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CLINICAL RESEARCH
Pacing and cardiac resynchronization therapy

Cardiovascular magnetic resonance imaging in patients with cardiac implantable electronic devices: best practice and real-world experience

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Aims Cardiovascular magnetic resonance (CMR) imaging has long been a contraindication for patients with a cardiac implantable electronic device (CIED). Recent studies support the feasibility and safety for non-thoracic magnetic resonance imaging, but data for CMR are sparse. The aim of the current study was to determine the safety in patients with magnetic resonance (MR)-conditional or non-MR-conditional CIED and to develop a best practice approach.

Methods and results All patients with a CIED undergoing CMR imaging (1.5 T) between April 2014 and April 2017 were included in the study. Devices were programmed according to the standardized protocol directly before and after the CMR examination. Follow-up interrogation was performed 6 months after CMR examination. Results were compared with a large, reference cohort of CIED patients not undergoing any MR examination. A total of 200 consecutive patients with a CIED (non-MR-conditional, $n = 103$) were included in the study. Directly after CMR imaging, one device failure (0.5%, battery status = end of service) was noted necessitating premature generator replacement. In three patients (2%) of pacemaker/implantable cardioverter-defibrillator (ICD) carriers a sustained ventricular tachycardia (VT) occurred during CMR imaging. Ten ICD showed a decrease in battery capacity immediately after CMR. Overall, the reference cohort showed comparable changes of CIED function during follow-up.

Conclusion With adherence to a standardized protocol and established exclusion criteria CMR imaging could safely be performed in patients with a CIED. The potential risks of device malfunction necessitate the presence of a device trained individual during the entire CMR examination. If there is a history of VT storm the attendance of an experienced cardiologist, should be mandatory.

Keywords Cardiac implantable electronic devices • Cardiac magnetic resonance imaging • Pacemaker • Implantable cardioverter-defibrillator • Magnetic resonance conditional devices • Safety

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What's new?

- The safety in patients with cardiac implantable electronic devices (CIEDs) in 200 patients undergoing cardiovascular magnetic resonance (CMR) imaging was determined.
- Three CMR examinations had to be aborted due to the occurrence of sustained ventricular tachycardia.
- Concerning one device failure directly after CMR imaging a careful risk-benefit consideration must be estimated.
- Comparison to a large reference cohort of CIED patients not undergoing any magnetic resonance (MR) examination showed comparable changes of CIED function during follow-up.
- Cardiovascular magnetic resonance imaging can safely be performed in patients with an implanted implantable cardioverter-defibrillator, pacemaker or implantable loop recorder with adherence to a standardized protocol and established exclusion criteria even in non-MR-conditional CIED.

Introduction

Cardiovascular magnetic resonance (CMR) imaging has established its role in the assessment of a wide spectrum of cardiac diseases particularly with regard to its unique capability for myocardial tissue characterization. In addition, CMR imaging has become fundamental to identify potential arrhythmogenic substrate in preparation for ventricular tachycardia (VT) ablation.[1] The number of patients with a cardiac implantable electronic device (CIED) is steadily increasing with a total over 1.8 million in the USA.[2]

Several serious events may occur during a CMR examination in a patient with a CIED. Besides the so called antenna effect[3] induced electrical currents mimicking intrinsic cardiac activity can result in oversensing or undersensing in implantable cardioverter-defibrillators (ICDs).

Until about a decade ago, CMR imaging has been a contraindication for patients with an implanted device. When the US Food and Drug Administration approved the first magnetic resonance (MR) conditional pacemaker system in 2011[4] the attitude towards CMR imaging in CIED patients started to change. But only the minority of hospitals offer magnetic resonance imaging (MRI) scans for patients with cardiac devices[5] and even in cases of MRI conditional device carriers many MRI scans are often declined.[6]

The biggest registry to date has compiled safety data for non-thoracic MRI[7] but data for CMR imaging is still limited. There are theoretical considerations as well as experimental findings suggesting an increased risk in patients undergoing MRI of the chest[8] and clinical studies reporting on MR exams specifically of the heart are sparse.[9,10]

Consequently, the aim of the current study was to determine the acute and mid-term safety of CMR imaging in a large cohort of patients that had been implanted with a wide range of MR conditional or non-MR-conditional CIED. Additionally, a protocol was proposed to improve the safety profile of CMR examinations in CIED carriers.

Methods

Patient study

All patients with a MR conditional or non-MR conditional pacemaker (PM), implantable loop recorder (ILR), ICD, or cardiac resynchronization therapy defibrillator (CRT-D) undergoing a clinically indicated CMR examination at 1.5 T between April 2014 and April 2017 were prospectively included in the study. All data were collected in accordance with the Declaration of Helsinki, in accordance with the local institutional review board and the standards of the University of Leipzig ethics committee. All patients provided written informed consent.

Patients were not considered for study inclusion in case of device implantation within the last 6 weeks, the presence of epicardial, abandoned or fractured leads or any general contraindications for CMR imaging. Otherwise, all patients were included regardless of the type of implanted CIED and/or leads and the patient's intrinsic heart rate and rhythm.

Standardized cardiovascular magnetic resonance procedure for cardiac implantable electronic device patients

Cardiovascular magnetic resonance examinations in CIED patients followed a rigorously applied standard procedure which is detailed in *Figure 1*. Patients were continuously monitored throughout the entire procedure. An experienced electrophysiologist with detailed knowledge in cardiac device programming was present in the console room of the scanner suite during the entire CMR examination. Physiologic monitoring consisted of vector-surface electrocardiogram, peripheral pulse oximetry, respiratory motion pattern, and non-invasive blood pressure measurements. Visual and voice contact with the patient was maintained throughout the entire examination. All attending staff was experienced and regularly trained in advanced cardiac life support; in addition, emergency evacuation of the patient from the scanner suite into the console room was regularly trained (targeted evacuation time <1 min).

Pre-cardiovascular magnetic resonance interrogation

Device interrogation was performed directly before and after the CMR examination. A full set of device parameters were evaluated including lead sensing, lead impedance, battery voltage, or state and capture threshold. For patients with a MR-conditional system, the device was programmed to MR safe mode according to the manufacturer's recommendation.

In non-MR-conditional systems, pacing was turned off (OVO), if the patient was not PM dependent or devices were programmed to an asynchronous mode (VOO) with a base rate of 70/min if the patient was PM dependent. Tachycardia detection and therapy were always deactivated before the CMR examination as shown in *Figure 1*.

Post-cardiovascular magnetic resonance evaluation

Interrogations for pacing threshold, lead sensing and impedances, battery voltage, and rate histograms were performed immediately after CMR examination. Since misregistration of implantable loop-recorders may occur during CMR imaging (possibly leading to misinterpretation on subsequent interrogations), the ILR memory was reset directly thereafter. Pacing mode was re-programmed to the initial settings and for ICD devices, the anti-tachycardia therapies were reactivated. In the case of elevated pacing thresholds, the output on the corresponding lead was adapted. Mid-term follow-up interrogation was performed 6 months after CMR examination.

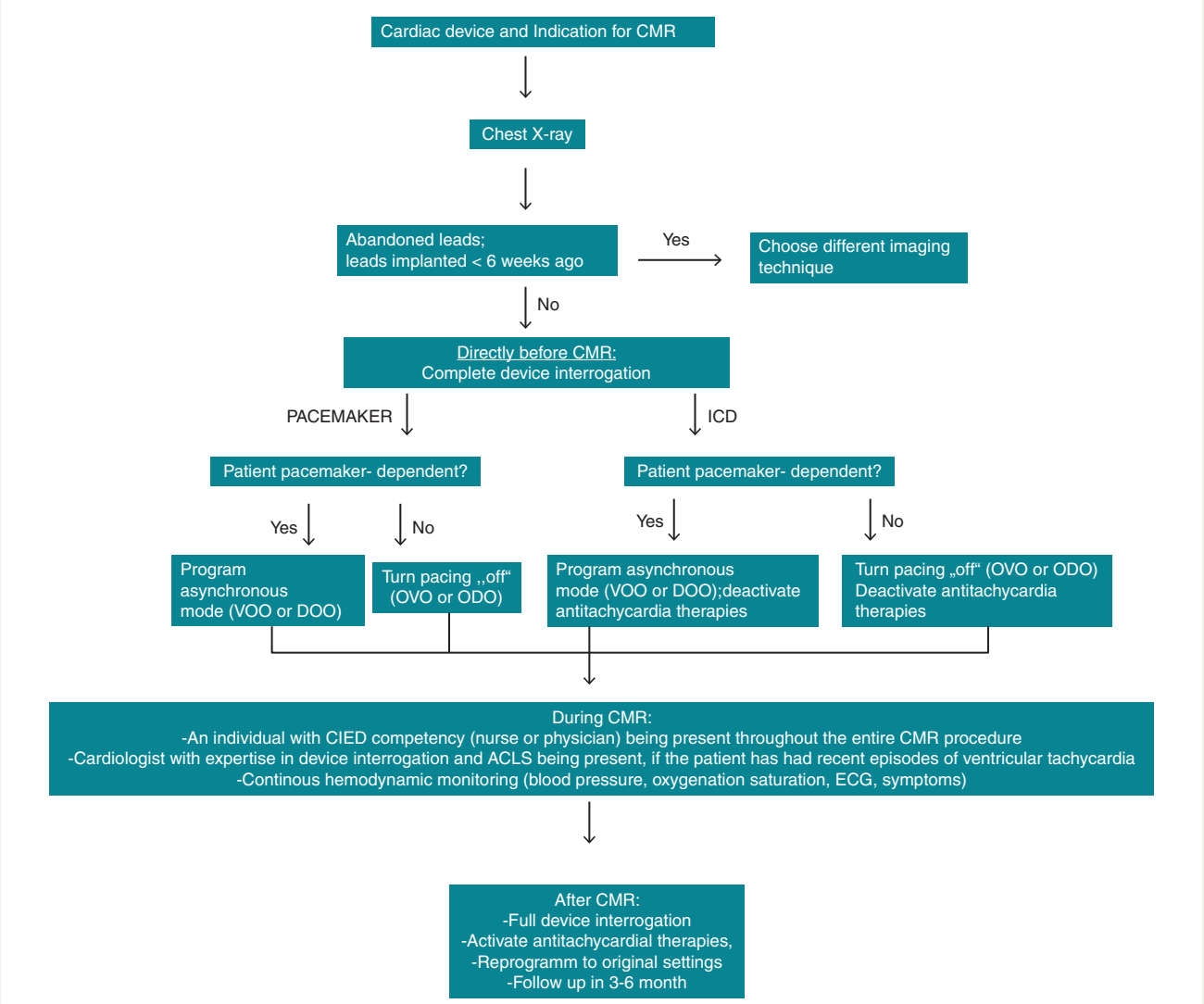

Figure 1 The 'Leipzig' protocol. Protocol for patients with a cardiac implantable electronic device undergoing a 1.5 T CMR. ACLS, advanced cardiac life support; CMR, cardiac magnetic resonance imaging; ECG, electrocardiogram; ICD, implantable cardioverter-defibrillator.

Cardiovascular magnetic resonance imaging protocol in device patients

Details of the CMR imaging protocol and strategy have been described previously.[11] In brief, all CMR examinations were conducted by an experienced, board-certified CMR cardiologist (I.P., C.J. both with >20 years of experience). All studies were performed using a 1.5 T MR scanner (Philips Ingenia, Best, The Netherlands). Cardiovascular magnetic resonance protocols were tailored to the clinical indication and rigorously followed a previously published standard CMR imaging strategy which allowed for combination of routine diagnostic CMR imaging modules (i.e. functional cine imaging, tissue characterization using T1-weighted, T2-weigthed and late-gadolinium enhancement imaging, first-pass dynamic perfusion imaging at rest and during adenosine-mediated coronary vasodilation and/or three-dimensional CMR angiography of thoracic vessels)[11] (*Figure 2* and Supplementary material online, *Video S1*). In general, examination duration (i.e. duration of exposition of the patient to the magnetic field/switching gradients) was kept to a minimum. Following current recommendations, whole-body specific absorption rate was restricted to 2 W per kilogram bodyweight for all imaging sequences; following the previously published standardized CMR imaging strategy, patient specific energy dose (SED, a measure of the total radiofrequency energy delivered) was ≤0.2 kilojoule (kJ) per kilogram bodyweight for all CMR examinations[11] Cardiovascular magnetic resonance imaging data were continuously evaluated during the imaging procedure by the cardiological CMR imaging expert being present throughout the entire examination.

Endpoints

Primary device-related endpoints were an acute malfunction of the active device directly after the CMR examination including battery depletion, acute lead failure or loss of capture. Primary clinical endpoints were death, cardiac arrest >5 s and the occurrence of sustained ventricular arrhythmias during CMR.

Following the protocol of the MagnaSafe registry which describes the device safety in non-cardiac MRI,[7] the secondary device-related

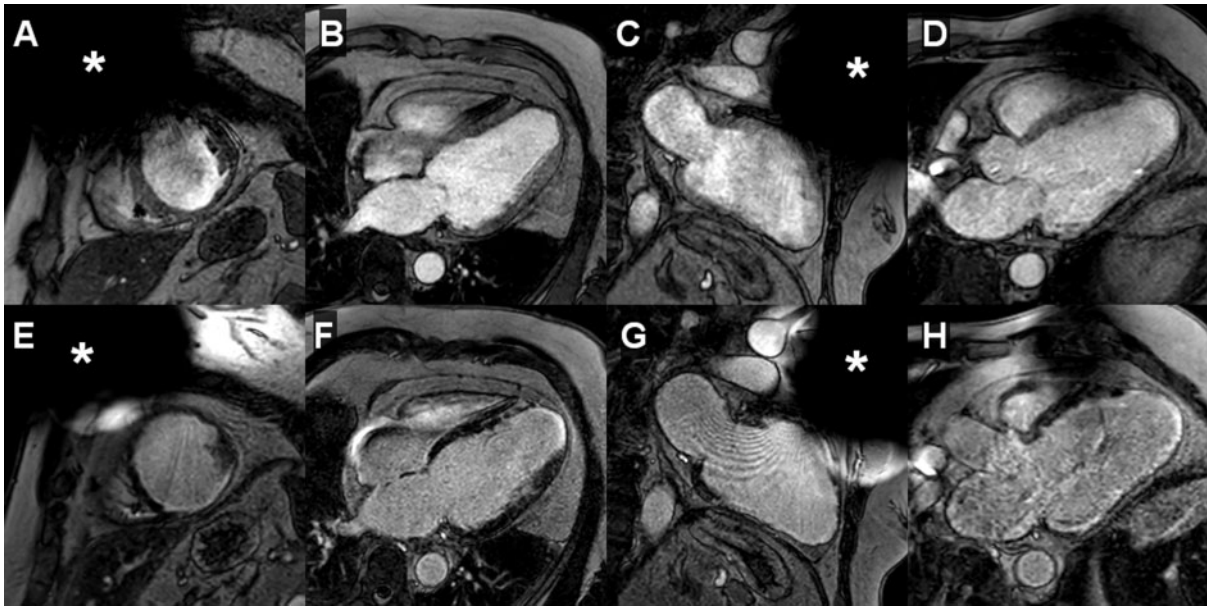

Figure 2 CMR examination in a device patient. CMR imaging data of a patient with left-sided single-chamber ICD who underwent basic functional cine and viability imaging for planning of coronary revascularization (intrinsic heart rhythm: sinus rhythm; antitachycardia therapy and pacing mode were switched off during the CMR examination). Spoiled gradient echo cine sequences were acquired in all cardiac standard geometries (i.e. short-axis and four-, two-, and three-chamber geometries) after application of a gadolinium-containing contrast agent (*A–D*); late-gadolinium enhancement (LGE) imaging was performed in identical scan geometries (*E–H*). Approximate device position (i.e. position of the ICD generator) is indicated by the asterisk. While image quality in anterior segments was moderately reduced, scan data still allowed for evaluation of the majority of left ventricular segments: transmural myocardial infarction of apical anterior and inferior segments as well as of the left ventricular apex together with extensive scar formation in all inferolateral left ventricular segments was identifiable. Hence, coronary revascularization in these coronary supply territories was deemed unsuitable. CMR, cardiac magnetic resonance imaging; ICD, implantable cardioverter-defibrillator.

endpoints were defined as a battery voltage decrease of at least 0.04 V, a pacing lead threshold increase of at least 0.5 V, an atrial sensitivity decrease of 50%, or a ventricular sensitivity decrease of 25%. A change of the pacing lead impedance was accepted if less than 50 Ohms and 3 Ohms in the shock coil. Secondary clinical endpoint was defined as patient complaints of heating sensations, palpitations, or dizziness.

Reference population

A reference cohort of CIED patients was established by analysing a database of 2487 devices (993 PMs, 1494 ICDs) that were interrogated at our centre between January 2013 and December 2014. Patients were included if the system had been implanted at least 8 weeks before the interrogation with available 6 months follow-up data and if patients did not undergo any MR examination within the respective time period. All patients with a recent generator exchange, lead revision, or placement of additional leads were excluded from analysis.

Statistical analysis

For continuous variables with a normal distribution, data are expressed as mean ± standard deviation. In case of non-normal distribution, median and interquartile ranges (25 and 75%) are given. Numbers and ratios were used to describe categorical variables. The χ^2 test was used for comparisons between groups in the case of categorical variables. Student's *t*-test was applied for continuous variables. A two-tailed *P*-value <0.05 was considered to be significant.

Results

Patient study

A total of 200 consecutive patients with a CIED undergoing CMR imaging were included into the study. Device interrogation was performed before and after the CMR examination in all patients. Mid-term follow-up was conducted in 164 patients. Data was not available in the remaining 36 patients. Of these, ten patients could not be contacted and 26 patients had undergone a generator exchange or a system upgrade (Supplementary material online, *Figure S1*).

A total of 46 PM (23%), 105 ICD (52.5%, including one subcutaneous ICD) and 49 ILR (24.5%) were included into the study. Twenty-two (11%) patients had a biventricular pacing system. A total of 97 atrial leads, 151 right ventricular (RV) leads and 22 left ventricular (LV) leads were evaluated.

Median patient age was 64 years, and 49 patients (30%) were female. The median body mass index was 27.9 kg/m^2 (interquartile range 25–31 kg/m^2). Baseline characteristics are shown in Supplementary material online, *Table S1*.

Forty-eight patients (24%) had a MR-conditional device (19 PM, 29 ICD), including one patient with a subcutaneous ICD. All 49 ILR were classified MR-conditional. The remaining 103 patients had a non-MR-conditional device (27 PM, 76 ICD). Nineteen patients (9.5%) were PM dependent or had an intrinsic heart rate below 40 b.p.m. In these

Table 1 Primary device associated endpoints immediately after cardiovascular magnet resonance imaging

Primary endpoint	Pacemaker	ICD	Implantable loop recorder
Events/cases (%)			
Death during the CMR examination	0/46 (0)	0/105 (0)	0/49 (0)
Generator failure requiring immediate replacement	0/46 (0)	1/105 (0.95)	0/49 (0)
Lead failure requiring immediate replacement	0/86 (0)	0/140 (0)	NA
Loss of capture during the CMR examination	0/11[a] (0)	0/8[a] (0)	NA
Asystole >5 s	0/46	0/105	0/49
Observed ventricular tachycardia	0/46 (0)	3/105 (2.8)	0/49 (0)
Electrical reset	0/46 (0)	0/105 (0)	0/49 (0)

CMR, cardiovascular magnetic resonance imaging; ICD, implantable cardioverter-defibrillator; NA, not applicable.
[a]Pacemaker dependent patients.

Table 2 Number of patients exceeding the predefined device limits immediately after cardiac magnetic resonance imaging and after follow-up

	Pacemaker		ICD		ILR	
	Immediate	Follow-up	Immediate	Follow-up	Immediate	Follow-up
Events/cases (%)						
Battery voltage decrease ≥0.04 V	0/46 (0)	1/38 (2.6)	10/105 (9.5)	11/95 (11.6)	0/49 (0)	0/36 (0)
Pacing lead threshold increase ≥0.5 V	0/86 (0)	0/76 (0)	5/184 (2.7)	4/174 (2.3)	NA	NA
P-wave amplitude decrease ≥50%	1/40 (2.5)	3/38 (7.9)[a]	0/57 (0)	1/55 (1.8)	NA	NA
R-wave amplitude decrease ≥50%	0/46 (0)	0/38 (0)	1/105 (0.95)	1/97 (1)	0/49 (0)	0/36 (0)
Pacing lead impedance change ≥50 Ohms	9/86 (10.4)	12/76 (15.7)	46/184 (24)	48/174 (27.6)	NA	NA
High-voltage lead impedance change ≥3 Ohms	NA	NA	38/105 (35)	48/97 (49)	NA	NA

ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; NA, not applicable.
[a]P-wave amplitude decrease due to onset of atrial fibrillation.

patients, the device was programmed to ventricular pacing (VOO 70 b.p.m.) before the CMR scan.

Clinical indications for CMR examinations are summarized in Supplementary material online, *Table S2*.

Clinical events during cardiovascular magnetic resonance examination

All 200 patients underwent CMR scanning. Of these, 191 patients completed their respective CMR imaging protocol. Three (2%) of PM/ICD carriers, VT was detected during CMR imaging; thus, the patients were immediately evacuated and treated successfully in the console room of the CMR unit. All three patients were initially referred to the hospital with an electrical storm and underwent CMR imaging in preparation for VT ablation; consequently, the VTs were not considered device or scan related (primary clinical endpoint *Table 1*).

A total of 12 patients (6%) had impaired image quality. Six CMR examinations (3.0%) were prematurely terminated due to severe device related imaging artefacts, precluding diagnostic image quality. In four patients, the image quality was reduced and an entire diagnostic CMR could only partly be acquired. Two patients had mildly affected imaging with still sufficient diagnostic value (*Figure 2*). In 94% of the patients CMR imaging was not affected by the cardiac device.

No asystolies >5 s during CMR were noted. All patients were included in the final analysis.

In summary, primary device related endpoints occurred in one patient, primary clinical endpoints occurred in three patients (*Table 1*); no secondary clinical endpoints were reported.

During follow-up two patients died because of end stage heart failure. Importantly, in both patients the last device interrogation was performed less than 1 week before death and did not show any sign of device or lead failure.

Device function immediately after cardiovascular magnetic resonance and during follow-up

Changes in pacing threshold, lead sensing, impedances, and battery voltage immediately after CMR and during follow-up are shown in *Tables 2 and 3*, Supplementary material online, *Tables S3* and *S4*. No episodes of loss of capture during CMR were noted.

Implantable loop recorder

There were no battery problems in the ILR group immediately after CMR 0.0005 ± 0.003, $P = 0.32$) and at the 6 month follow-up (−0.0008 ± 0.005, $P = 0.19$). Two of the ILR had reduced sensing post CMR (0.125 ± 0.61 mV, $P = 0.67$) and at follow-up (0.1 ± 0.28, $P = 0.09$). Two additional ILR reached the predefined sensing threshold during the follow-up period. None of the devices had recorded any events misclassified as arrhythmias (asystole, bradycardia, tachycardia) during CMR imaging.

Post-cardiovascular magnetic resonance device function

Pacemaker

Atrial (0.084 ± 0.99 mV, $P = 0.39$) and ventricular amplitudes (−0.054 ± 1.84 mV, $P = 0.23$) did not change significantly immediately after CMR examination. Thresholds changes of the right atrial (RA) and RV leads were 0.004 ± 0.08 V ($P = 0.5$) and 0.01 ± 0.14 V ($P = 0.64$). Change in RA and RV impedances were 4.1 ± 33 Ohms ($P = 0.45$) and −3 ± 34.2 Ohms ($P = 0.37$). A relevant change of lead impedance became evident in nine (10%) PM leads. Battery levels had decreased by −0.0005 ± 0.003 V ($P = 0.32$).

Implantable cardioverter-defibrillator

Atrial and ventricular amplitudes did not change significantly directly after CMR (0.126 ± 1.63 mV; $P = 0.4$ and −0.059 ± 2.31 mV; $P = 0.8$). Atrial sensing did not change above the threshold in any patient. A sensing decrease above cut-off > 50% was seen in one patient's RV lead (*Table 2*). Threshold changes of the RA, RV, and LV leads were 0.01 ± 0.15 V, ($P = 0.61$), 0.02 ± 0.2 V ($P = 0.4$), and 0.07 ± 0.22 V ($P = 0.13$). Four RV and one LV lead showed an increase in pacing threshold above 0.5 V. No atrial ICD lead showed a clinically relevant change. Changes in RA, RV, LV, and shock lead impedances were −10.2 ± 39.79 Ohms ($P = 0.06$), −11.16 ± 53.23 Ohms ($P = 0.03$), −18.63 ± 64.92 Ohms ($P = 0.56$), and −0.32 ± 7.07 Ohms ($P = 0.65$). A relevant change of lead impedance became evident in 46 (25%) ICD leads. A change of 3 Ohm or more in shock coil leads occurred in 38 patients (35%) (*Table 2*).

Battery levels had decreased by 0.01 ± 0.07 V ($P = 0.17$) (*Table 3*, Supplementary material online, *Table S4*). In 10 ICD (9.5%), a significant decrease in battery capacity (0.04 V or more) was observed immediately after CMR. One of these devices (0.95%) reported complete battery depletion (end of service, EOS) after the CMR scan. The device was pacing in backup mode. Lead sensing and threshold could not be interrogated after CMR but showed unchanged values after generator replacement.

Mid-term follow-up device function

Pacemaker

Atrial and ventricular amplitudes did not change significantly over the 6 months interval 0.15 ± 0.995 mV ($P = 0.16$) and 0.29 ± 1.39 mV ($P = 0.46$). P-wave amplitude was reduced above threshold in three patients due to new onset of atrial fibrillation. Thresholds changes of the RA and RV leads were 0.02 ± 0.12 V ($P = 0.36$) and 0.06 ± 0.24 V ($P = 0.13$). Change in RA and RV impedances were 8.5 ± 37.8 Ohm ($P = 0.17$) and −11.0 ± 45.5 Ohm ($P = 0.47$). At 6 months follow-up, battery levels had changed by 0.002 ± 0.03 V ($P = 0.27$).

Implantable cardioverter-defibrillator

Atrial and ventricular amplitudes did not change significantly over the 6 months interval 0.175 ± 1.86 ($P = 0.23$) and 0.0143 ± 2.66 ($P = 0.9$). An increase in pacing threshold was seen in one RA lead, one LV lead, and two RV leads. Threshold changes of the RA, RV, and LV leads were 0.05 ± 0.19 ($P = 0.07$), 0.03 ± 0.20 ($P = 0.28$), and 0.10 ± 0.28 ($P = 0.12$). Change in RA, RV, LV, and shock lead impedances were −0.5 ± 101.19 ($P = 0.11$), −7.21 ± 51.20 ($P = 0.11$), −9.04 ± 57.56 ($P = 0.50$), and −0.45 ± 59.61 ($P = 0.55$). Shock coil impedance change above cut-off increased to 49%. At 6 months follow-up, battery levels had decreased by 0.02 ± 0.13 ($P = 0.25$) (*Table 3*, Supplementary material online, *Table S4*). Additionally, five ICDs reached the predefined cut-off for change in battery capacity over the course of the follow-up period. Interestingly, in four ICD patients with an initial decrease of battery capacity returned to pre-CMR values during the follow-up period while in two cases capacity decreased even further.

Magnetic resonance-conditional vs. non-magnetic resonance-conditional

Between MR-conditional and non-MR-conditional CIED no significant differences have been documented in battery voltage ($P = 0.14$ vs. $P = 0.364$), ventricular pacing thresholds ($P = 0.51$ vs. $P = 0.35$), ventricular lead impedance ($P = 0.19$ vs. $P = 0.14$), atrial ($P = 0.85$ vs. $P = 0.70$), and ventricular wave amplitude ($P = 0.18$ vs. $P = 0.48$) after CMR, respectively.

Reference population

Data on 993 PM systems [152 single chamber, 773 dual chamber, 68 cardiac resynchronization therapy (CRT)], and 1494 ICD systems (689 single chamber, 231 dual chamber, 574 CRT-D) was available. A total of 1901 PM leads and 2873 ICD leads were analysed. Since there were no CRT PMs in the CMR cohort, reference values for CRT systems are not reported here.

Device function

Pacemaker

Atrial and ventricular amplitudes did not change significantly over the 6 months interval −0.11 ± 0.59 ($P = 0.12$) and 0.23 ± 1.81 ($P = 0.84$). Thresholds changes of the RA and RV leads were 0.06 ± 0.19 V ($P = 0.36$) and 0.0437 ± 0.2 V ($P = 0.48$). Change in RA and RV impedances were −3.2 ± 35.4 Ohms ($P = 0.31$) and −12.4 ± 67.4 Ohms ($P = 0.14$).

At 6 months follow-up, battery levels had decreased by −0.0007 ± 0.05 V (range −0.27 to 0.19 V, $P = 0.37$) (Supplementary material online, *Table S3*).

Implantable cardioverter-defibrillator

Atrial and ventricular amplitudes did not change significantly over the 6 months interval [0.17 ± 1.18 ($P = 0.3$) and 0.42 ± 0.365 ($P = 0.24$)]. Threshold changes of the RA and RV leads were 0.09 ± 0.21 V ($P = 0.43$) and 0.02 ± 0.31 V ($P = 0.36$). Change in RA, RV, and shock lead impedances were 6.75 ± 237 Ohms ($P = 0.41$), 1.63 ± 213.5 Ohms ($P = 0.76$), and 0.18 ± 11.37 Ohms ($P = 0.54$). At 6 months follow-up, battery levels had decreased by −0.04 ± 0.01 V

Table 3 Changes in ICD, pacemaker, and ILR parameter directly post-CMR and at 6 month follow-up

	Pacemaker		ICD		ILR	
	Immediate	Follow-up	Immediate	Follow-up	Immediate	Follow-up
Pacing lead impedance						
Atrial leads	4.1 ± 33 ($P = 0.45$)	8.5 ± 37.8 ($P = 0.17$)	−10.20 ± 39.79 ($P = 0.06$)	−0.5 ± 101.19 ($P = 0.11$)	NA	NA
LV leads	NA	NA	−18.63 ± 64.92 ($P = 0.56$)	−9.04 ± 57.56 ($P = 0.50$)	NA	NA
RV leads	−3.0 ± 34.2 ($P = 0.37$)	−11.0 ± 45.5 ($P = 0.47$)	−11.16 ± 53.23 ($P = 0.03$)	−7.21 ± 51.20 ($P = 0.11$)	NA	NA
High-voltage lead impedance	NA	NA	−0.32 ± 7.07 (($P = 0.65$)	0.45 ± 59.61 ($P = 0.55$)	NA	NA
Pacing lead threshold						
Atrial leads	0.004 ± 0.08 ($P = 0.5$)	0.02 ± 0.12 ($P = 0.36$)	0.01 ± 0.15 ($P = 0.61$)	0.05 ± 0.19 ($P = 0.07$)	NA	NA
LV leads	NA	NA	0.07 ± 0.22 ($P = 0.13$)	0.10 ± 0.28 ($P = 0.12$)	NA	NA
RV leads	0.01 ± 0.14 ($P = 0.64$)	0.06 ± 0.24 ($P = 0.13$)	0.02 ± 0.20 ($P = 0.40$)	0.03 ± 0.20 ($P = 0.28$)	NA	NA
Battery voltage	−0.0005 ± 0.003 ($P = 0.32$)	0.002 ± 0.03 ($P = 0.27$)	−0.01 ± 0.07 ($P = 0.17$)	−0.02 ± 0.13 ($P = 0.25$)	0.0005 ± 0.003 ($P = 0.32$)	−0.0008 ± 0.005 ($P = 0.19$)
P-wave amplitude	0.084 ± 0.16 ($P = 0.39$)	−0.15 ± 0.995[a] ($P = 0.16$)	0.126 ± 1.63 ($P = 0.4$)	−0.175 ± 1.86 ($P = 0.23$)	NA	NA
R-wave amplitude	−0.054 ± 1.84 ($P = 0.23$)	0.29 ± 1.39 ($P = 0.46$)	−0.059 ± 2.31 ($P = 0.8$)	0.0143 ± 2.66 ($P = 0.9$)	0.125 ± 0.61 ($P = 0.67$)	0.1 ± 0.28 ($P = 0.09$)

ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; NA, not applicable.
[a]P-wave amplitude decrease due to onset of atrial fibrillation.

(range −0.27 to 0.19 V) ($P = 0.97$) (Supplementary material online, *Table S4*).

Discussion

The aim of the current study was to determine the acute and mid-term safety of CMR imaging in a large consecutive patient population with a wide range of implanted device types including MR-conditional and non-MR-conditional devices. In addition, in order to compensate for inherent inter-interrogation variability of device parameters, a reference cohort of CIED patients not exposed to any MR/CMR examination was introduced; this allowed to objectively judge the extent/effect of possible parameter changes observed during routine device interrogation in comparison to the parameter changes possibly related to a CMR examination. Finally, with adherence to our proposed flowchart (*Figure 1*) a very high proportion of comprehensive CMR examinations could be carried out safely.

The present study data dealt with cardiovascular (i.e. thoracic) MRI in CIED patients and, thus, significantly extended the knowledge database derived from the MagnaSafe registry[7] which reported on non-thoracic MR examinations only. Most previous data on safety of MRI in CIED patients has been derived from mixed study populations combining data on the effects of thoracic and non-thoracic MR examinations with generally only a small proportion of cardiovascular MRI in CIED patients.[2,12] Notably, the current safety data was derived from the largest single-centre study population of CIED patients (including a high proportion of ICD patients) undergoing cardiovascular MRI at 1.5 T covering a broad spectrum of clinical indications yet.

Our study was in line with previous guidelines and consensus statements regarding safety of MRI in CIED patients.[13–15] As recommended, our standardized institutional protocol included assessment of risk and benefit for the performance of CMR, precise exclusion criteria, device interrogation and device programming with a standardized pacing mode dependent on patient rhythm characteristics, monitoring and the presence of appropriate trained staff throughout the procedure.

With strict adherence to the proposed procedural flowchart, CMR was found to be safe in CIED patients. However, despite all recent evidence this assumption cannot be extrapolated to all patients. The standardized protocol needs to include careful examinations of the CIEDs to detect devices that are at increased risk of failure. This applies to MR-conditional and non-MR-conditional CIED. As previously described in particularly patients undergoing non-thoracic MRI[2,7,12,16,17] changes in pacing threshold, lead sensing, impedances did not lead to device revision in our patient population. But compared to previous data[7] in non-thoracic MRI in non-MR-conditional devices, significant device changes post-CMR in our patient population were distinctly different in PM and ICD lead impedances (PM 10% vs. 3.3%, ICD leads 25% vs. 4.2%) in pacing threshold (2.5% vs. 0.8%) and in a persistent decrease of battery voltage (6.3% vs. 4.2%), while a sensing decrease on ventricular ICD leads was seen in a similar quantity (0.5% vs. 0.2%). Explanation for this finding may be the location of MRI assuming CMR imaging leads to an augmentation of lead changes. Similarly as in the MagnaSafe registry[7] one generator replacement was necessary, but in contrast to Russo *et al.* the one in our study had been programmed appropriately before MRI. The one

device in our cohort reporting EOS after CMR was a non-MR-conditional ICD and retrospective analysis showed fluctuating battery levels over a period of 12 months before the CMR. Interestingly, there were five patients in our registry which carry the exact same ICD and did not expose a similar behaviour. There is at least one report of device alteration due to magnet exposure[18] and we are aware of another MR-conditional ICD which could not be interrogated after MRI of the chest. Between MR-conditional and non-MR-conditional CIED no significant differences have been documented after CMR in our cohort confirming previously published data in patients undergoing in a small portion also thoracic MRI with MR- and non-MR-conditional CIED.[9]

In previous studies, the potential impact of the CMR examination on inducing VT has been discussed and even if the possibility seems to be rare, arrhythmia inductions seems to be the most probable explanation for fatal outcomes in PM patients undergoing MR examinations in the previous studies.[19,20]

In three (2%) of PM/ICD carriers undergoing CMR, a VT occurred. In all three patients, the indication for CMR was myocardial substrate characterization before ablation of VT. Turning off the antitachycardia therapies in patients who have received the ICD for secondary prevention of sudden cardiac death is always a risk. In patients without a history of recurrent VT's/VT storm it is feasible that a device trained individual not specifically a medical doctor is present during the CMR scan.

This study included PM dependent patients, which were excluded in other studies.[8] Furthermore, we included PM dependent ICD patients which were excluded even in recent studies.[7,16] There were no adverse events in this group.

The radiofrequency energy generated during CMR scanning can create a temporary decrease in battery voltage, which has typically been reported to resolve after several weeks.[7] This is consistent with our findings. It is not easy to differentiate between CMR induced and usage-dependent reduction of battery capacity. None of the patients with a significantly reduced battery voltage had clinical events (e.g. ICD shock) which could explain a decreasing battery voltage. This did not relate to the CIED being MR-conditional. However, this evaluation is limited by the low number and wide variation of affected generators as well as lack of data on battery kinetics over time. For this reason, we analysed a large reference cohort of PM and ICD patients and demonstrated a similar trend for the battery voltage in patients who did not obtain a CMR scan.

Despite a recent meta-analysis (Shah *et al.* 2018) where all lead impedances changed significantly directly after CMR our results only showed a significant change for ICD RV leads. Especially lead impendence is influenced by constant changes and wide range of lead parameters is considered as normal. Therefore, the significant changes are most probably an expression of these wider impedance ranges.[21]

As all ILRs in our registry were labelled MR conditional it is no surprise that no CMR related battery issues occurred. For the four cases in which a decrease in R wave sensing occurred, it cannot be ruled out that these changes needed to be attributed to the CMR examination. However, sensing heavily relies on ILR position relative to the heart axis and can vary considerably.[22]

In summary, our data indicates that CMR imaging can be applied safely to a wide range of clinical indications requiring a broad spectrum of sequences.

Study limitations

Our prospective registry included consecutively enrolled patients with a wide range of CIEDs and a profound clinical indication for CMR imaging. It included device dependent patients but excluded patients with abandoned or epicardial leads. Patients, devices and device-lead combinations were not matched in the CMR cohort and the reference cohort. Therefore, changes seen in the CMR cohort might not fully be covered by the large reference cohort. However, given the number of lead, generator combinations it is beyond the scope of the manuscript to evaluate the impact of this. Results from this study cannot be easily extrapolated to all market-available CIEDs as each device has its own unique set of programmable parameters and hardware components.

Conclusion

The current study demonstrated that with adherence to a standardized protocol and established exclusion criteria CMR imaging can safely be performed in patients with an implanted ICD, PM, or ILR. Nevertheless, the clinical indication for CMR imaging must follow the rule of a careful risk-benefit consideration. In addition, some reduction in CMR image quality due to device-related artefacts should be taken into account either. Finally, the potential risks of device malfunction render the presence of a device trained individual during the entire CMR examination. If there is a history of VT storm the attendance of an experienced cardiologist, should be mandatory.

Perspectives

Clinical competencies

The findings of the study demonstrated that CMR imaging can safely be performed in patients with an implanted ICD, PM, or ILR with adherence to a standardized protocol and established exclusion criteria even in non-MR-conditional CIED. With regard to the potential risk of device malfunction a device trained individual should be present during the entire CMR examination. If there is a history of VT storm the attendance of an experienced cardiologist, should be mandatory.

Translational outlook

The feasibility of CMR imaging in CIED implicates the routine application with respect to a careful risk-benefit consideration and with regard to an experienced setting in clinical practice. Our data supports further studies of CMR imaging in CIED for the improvement of CMR image quality due to device-related artefacts.

Supplementary material

Supplementary material is available at *Europace* online.

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