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Magnetic resonance imaging in patients with cardiac implantable electronic devices in the cardiooncology center

Short title: MRI in patients with CIEDs

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INTRODUCTION

Magnetic resonance imaging (MRI) has been for years contraindicated in patients with

cardiac implantable electronic devices (CIEDs) due to the possibility of the occurrence of adverse events, such as acute depletion of battery voltage, changes in the lead parameters leading to unsuccessful pacing or antiarrhythmic therapies, or acute device reset. However, patients with CIEDs often require diagnostics with MRI due to various causes. Despite the recommendations of scientific societies, such as the consensus document of Heart Rhythm Society (HRS) and the recent European Society of Cardiology guidelines for cardiac *pacing* and cardiac resynchronization therapy, which recommend physicians to perform MRI in patients with CIEDs under specific conditions, this imaging modality is still rarely performed in patients with CIEDs, and often time from an initial assessment to MRI is prolonged, which can be particularly critical in patients with cancer who require fast and accurate diagnostics [1, 2].

Therefore, across the globe, MRI scans in patients with CIEDs were initiated under strict surveillance of cardiac electrophysiologists, according to the local prespecified protocols, being in line with manufacturers' recommendations. In 2018, in a partnership between the 3rd Department of Cardiology of the Silesian Center for Heart Diseases and Maria Skłodowska-Curie National Research Institute of Oncology, Gliwice Branch, the MRI exams in patients with various types of CIEDs were initiated [3]. The aim of this manuscript is to briefly summarize the characteristics of these patients, as well as the immediate outcomes of the procedures.

METHODS

All patients referred for MRI due to any reasons had undergone a screening visit, during which the eligibility of the patients' CIED system for MRI was assessed. In each patient, the type of device and leads were assessed, and the devices were interrogated. Both MRI-conditional, and non-MRI-conditional devices were considered eligible for MRI. However, in the presence of either an epicardial, abandoned, or fractured lead, or if the device was approaching elective replacement indicator, or if the device had been implanted in the recent 6 weeks, as well as if there were any prior signs of the device malfunctions, the patient was disqualified from the procedure, pending reassessment after resolving of those conditions.

On the day of the MRI scan, each patient had the device interrogated and programmed by the experienced cardiologist according to the HRS expert consensus on MRI in patients with CIEDs [1]. The programming of the device was at the discretion of the cardiologist, including the possible activation of the MRI-compatible modes. During each procedure the patient had pulse oximeter oxygen saturation, noninvasive blood pressure assessment, and electrogram —

continuously measured, and the cardiologist, the MRI technician, and the nurse were present throughout the entire MRI analysis. An external defibrillator was available on-site during every study. After completion of the MRI scan, the devices were interrogated and reprogrammed to the settings from the period before the MRI scan. The device software or hardware parameters, including variables indicating generator and lead functioning were documented before and after MRI. Each patient was advised to undergo routine follow-up after 1–3 months in the patient's local referring center, although if any of the following changes in device parameters occurred (pacing lead threshold increase by ≥1.0 V; P-wave or R-wave amplitude reductions by ≥50%; pacing lead impedance changes by ≥50 Ohm or shock lead impedance alterations by ≥5 Ohm), the physicians were obliged to instruct the patient to report for follow-up after 1 week in the patient's local center. All scans were performed with the use of 1.5T MRI Magnetom Aera scanner (Siemens AG, Munich, Germany).

Categorical variables were presented as absolute numbers and percentages, numerical as median with minimal and maximal value for each numerical variable. The approval of the ethics committee and patient informed consent were not required for the purpose of this study.

RESULTS AND DISCUSSION

During the years 2018–2022, there were 122 patients with CIED, who were qualified and underwent a total of 149 MRI studies in the presence of the cardiologist, as listed in Table 1. The majority of patients underwent either MRI of the brain (29.5%) or the abdominal/pelvic region (30.9% in aggregate). The most common type of CIED was a double-chamber pacemaker (52.3%) and the majority of the devices were Medtronic/Vitatron devices (54.4%). Of note, there was 1 patient with an implanted loop recorder, and one patient with subcutaneous ICD who underwent the MRI scan. None of the procedures were associated with any programming alterations. Moreover, no immediate changes in either battery voltage, pacing threshold, or sensing were observed. In three patients, a change in high-voltage lead impedance by respectively 5 Ohms, 6 Ohms and 8 Ohms was observed, without any other alterations in device parameters observed.

The number of patients with malignancy and concomitant heart failure, or any other cardiac disease requiring the implantation of CIEDs grows each year. The prior calculations estimated that approximately 50%–75% of patients with a CIED could need an MRI scan over the lifetime of the device, which could potentially increase even further with constantly prolonged device longevity, and wider adoption of MRI into diagnostic processes [4]. Nonetheless, in some MRI-equipped facilities, the presence of CIEDs is continuously considered a

contraindication to performing MRI. Therefore, it is crucial to demonstrate that in the real-world setting, patients with CIEDs may undergo safe MRI scan, which is often the most important diagnostic modality in the course of their disease.

In order to facilitate easier access to MRI, the device manufacturers have introduced MRI-conditional devices, the structure and design of which reduce the risk of overheating of the system, or any other form of electromagnetic interference [5, 6]. Nonetheless, it should be noted that these devices aren't completely prone to dysfunction during MR [7], and the presence of dedicated personnel, conversant with CIED programming is still recommended during the MRI scan. The European Society of Cardiology guidelines for cardiac *pacing* and cardiac resynchronization therapy from 2021 recommend performance of MRI in MRI-conditional devices, provided the manufacturers' guidelines are followed, while in the non-MRI-conditional devices the examination should be recommended, unless no other alternative imaging methods are available, and there are no epicardial, abandoned or dysfunctional leads [2]. Similarly, the HRS Consensus on MRI and radiation therapy in patients with CIEDs from 2017, recommends a rigorous structured approach in patients with both MRI-conditional and non-MRI-conditional devices [1].

Previously published data from the other facilities are in line with our results. In the large, retrospective analysis of more than 2100 MRI scans performed in non-MRI-conditional devices, in only nine devices power-on resets were identified [8]. In the other multicenter registry of non-MRI-conditional devices in patients who underwent nonthoracic MRI, of 1500 scans performed, if the device was programmed according to the prespecified protocol, no hardware failures were identified, as far as generator or lead were concerned [9]. However, the cited evidence included also long-term follow-up of the devices, which was not available in our analysis. Thus, it should be considered as a limitation of our study.

Our results, as well as the cited evidence indicate, that a structured, rigorously planned, and followed strategy of MRI under the surveillance of a cardiologist experienced in the interrogation and management of CIEDs enables a safe procedure, enhances the availability of imaging diagnostics in patients requiring MRI, in whom the scan is often crucial for diagnosis and monitoring of the disease.

Article information

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Table 1. Characteristics of patients undergoing MRI under cardiologists' surveillance during the analysed period

Demographics	
Female gender, n/N (% of all patients)	42/122 (34.4)
Age, years, median (min–max)	68 (16–90)
Region of MRI analysis	**N (% of procedures)**
Abdomen MRI	17 (11.4)
Brain MRI	44 (29.5)
Prostate MRI	29 (19.5)
Cardiac MRI	5 (3.6)
Spine MRI	8 (5.4)
Breast MRI	3 (2.0)
Cardiac MRI	3 (2.0)
Others	40 (26.8)
Type of CIED	**N (% of procedures)**
ICD-DR	12 (8.0)
ICD-VR	17 (11.4)
CRT	21 (14.1)
PM-DR	78 (52.3)
PM-VR	15 (10.1)
CIED manufacturers	**N (% of procedures)**
Medtronic/Vitatron	81 (54.4)
Biotronik	26 (17.4)
Boston Scientific	18 (12.1)

St Jude/Abbott	24 (16.1)
Device characteristics	**N (% of procedures)**
Pacing dependency	34 (22.8)
Secondary prevention of SCD, of all ICD/CRT-D devices	6 (12.0)
MRI-conditional device	60 (40.3)

No events with regard to the device functioning, including the hardware and software issues were reported in the device interrogation immediately after MRI

Abbreviations: CIED, cardiac implantable electronic device; CRT-D, cardiac resynchronisation therapy-defibrillator; ICD-DR, double-chamber implantable cardioverter-defibrillator; ICD-VR, single-chamber implantable cardioverter-defibrillator; MRI, magnetic resonance imaging; PM-DR, double-chamber pacemaker; PM-VR, single-chamber pacemaker; SCD, sudden cardiac death