



Research article

Safety and efficiency of low-field magnetic resonance imaging in patients with cardiac rhythm management devices



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ABSTRACT

Purpose: Low-field magnetic resonance imaging (MRI), i.e. MRI with a static magnetic field strength < 0.5 T, has been reported to be safe in patients with pacemakers, however there are no data about the safety of low-field MRI in patients with implantable cardioverter defibrillators (ICD) and/or cardiac resynchronization therapy (CRT). We aimed to investigate the safety and diagnostic efficiency of routine low-field MRI in patients with different devices for cardiac rhythm management (i.e. pacemakers and ICD, including devices with CRT).

Method: MRI scans of 446 regions of interest were evaluated with field strength of 0.2 T in 338 patients (62% male; age at MRI scan 76.1 ± 9.2 years; time since device implantation 4.1 ± 3.2 years) with cardiac rhythm management devices (298 pacemakers, 25 ICD, 8 CRT-ICD, and 7 CRT pacemakers). This analysis included 62 pacemaker-dependent patients (18.3%), 52 patients with 1.5-Tesla-MR conditional pacemakers (15.4%) and 13 patients with abandoned leads (3.9%).

Results: Except for one examination, which was interrupted because of recurrent severe nausea, all MRI scans could be analyzed efficiently. No induction of arrhythmia or inhibition of pacemaker function occurred. Compared to the device interrogation before MRI, there were no significant changes in battery voltage, pacing capture threshold, sensing of intrinsic ECG, lead impedance, as well as shock impedance in ICD devices after completed examination.

Conclusions: Low-field MRI examinations (0.2 T) were efficient and safe regarding clinical and technical complications in patients with devices for cardiac rhythm management, even in case of pacemaker-dependency or the presence of abandoned leads.

1. Introduction

Because of various potential interactions between the electric circuits of implantable cardiac devices and the different magnetic fields (i.e. static and gradient magnetic fields, as well as radio-frequency fields), safety issues play an important role in the performance of magnetic resonance imaging (MRI) in patients with pacemakers or implantable cardioverter-defibrillators (ICD, i.e. pacemakers able to deliver electric shocks for defibrillation). Both of these device types are available with or without cardiac resynchronization therapy (CRT, i.e. devices with two ventricular leads for resynchronizing cardiac pacing in case of chronic heart failure). There are reports about serious complications such as heating of lead tips by induction of high currents [1–3], lead dislocation [4,5], inappropriate pacing [1,6–8], change in pacing

capture threshold [9,10], depletion of battery voltage [9,10], system reset [10], as well as induction of ventricular fibrillation and even cases of death [11,12]. Indeed, all these potential complications apply equally to all implantable cardiac devices mentioned above.

Low-field magnetic resonance imaging, i.e. MRI with a static magnetic field strength < 0.5 T, has been reported to be safe in patients with single- and dual-chamber pacemakers [13], however there are still no data about the safety of low-field MRI in patients with ICD and/or CRT, especially when not "MR conditional".

The aim of this retrospective analysis was to investigate the safety and diagnostic efficiency of a routinely performed low-field MRI in patients with different devices for cardiac rhythm management (even when "MR conditional" for 1.5 T), independently of the scanned region of interest, the presence of abandoned leads, or pacemaker-dependency.

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2. Methods

2.1. Definitions

Implanted devices for *cardiac rhythm management* (CRM) were defined as pacemakers and ICD, including devices with CRT function. There was absolutely no restriction regarding the type of CRM devices or the manufacturer (pacemakers/ ICD: Medtronic 117/17, Biotronik 58/6, St. Jude Medical 37/4, Boston Scientific 29/6, Sorin-Ela 44/0, Vitatron 20/0). Other cardiovascular implantable electronic devices without active cardiac rhythm management function – such as implantable loop recorder or devices for cardiac contractility modulation – were not included in this analysis.

Pacemaker dependency was defined by a missing sensing of intrinsic ventricular potentials, because of persistent ventricular pacing during at least 10 s (the detection period varied depending on the device model) in a temporary VVI mode at a heart rate of 30 bpm. *Pacing capture threshold* is the minimal electrical voltage that consistently produces an efficient cardiac depolarization.

Abandoned leads were defined as implanted leads, which are physically not connected to the CRM device, and isolated at the connector pin by a special cap.

2.2. Study population

Over a period of four years, routine MRI examinations of overall 446 regions of interest were evaluated with a static magnetic field strength of 0.2 T in 338 consecutive patients (62% male; age at MRI scan 76.1 ± 9.2 years; range of age 19–98 years) with „active“ cardiac rhythm management devices implanted for 4.1 ± 3.2 years. In 41 of these patients, more than one MRI session was performed; the maximum was 6 examinations for one patient. One further patient was excluded *a priori* from the statistical analysis, as her pacemaker was programmed in an „inactive“ ODO mode and was already planned for explantation.

This analysis included 62 pacemaker-dependent patients (18.3%), 52 patients with „MR conditional“ pacemakers for 1.5-Tesla scanners (15.4%) and 13 patients with abandoned leads (3.9%). One further patient had a single-chamber pacemaker implanted with an epicardial ventricle lead. At the time of completion of this analysis, „MR conditional“ ICD devices were not available in the clinical routine.

Patients were eligible for MRI if CRM-lead implantation had been performed at least two months prior to examination (corresponding to the estimated time for intra-myocardial healing of the lead tip) and if CRM functional parameters were acceptable: battery voltage ≥ 2.6 V (respectively „battery OK“ or „battery BOL/MOL“, i.e. „begin/middle of life“); pacing capture threshold and sensing of intrinsic ECG signal comparable to data at implantation; pacing lead impedance 200Ω – 2000Ω ; „shock impedance“ 20Ω – 100Ω for ICD devices. In the observation period, four examinations were cancelled because of one case of too low battery voltage (the „elective replacement indicator“ was reached), two cases of relatively high pacing capture threshold (2.5 V at 0.4 ms, and 2.6 V at 1.0 ms), as well as one case of suspected lead fracture (pacing lead impedance $> 2000\Omega$, and the capture threshold was not measurable) in the pre-MRI device interrogation. Written informed consent for examination was given by every patient prior to the examination, after being informed about the potential pacemaker-related risks of MRI as mentioned above.

2.3. Magnetic resonance imaging and patient monitoring

Including examinations with intravenous administration of gadolinium, low-field MRI scans were routinely performed in different regions of interest using an „open“ Magnetom Concerto 0.2 T scanner (Siemens Medical, Erlangen, Germany) with the following specifications: operating Larmor frequency 8.25 MHz; maximal gradient amplitude 20 m T/

Table 1

Regions of interest and MRI sequences.

Region of interest	n	MRI sequences
Lumbar spine	206 (46.2%)	T1-TSE, T2-TSE, T2-HASTE, TIRM
Cerebrum	69 (15.5%)	T2-TSE, CISS, FLAIR, FLASH 3D +/- CA, Angiography
Knee	56 (12.6%)	T2-TSE, TIRM, PD
Cervical spine	42 (9.4%)	T1-TSE, T2-TSE, T2-HASTE, TIRM
Foot	16 (3.6%)	T1-TSE, T2-TSE, TIRM
Thoracic spine	15 (3.4%)	T1-TSE, T2-TSE, T2-HASTE, TIRM
Shoulder	13 (2.9%)	T1-TSE, T2-TSE, TIRM
Hip	11 (2.5%)	T1-TSE, T2-TSE, TIRM
Abdomen	5 (1.1%)	T1-TSE +/- CA, T2-TSE, FLASH 2D
Pelvis	3 (0.7%)	T1-TSE, T2-TSE, TIRM
Muscle	3 (0.7%)	T1-TSE, T2-TSE, TIRM
Hand	2 (0.4%)	T1-TSE, T2-TSE, TIRM
Mandibular joint	1 (0.2%)	T1-TSE
Breast	1 (0.2%)	T2-TSE, dynamic FLASH 3D
Parotis	1 (0.2%)	T1-TSE, T2-TSE, TIRM
Elbow	1 (0.2%)	T1-TSE, T2-TSE, TIRM
MRCP	1 (0.2%)	T1-TSE, T2-TSE, T2-HASTE, TIRM

CA, contrast agent (gadolinium).

CISS, Constructive Interference in Steady State.

FLAIR, Fluid Attenuated Inversion Recovery.

FLASH, Fast Low Angle Shot.

HASTE, Half-fourier Aquired Single-shot Turbo spin Echo.

MRCP, Magnet Resonance Cholangio-Pancreaticography.

PD, Proton Density weighted.

TIRM, Turbo-Inversion Recovery Magnitude.

TSE, Turbo Spin Echo.

m; maximal slew rate 40 m T/m/ms; maximal radiofrequency power 1800 W. During the examinations, there was no limitation regarding the exposure to static magnetic field, the total active scan time and the specific absorption rate (routinely 20–40 W/kg). Mean MRI scanning time was 34 ± 12 min (range: 22–49 min). The examined regions of interest and the corresponding MRI sequences are summarized in [Table 1](#).

In the presence of a cardiac electrophysiologist, heart rate and oxygen saturation were routinely recorded with MR-compatible pulse oximetry. Resuscitation equipment including an external defibrillator was available during all examinations. Patients were asked to report immediately the occurrence of any symptoms, such as heat sensation, dizziness, or any kind of pain.

2.4. Interrogation of cardiac rhythm management devices

The safety of low-field MRI scans was assessed by interrogation of all CRM devices *immediately* before and after the MRI examination by the same electrophysiologist. In „MR conditional“ pacemakers, an asynchronous mode (V00 or D00, i.e. a strict continuous pacing without sensing function) was programmed according to the manufacturers' recommendations for MR examinations (these device types were: *EnRhythm MRI* or *Advisa MRI*, manufacturer Medtronic; *Evia ProMRI* or *Estella ProMRI*, manufacturer Biotronik; *Ingenio MRI*, manufacturer Boston Scientific; *Accent MRI*, manufacturer St. Jude Medical). An asynchronous mode was also programmed in case of pacemaker dependency [14,15]. The following device function parameters were controlled: battery voltage (V), pacing capture threshold (V) at a fixed pulse duration (ms), sensing of the intrinsic ECG signal (mV), pacing lead impedance (Ω), as well as „shock impedance“ (Ω) in patients with ICD. CRM device modes – according to the NASPE/BPEG generic code for anti-bradycardia pacing [16] – as programmed at implantation and at the day of MRI examination are displayed in [Table 2](#).

In patients with ICD devices, all therapies for ventricular tachyarrhythmia (i.e. anti-tachycardia pacing and shock delivery for termination of ventricular tachycardia or ventricular fibrillation) were programmed off for the time of MRI scan [14,15]. This action was taken to

Table 2
Permanently programmed modes of CRM devices [16] at implantation and at the day of MRI examination.

Mode	at implantation		at MRI examination	
	Pacemaker	ICD	Pacemaker	ICD
AAI	3 (1%)	–	7 (2.3%)	–
VVI	55 (18%)	10 (30.3%)	62 (20.3%)	11 (33.3%)
DDI	–	–	3 (1%)	–
VDD	5 (1.6%)	–	5 (1.6%)	–
DDD	154 (50.5%)	7 (21.2%)	141 (46.2%)	6 (18.2%)
AAI ⇔ DDD	81 (26.6%)	8 (24.25%)	80 (26.3%)	8 (24.25%)
CRT	7 (2.3%)	8 (24.25%)	7 (2.3%)	8 (24.25%)

AAI = Pacing and sensing in the atrium.

VVI = Pacing and sensing in the ventricle.

DDD = Pacing and sensing in atrium and ventricle.

DDI = Pacing and sensing in atrium and ventricle (mode during atrial fibrillation).

VDD = Pacing in the ventricle, sensing in atrium and ventricle.

CRT, Cardiac resynchronization therapy.

prevent inappropriate shock delivery because of ventricular over-sensing due to electromagnetic interference, with or without precedent acceleration after inappropriate anti-tachycardia pacing [17].

A significant change in pacing capture threshold was defined by an increase of > 0.5 V after MRI scan. For the other function parameters, changes of ± 20% compared to the values before MRI were tolerated.

2.5. Statistics

Data were expressed as percentages for discrete variables and as mean ± standard deviation for continuous variables, i.e. parameters of CRM device function. Normal distribution was assessed by the Shapiro-Wilk test. Comparisons were made using the Student *t* test for continuous variables. Statistical significance was considered if *P* < 0.05.

3. Results

Except for one single examination – which was interrupted after a few minutes because of recurrent severe nausea – all 446 MRI scans (Table 1) were of good quality and could be interpreted efficiently by the responsible radiologist. No device-related artifacts were noticed, even in case of scanning the *ipsilateral* shoulder. No potential examination-related symptom such as heating sensation, pain, or dizziness occurred. After accomplished scans, no induction of arrhythmia or inhibition of any pacemaker function was recorded in the device memory.

Compared to device interrogations before MRI, there were no statistically significant changes after completed examination concerning pacing capture threshold, sensing of intrinsic ECG, lead impedance, as well as shock impedance for ICD devices (Table 3). Similarly, no change was found regarding battery voltage before and after MRI: a constant voltage of 2.86 ± 0.13 V was recorded in 195 patients, respectively „battery OK“ or „battery BOL/MOL“ in 143 patients. Altogether, no alteration of technical parameters was registered after completed MRI.

Because of pacemaker-dependency, no sensing of intrinsic ventricular potentials was measured in 62 patients (18.3%). Because of atrial fibrillation or atrial flutter, no atrial pacing threshold and atrial intrinsic sensing was measured in 31 patients (11.9% of 260 patients with an atrial lead). Because of a low sinus rate < 30 bpm during at least 10 s, atrial intrinsic sensing could not be measured in 25 patients (9.6% of 260 patients with an atrial lead). In 11 patients neither atrial nor ventricular intrinsic sensing was measurable. Left ventricular pacing threshold was measured in 3 patients only, as this parameter is not detected in most CRT devices (Table 3). Overall 14 leads (9 atrial and 5 ventricular leads) were abandoned in 13 patients because of lead fracture or insulation defect.

Table 3
Parameters of CRM device function before and after MRI.

	Patients	Before MRI	After MRI	<i>P</i>
Atrial lead				
Pacing capture threshold (V)	220	0.8 ± 0.3	0.7 ± 0.3	0.597
Pulse duration (ms)	220	0.4 ± 0.1	0.4 ± 0.1	1.000
Pacing lead impedance (Ω)	249	484.0 ± 114.0	477.6 ± 111.0	0.482
Intrinsic sensing (mV)	226	3.0 ± 1.8	3.1 ± 1.8	0.782
Right ventricular lead				
Pacing capture threshold (V)	331	0.8 ± 0.3	0.8 ± 0.3	0.902
Pulse duration (ms)	331	0.4 ± 0.1	0.4 ± 0.1	1.000
Pacing lead impedance (Ω)	331	587.7 ± 150.7	582.7 ± 147.6	0.507
Intrinsic sensing (mV)	269	11.0 ± 5.1	10.9 ± 5.0	0.791
ICD: Shock impedance (Ω)	33	47.3 ± 8.4	46.8 ± 7.7	0.690
Left ventricular lead, CRT*				
Pacing capture threshold (V)	15	1.2 ± 0.6	1.2 ± 0.6	0.870
Pulse duration (ms)	15	0.6 ± 0.3	0.6 ± 0.3	1.000
Pacing lead impedance (Ω)	15	795.0 ± 200.3	806.7 ± 206.0	0.611

* Intrinsic sensing was measurable in 2 CRT devices only.

Reasons for low-field MRI in 52 patients with „MR conditional“ pacemakers for a static magnetic field strength of 1.5-Tesla (i.e. 31 patients with *EnRhythm MRI* or *Advisa MRI*, 18 patients with *Evia ProMRI* or *Estella ProMRI*, 2 patients with *Ingenio MRI* or *Vitalio MRI*, and 1 patient with *Accent MRI*) were claustrophobia in 29 patients (55.8%), fear of potential device-related complications in a 1.5 T MRI scanner in 12 patients (23.1%) and implantation of “incompatible” leads (i.e. these leads were not approved for implantation with a specific “MR conditional” pacemaker) in 11 patients (21.1%).

4. Discussion

4.1. Programming of CRM devices during MRI examination

Temporary re-programming of some CRM device-parameters is an important safety measure to avoid potential complications caused by electromagnetic interferences (EMI) during MR scanning. Temporary programming of an asynchronous mode (*V00* or *D00*) is a primary recommendation in pacemaker dependent patients [15], because of the risk of inhibited ventricular pacing due to EMI-associated ventricular over-sensing when “on-demand” modes (i.e. *DDD*, *VVI*, *DDI* or *VDD*) are programmed.

According to the manufacturers’ recommendations for safe magnetic resonance imaging, an asynchronous mode was indeed programmed in all patients with “MR conditional” pacemakers. In these special cases, the only unfulfilled safety criterion in our collective was indeed the “static magnetic field strength of 1.5 T”.

In ICD patients, electromagnetic interferences may lead to inaccurate detection of ventricular tachyarrhythmia [14]. In order to avoid inappropriate shock delivery or inappropriate anti-tachycardia pacing, which may also lead to shocks after acceleration of ventricular tachyarrhythmia [17], all anti-tachycardia therapies were programmed off during the MRI scan [14,15]. Of course, re-activation of these therapies after completed examination is mandatory.

4.2. High-field MRI in patients with CRM devices

High-field MRI is defined by a static magnetic field strength of at least 1.5 T and represents today’s routine technique with relatively faster image acquisition times. Currently, “MR conditional” CRM device-systems (i.e. pacemaker and ICD devices with *compatible* leads) are approved mainly for 1.5 T MRI scanners.

So far, three studies with CRM devices showed no significant change in function parameters after examinations in a 1.5 T MRI [18–20].

However, these were comparably small series with 10 and 55 patients, respectively. In other studies on pacemaker patients in 1.5 T MRI, significant changes of function parameters (especially, significant increases of the mean pacing capture threshold) were reported in up to 9.4% of the controlled leads [9,10]. A recent small series on ICD patients showed a significant decrease of battery voltage after 1.5 T imaging [20].

The MAGNASAFE registry on non-thoracic 1.5 T MRI in patients with "non-MRI-conditional" CRM devices revealed no significant device or lead failure in overall 1500 MRI scans (1000 pacemakers and 500 ICD), when devices were appropriately programmed prior to the scan. Only one ICD generator could not be interrogated after MRI and required immediate replacement, but this device had not been programmed appropriately per study protocol before performing MRI [21]. In another recent study on 438 pacemaker- and ICD-patients, reset of the CRM device into a back-up programming mode was noticed in 3 cases, besides changes in sensing and impedances after 1.5 T MRI scanning [22].

4.3. Low-field MRI in patients with CRM devices

Low-field MRI is defined by a static magnetic field strength < 0.5 T. Despite the disadvantage of prolonged image acquisition times and the limitation to "simple" routine MRI scans only (i.e. joints and cranium), this technique reveals some benefits for the clinician. Besides the comparatively lower overall costs for purchasing and technical maintenance, the "open" design of low-field MRI scanners enables not only an easier access to the patient for interventional studies [23], but also examinations in special conditions, such as claustrophobic [24], obese and pediatric patients.

To date, there is only one publication proving the safety of low-field MRI examinations in 114 patients with single- and dual-chamber pacemakers, including also patients with pacemaker dependency and abandoned leads (used 0.2 T scanner: Magnetom Concerto; maximal gradient amplitude 20 m T/m; maximal slew rate 10 m T/m/ms) [13]. Comparably to our findings, this study revealed neither induction of arrhythmia during the scan, nor significant changes in device function parameters after completed scan. Remarkably, low-field MRI is the only one without any documented cases of death in patients with pacemaker or ICD. On the other hand, at least a total of 12 fatal cases (including three patients with documented ventricular fibrillation) have been reported during MR scans with static magnetic field strengths of 0.5, 1.0 and 1.5 T [11,12]. Remarkably, there was lack of a continuous monitoring of vital parameters in these patients, which actually is unconceivable nowadays.

Even in case of "MR conditional" pacemakers for 1.5 T, low-field MRI was a safe and efficient alternative for patients with incompatible leads or claustrophobia, as well as for patients still fearing the potential complications of 1.5 T MRI scans.

Another upcoming application of a comparably low magnetic field is the remote magnetic navigation of cardiac ablation catheters (Niobe II system, Stereotaxis Inc., St.Louis, USA) with maximal static field strength of 0.1 T. Alterations of CRM devices *without* connected leads – such as system reset and battery voltage depletion – were reported in one *in vitro* analysis only [25]. In contrast, two *in vivo* studies revealed no significant changes of function parameters in different CRM devices (including regularly connected leads) [26,27], except from two cases of pacing capture threshold alteration at the site of radiofrequency ablation [26].

Although gradient magnetic fields and especially radiofrequency pulses are responsible for induction of high currents and lead heating [2], it is worth mentioning that "clinical magnets" – widely used for temporary inhibition of ICD therapies during surgery with electrocautery – have a similar static field strength of 0.06 T [28].

4.4. The issue of "non-MR conditional" CRM devices

Both, radiologists and cardiologists, have to accept that there are still several thousands of patients with "non-MRI-conditional" CRM systems worldwide. (Indeed, extraction of "non-MRI-conditional" endocardial leads is a complex procedure that is performed just in specific clinical circumstances.) For these patients, we absolutely have to provide a safe alternative when standard high-field MRI cannot be performed without concerns. Taking into consideration our clinical results, low-field MRI is an efficient diagnostic modality for routine scans, and provides a high safety regarding clinical and technical complications in this collective.

4.5. Limitations

All our findings are limited to a 0.2 T MRI scanner and are based on a singular device interrogation immediately after the scan. We have to stress that other low-field MR scanner with higher gradient amplitudes and slew rates may present a different safety profile. Due to a lack of sufficient information, we could not present reliable data on the implanted leads. Finally, safety of abandoned leads was only assessed by the lack of complications after the MRI scan, as there is no specific test available.

5. Conclusion

Low-field MRI examinations of various regions of interest with a static magnetic field strength of 0.2 T were diagnostically efficient and safe regarding clinical and technical complications in patients with different devices for cardiac rhythm management, including pacemakers, ICD and CRT devices, even in case of pacemaker-dependency or the presence of abandoned leads.

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Conflict of interest

None declared.

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