patients with a need for chest scans. Even though theoretical considerations as well as experimental findings suggest additional risks in these patients, there is no clear evidence yet in these clinical trials that chest scanning is more prone to adverse events than scanning with a thoracic exclusion zone.

### Table 1: Clinical trials of magnetic resonance imaging in pacemaker patients

| Field strength | Trial | No. of patients | Adverse events |
|----------------|-------|-----------------|----------------|
| 0.2            | Strach et al. | 114             | –              |
| 0.5            | Sommer et al. | 18              | Reed switch activation, continuous pacing in the static field |
|                | Sommer et al. | 44              | –              |
|                | Valhaus et al. | 32             | Decrease in battery voltage, reed switch activation |
|                | Gimbel et al. | 5               | One power-on-reset |
| 1.5            | Martin et al. | 54              | Significant threshold changes in 9% of leads |
|                | Gimbel et al. | 10             | Seven patients had alterations in pacing thresholds |
|                | Sommer et al. | 82             | Increased capture threshold. In 4/115 patients troponin increased |
|                | Nazarian et al. | 31 (55 total) | –              |
|                | Mollerus et al. | 32 (37 total) | –              |
|                | Mollerus et al. | 46 (52 total) | Ectopy |
|                | Naehele et al. | 47             | Repetitive scans (171 examinations in 47 patients) caused decreased pacing capture, battery voltage |
|                | Mollerus et al. | 105 (127 total) | Decreased sensing amplitudes and impedances |
|                | Halshoek et al. | 9 (18 total) | Five power-on-resets |
|                | Burke et al. | 24 (38 total) | –              |
|                | Buendia et al. | 28 (33 total) | Two temporary communication failures, one sensing error, one safety signal |
|                | Nazarian et al. | 237 (438 total) | Two power-on-resets, significant changes in lead parameters |
|                | Cohen et al. | 69 (109 total) | Decreases in battery voltage in 4%, pacing threshold increases in 3%, impedance changes in 6% |
|                | Boilson et al. | 32             | 5 x power-on-reset, 3 × asynchronous pacing |

| 2.0            | Del Ojo et al. | 13             | –              |
| 3.0            | Naehele et al. | 44             | –              |
|                | Gimbel | 14             | –              |
Imaging artefacts in patients with cardiovascular implanted electronic device

Metallic and other electrically conductive medical devices might not only cause direct harm to the patient in the MRI environment but also bear the risk to disturb MR images. This can significantly hamper diagnostic value of MRI, particularly if the cardiovascular devices are implanted close to the area of interest, like in cardiac or breast imaging (Figure 3). While accordanant investigations found most modern pacemaker systems to show only little effect on cardiac MR images—at least when implanted in the right pectoral region—especially ICD systems will often cause larger imaging artefacts or even total signal void in cardiac images mainly due to the larger battery.59,60 This effect can even be experienced in MR conditional devices and should already be taken into account before the patient is admitted to the MRI rather than referred for an alternative diagnostic technique.

Magnetic resonance-conditional cardiovascular electronic devices

As a superordinate system to classify MRI safety, the following terminology has been established in medical products15:

- MRI Safe: The item is safe for use in MRI under all conditions.
- MRI Unsafe: The item is not safe for use in MRI under any conditions.
- MRI Conditional: The item is safe for use in MRI only under certain conditions.

Comprehensive research over the last decade has led to the development of MR-conditional CIED. These systems contain specific

Table 2  Clinical trials of magnetic resonance imaging in implantable cardioverter defibrillator patients

| Field strength | Trial               | No. of patients | Adverse events                                                                 |
|---------------|---------------------|-----------------|-------------------------------------------------------------------------------|
| 1.5           | Coman et al. 55      | 11              | One short asymptomatic pause in pacing during scanning, One power-on-reset     |
|               | Gimbel et al. 58     | 7               | One power-on-reset                                                            |
|               | Nazarian et al. 41   | 24 (55 total)   | –                                                                             |
|               | Mollerus et al. 42   | 5 (37 total)    | –                                                                             |
|               | Pulver et al. 57     | 8               | –                                                                             |
|               | Mollerus et al. 44   | 22 (127 total)  | Decreased sensing amplitudes and impedances                                  |
|               | Halshink et al. 46   | 9 (18 total)    | –                                                                             |
|               | Burke et al. 47      | 14 (38 total)   | –                                                                             |
|               | Buendia et al. 48    | 5 (33 total)    | One sensing error                                                             |
|               | Nazarian et al. 49   | 201 (438 total) | One power-on-reset, changes in pacing threshold                              |
|               | Cohen et al. 50      | 40 (109 total)  | Decreases in battery voltage, pacing threshold increases, and impedance changes|

Figure 3. Representative magnetic resonance imaging artefacts in patients with a left thoracic cardiovascular implanted electronic device. (A) Four-chamber view. (B) Short-axis view. Image distortion/void hampering diagnostic image quality particularly regarding the right ventricle and anterior wall of the left ventricle is apparent. RV, right ventricle; LV, left ventricle.
硬件和软件组件，都经过了测试，并且被官方批准用于MRI环境，但在某些预设条件下。这些硬件和软件的改变对于设备来说意味着降低机械力和振动，使用特定的过滤器来防止过载和低敏性，以及替换Reed开关为Hall传感器，以减少激活在磁场中的不可预测性。在磁场中，磁共振成像配对起搏器和ICDs也被特别提供给MRI软件模式，该模式可以由医生激活。这项软件模式通常包括像双极刺激和高电压输出这样的一些特性，为依赖起搏器的患者提供VOO模式。63

作为主要优势，这种设备没有显著的变化，在捕获和感知值上只有轻微的变化，从而证实了MRI在这些设备中的效果。从2008年开始，美国首个FDA批准的用于MRI的起搏器问世。2011年，随着几款新的模型线被FDA和EMA批准用于临床使用，以及在MRI环境中被批准的起搏器和ICDs数不胜数。最新的研究和临床试验表明，MRI在这些设备中没有导致严重的并发症。其他设备公司也遵循了这个例子，开发出MR条件下的起搏器。这些设备在2010年和2012年之间被广泛使用。

目前，越来越多的起搏器和ICDs被批准用于MRI，由监管机构批准，并且在磁场中有持续的有活力的开发。主要的考虑因素是设备对磁场强度的适应性（主要是1.5 T），允许的扫描区域（无胸腔排斥区域），以及特定的SAR（<2.0 W/kg）。在2011年11月，第一款术前MR条件下的ICD被批准用于1.5 T。目前，3.0 T MRI在这些设备中是可能的，并且第一款CRT-D系统被批准用于MRI。目前，制造商具体推荐列在补充材料在线，Table S1。一个概述包括了被标记为MR条件下的起搏器和ICDs，且也包括了非MR条件下的起搏器和ICDs，分为单独标记为MR条件下的，带有被废弃的导线的，以及非MR条件下的。

如果考虑了MRI在这些患者中使用，那么应该制定一个全面的患者具体方案，其中包括以下几点：
- 无MR条件下的起搏器
- 有MR条件下的起搏器和废弃导线
- 有MR条件下的起搏器和ICDs（脉冲发生器）但非条件下的
- 有MR条件下的起搏器和ICDs和废弃导线
- 无MR条件下的起搏器和ICDs

可能由治疗医生在患者被转介到MRI检查时考虑的其他因素包括：
- 患者应该具有正常体重（无儿童），
- 设备应该植入在胸部/胸壁区域。
- 所有设备应该植入在4-6周以上。
- 设备应该植入在心胸区/胸壁区域。

一般性建议

“非标签下的磁共振成像”在心血管植入电子设备患者中

作为对全面研究和几次临床试验的总结，以及通常被接受的观点，未来的市场很可能被标记为“MR条件下的”起搏器。在这些设备中，制造商推荐应该严格按照这些作为指导。

磁共振成像条件下的心血管植入电子设备

在考虑了MRI在这些患者中使用的情况下，应该进行全面的患者具体分析，其中一些因素考虑在内：
- 感应、起搏阈值，和导线阻抗应在一个正常范围内。
- 没有其他植入物应该出现在病人体内。
- 没有废弃的或起搏电极应该出现在病人体内。
- 所有设备应该在4-6周内植入。
- 设备应该植入在心胸区/胸壁区域。
- 病人应该有正常体重和形状（无儿童），有特定急性或慢性疾病的患者，如极度或糖尿病，可能会增加患者风险。
In case a careful risk-to-benefit analysis favours MRI, the following general recommendations regarding device programming and MR imaging should be considered:

- Devices should be programmed to special MRI mode if available.
- In non-MR conditional pacemakers: D00/V00 with maximized output for pacemaker-dependent patients, otherwise pacing off (e.g. O00).
- Tachycardia detection and therapy (ICDs): off.
- 1.5 T MRI should be preferred.18
- Gradient slew rate should not exceed 200 T/m/s.20
- Emergency equipment/external defibrillator as well as a device programmer should be present during the MRI.
- Continuous patient monitoring (electrocardiography/pulse oximetry) during the MRI.
- Dorsal patient position.28
- Imaging landmark near the device (thorax) should be avoided.30
- Local transmit coils should be avoided.
- SAR and scan time should be limited.15

If applicable, these general safety issues should be followed in both conventional pacemakers/ICDs and in MRI conditional devices.

Conclusions

Magnetic resonance imaging in patients with cardiovascular implanted electronic devices has historically been regarded a general contraindication. However, research over the last decade led to the recommendations in the 2013 ESC guidelines, where MRI might be possible if following certain prerequisites.64 Today, a broad selection of device systems is available which are approved for the MRI environment under certain defined conditions, typically also including a dedicated device-specific ‘MRI mode’. Both cardiologists and radiologists should generally aim to strictly follow these manufacturer recommendations, in order to avoid unnecessary risks for the patient. In cases where these recommendations cannot be met, or if a device not labelled MR conditional has been implanted, a careful case-by-case analysis should be performed by the responsible physicians, specifically including alternatively available imaging techniques, thoroughly balancing the patient-specific risks vs. the anticipated diagnostic benefits. If this analysis brings about a decision in favour of MRI, specific general precautions should be taken on the basis of the available preclinical and clinical studies, particularly including attentive patient surveillance during the procedure and carefully implicating convenient options for device reprogramming directly before and after the MRI.

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