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Review article

State-of-the-art approach towards magnetic resonance imaging of the nervous system structures in patients with cardiac implantable electronic devices

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ABSTRACT

Introduction: MRI generated forces are the source of potential complications in patients with cardiac implantable electronic devices (CIED). The technological progress, and growing clinical evidence concerning the operation of the contemporary MR non-conditional CIEDs during MRI, have started to significantly change our every-day clinical practice. Nevertheless, a lot of patients who could have an MRI performed safely, still have been refused the examination. **State-of-the-art:** In many clinical situations, an MRI examination in a patient with a CIED is reasonable, and is linked to a negligible risk of complications if performed under strict precautions. The MagnaSave Registry that evaluated the influence of nonthoracic MRI on the function of MR non-conditional CIEDs, and numerous studies involving thoracic and non-thoracic MRIs in patients with legacy CIEDs, have confirmed the feasibility and safety of such examinations. In this article, practical tips aimed towards improving the safety of MRI in MR conditional and non-conditional CIED patients are largely based on the very recently released (2017) HRS expert consensus statement.

Clinical implications: Clinical data emphasize the necessity of making the MRI more accessible to CIED patients, also in the case of MR non-conditional systems or when the thorax MR imaging is clinically reasonable. This goal should be achieved by increasing the number of centers complying with respective recommendations and applying protocols that would guarantee the highest safety level.

Future directions: Further studies are warranted to assess safety issues related to the main current contraindication to MRI, i.e., the presence of abandoned leads.

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1. Introduction

Magnetic resonance imaging (MRI) of the central nervous system or nerve roots in patients with a cardiac implantable electronic device (CIED) is an extremely important issue as the inability to perform MRI may prevent diagnosing certain neurological diseases and consequently delay or even preclude adequate therapeutic decisions [1] (Fig. 1). In the aging European population, the number of patients requiring the implantation of devices modifying the heart activity, i.e. pacemakers as well as implantable cardioverter defibrillators (ICDs), keeps growing [2,3] as does the number of CIED patients referred to MRI. The Really ProMRI study, including 555 MR conditional systems, showed that a lot of patients who could have had an MRI safely performed, had been refused the examination [4]. The problem concerned especially patients

with ICDs [4], although the current studies do not show any associations between MRI-related risk and CIED type (pacemaker vs. ICD) [5]. The principal reason for the refusal seems to be a lack of standardized institutional investigational policies [6] guaranteeing jointly: the appropriate cooperation between radiologists and cardiac electrophysiologists, the assessment of MRI advantages over the alternative imaging modalities in respective cases, applying protocols for prescan and postscan CIED evaluation, appropriate CIED programming during the scan, and implementation of the effective emergency procedures in the case of an adverse clinical event during the scan. Additionally, a further convergence of appearing recommendations [6,7], their extensive dissemination, and improvement of personnel awareness are necessary to broaden the clinical application of MR imaging in CIED patients [4].

The International Electro-technical Commission regulations in force stipulate that in life-supporting equipment the

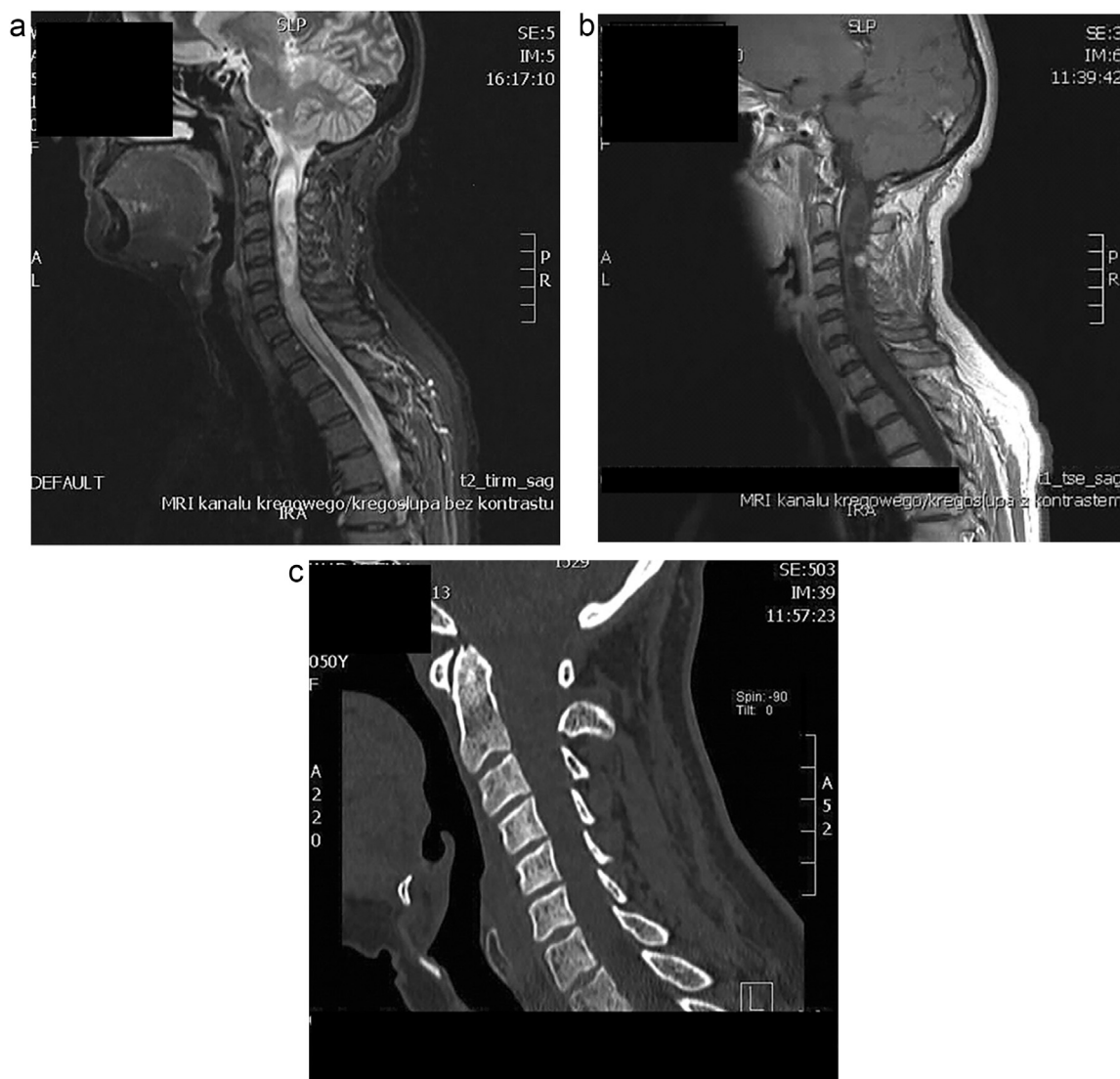


Fig. 1 – Non-contrast MRI (A) and MRI scan after contrast administration (B) in a patient with a pacemaker and symptoms suggestive of brachial plexus damage. MR imaging, applied because of the inconclusive CT cervical spine scan (C) and ambiguous neurophysiological results, showed a tumour within the spine (from “Lekarz Wojskowy” [1], with permission from the Publisher and Authors).

manufactured device should be resistant to the action of the magnetic field. The following groups of medical devices have been distinguished [8]: (i) MR-safe, carrying no hazard in any MR environment; (ii) MR-unsafe, posing known hazards in all MR environments; (iii) MR conditional and (iiii) MR non-conditional. Cardiac implantable electronic devices have either MR conditional status, indicating a lack of hazards in a strictly specified MRI environment with unambiguously defined conditions of use, or non-conditional status referring to all CIED systems other than those classified as MR conditional [6].

The greatest hazard of an MRI examination in a CIED patient may be related to the presence of fractured, epicardial, or abandoned endocardial or epicardial leads from a previous system, not linked to the now-operating cardiac device. MRI generated forces: static and gradient magnetic fields, and RF energy, are the source of potential complications in patients with implantable devices [9]. A static magnetic field can lead to a dislocation of ferromagnetic elements of a CIED. In order to prevent the dislocation of device components, a rule of 6 weeks is applied which says that an MRI examination can be performed no earlier than 6 weeks after the implantation. Nevertheless, if clinically warranted, an MR scan is reasonable in patients with recently implanted CIEDs, including MR non-conditional systems [6]. Other potential complications generated by the static magnetic field are: – closure of the reed-switch in an MR non-conditional CIED, resulting in temporary asynchronous pacing at the pacemaker-specific rate, and in temporary suspension of tachyarrhythmia detection and therapy in most ICDs [9], – reversion to power-on reset mode [9], possible at any magnetic field strength, wherein the oversensing the MRI-generated noise signals in VVI mode may lead to pacing inhibition or, in a patient with the ICD “shock-box” configuration, to spurious ICD tachyarrhythmia detection due to the MRI pulse-sequence, and in consequence to triggering inappropriate shock therapy. MRI-generated noise signals occurring due to the high-energy electromagnetic interference, being the result of RF energy pulses and rapidly changing magnetic field gradients, may be oversensed during VVI mode pacing, and if sustained in a pacing-dependent patient, lead to catastrophic asystole [9]. In conductive components of the lead, a gradient magnetic field may induce an electrical current that, when captured by myocardium in the vulnerable period of the ventricular potential, may initiate a life-threatening ventricular tachyarrhythmia. A radiofrequency electromagnetic field may cause heating of the cardiac muscle at or near the lead tip [10], edema of the adjacent tissues, or even perforation. It may be manifested, among others, by increased pacing capture thresholds, or by loss of capture. The risk of injury has been found to depend on the distance between the examined body part, that is, the isocenter of the MR scan, and a cardiac device. It raises big safety concerns for thorax MR imaging in CIED patients. In MR conditional pacemakers and ICDs, MR imaging procedure should comply with manufacturer specific restrictions regarding also the body area exclusion that depends on the device model. It may impose no restrictions, or exclude the certain area, i.e. from C1 to Th12, L4, or to L5 [11]. On the other hand, numerous studies have confirmed the safety of MRI examinations of the thoracic

spine, chest or heart performed under the strict precautions in MR non-conditional CIED patients [5,12].

2. State-of-the-art

In justified clinical situations, an MRI examination in a patient with a CIED allows to give an accurate diagnosis [1], and is linked to a negligible risk of complications when performed under strict regulations. The landmark MagnaSave Registry examined the influence of nonthoracic MRI examinations on function of MR non-conditional CIEDs (1000 pacemakers and 500 ICDs), and proved its safety [13]. The prospective, single-center study referring to unrestricted clinical practice, and to both MR conditional and non-conditional systems, and also to thoracic MRIs, was recently reported by Mason et al. [14]. The primary end-points included patient's death and failure of CIED components, and secondary end-points were specified as the pacemaker/ICD battery voltage loss and predetermined changes in intrinsic signals amplitude, pacing thresholds, and leads impedance. The study was conducted on 178 consecutive patients who had 212 MRI examinations performed (78 scans in pacing-dependent patients). It did not reveal any malfunction of the pacemaker/ICD nor any threats to the health and life of the patient due to MRI, regardless of MR conditional or non-conditional status of a contemporary CIED or examined body areas. A large prospective nonrandomized study [12] that included 1509 patients (137 pacing-dependent), who were implanted with MR non-conditional (legacy) CIEDs (880 pacemakers and 629 ICDs), and underwent in total 2103 thoracic and non-thoracic MRI examinations, did not show any clinically significant adverse events during long-term follow-up. It should be stressed that all MR scans in CIED patients were performed under the strict safety regulations. The most important event associated with MR imaging in this study was a power-on reset that occurred in 1 in 200 examinations. In 1 case it resulted in the replacement of the device, which was near the end of the battery life during the examination, and afterwards could not be reprogrammed, and in another case – in transient inhibition of pacing [12]. The very recently published, single-center prospective cohort study of 238 MR non-conditional CIED patients, in which originally the safety of thoracic (including 18 thoracic spine) MR scanning was compared to non-thoracic (among others, 83 brain and 22 cervical spine) MRI, showed no adverse clinical outcomes, and no differences concerning safety issues between the juxtaposed groups [5]. According to the study protocol, pacing dependent patients and those within 6 months of CIED implantation were excluded, unless strong clinical reasons for MRI occurred. However, the study conclusions implied subsequent removal of these restrictions from the institutional electrophysiological recommendations [5].

In this article the practical tips aimed towards improving safety of MRI both in MR conditional and in non-conditional CIED patients are largely based on the recently released (2017) HRS expert consensus statement [6].

The decision whether it is necessary to perform an MRI should be discussed by a team composed of a specialist in a respective disease-related field, a cardiac electrophysiologist and a radiologist. The team should first consider the

indications for the examination and make sure that there are no alternative imaging diagnostic methods which might replace MRI. What should be excluded at an early stage, is the presence of other contraindications to an MRI examination. In the case of an uncertain CIED hardware, a chest X-ray is mandatory to confirm absence of abandoned, fractured or epicardial leads [5]. The information thus gathered should serve as grounds for weighing the advantages and possible complications which might result from the procedure.

Before the MRI it is necessary to interrogate a CIED in order to assess: battery voltage, pacing leads thresholds, P-wave and R-wave amplitudes, pacing impedance and where applicable (ICD) high-voltage (shock) lead impedance, and to exclude life-threatening arrhythmias over the past few weeks. At a pretest capture threshold over 2.5 V at pulse width of 0.5 ms, or battery life expectation ≤ 1 year (the risk of premature battery depletion and sudden loss of therapy), MRI scanning is contraindicated [14].

It is crucial to assess the patient in terms of pacemaker dependence. During MRI, an MR non-conditional CIED in a pacing-dependent patient should be programmed to an asynchronous pacing mode. Pacing-dependent patients with both atrial and ventricular lead should have D00 mode selected, and those with a single chamber device – either V00 or A00 mode. The rate of asynchronous pacing should be determined properly to avoid competitive native rhythms, and thus, to eliminate ventricular activation during the vulnerable period and initiation of ventricular tachyarrhythmias [6]. It is also advisable to increase the stimulation amplitude to 5.0 V at pulse width of 1.0 ms in order to avoid loss of capture during the examination. In not pacing-dependent patients with an MR non-conditional CIED, either a non-pacing mode (ODO/OVO/OAO) or, at stable but slow the underlying rhythm, an inhibited mode (DDI/VVI/AAI) is reasonable, with stimulation and detection set to bipolar mode. In each above-mentioned case, advanced and adaptive features should be deactivated for scanning. Regardless of pacing-dependent status, in a patient with an MR non-conditional ICD, anti-tachyarrhythmia functions should be deactivated to avoid delivery of unwarranted therapies [6].

Similarly, MR conditional programming before the scan should assure the proper choice of a pacing rate and mode (asynchronous or non-pacing), depending on patient's intrinsic rhythm rate and pacing dependence. Alike, in MR conditional systems, advanced pacing algorithms should be deactivated, and in ICDs- the tachyarrhythmia detection and therapies disabled [6]. The manufacturer specific requirements for MR conditional pacemakers and ICDs should be strictly followed.

It is recommended that the MRI examination should be performed in the following electromagnetic field conditions: magnetic flux density of maximum 1.5 T, a maximal electromagnetic energy absorption expressed in Specific Absorption Rate (SAR) of ≤ 2 W/kg, and gradient magnetic field (gradient slew rate) ≤ 200 T/m/s [6]. The duration of the examination should be as short as possible, which requires a well thought-over choice of sequences that limits their length and number. In general clinical practice, recommendations based on the conclusions from the study involving, inter alia, thoracic MRIs [14] suggested the maximal scanning time limitation to

120 min, whereas the average value of the time reached 40 min in ICD and 43 min in pacemaker patients.

The method of monitoring the patient during the MRI examination should be predetermined, and should include: – continuous MR conditional ECG monitoring, which may be however associated with significant MRI-related artifacts, – pulse oximetry that is rather unaffected by MR scan, and – visual and voice contact. The nursing staff trained in advanced cardiac life support performance should be immediately available during the examination until clinically appropriate CIED settings are restored [6]. Other prerequisites are: – the immediate availability of a cardiac electrophysiologist (a CIED cardiologist) in the examination-performing center, – a resuscitation unit in a magnetically safe area close to the scanning location and adequately equipped with emergency equipment, such as an external cardiac defibrillator with external pacing function, a manufacturer-specific device programming system, or any other MR-unsafe equipment, as well as – a readily accessible Intensive Care Unit.

After the examination, it is necessary to thoroughly assess the CIED's status and to restore the original settings of a device as well as to make an entry in its logbook describing the performed procedure. Within one week after an MR scan, a complete CIED evaluation should be repeated, and thereafter, it should be scheduled as clinically indicated [6].

Modern CIEDs allow making MRI examinations with the high level of safety. The most important approach was to diminish the content of ferromagnetic elements in order to avoid any unwanted displacement of the implant. The other improvement consisted in the special arrangement of the leads to decrease the voltage induced at the tips by the radiofrequency electromagnetic field. The essential technological change in the CIED was to replace the reed switches by the Hall ones. More and more new products present favorable safety profiles, e.g., a small-sized and leadless transcatheter pacemaker may be placed both in 1.5 and 3 T MRI scanners without danger to the device or a patient, and regardless of the examined body area [15].

3. Clinical implications

Aside from the significant technological progress, increasing clinical data on the function of contemporary MR non-conditional (legacy) systems in an MR environment undoubtedly will alter our every-day clinical practice. However, it should be emphasized that in order to make the MRI more accessible and also safer to CIED patients, including examinations in MR non-conditional CIED subjects or a clinically reasonable MRI of thorax, it would be crucial to increase the number of centers complying with respective recommendations and applying protocols that will guarantee the highest precautions during diagnostic procedures involving the electromagnetic field in a CIED patient.

4. Future directions

The recent study comprising CIED patients with abandoned leads who underwent an MR imaging (80 subjects, 97 MRI

scans, 90 abandoned leads during the scan) reported a favorable risk-benefits ratio of such a procedure [16]. Nevertheless, further studies are warranted to assess the safety issues related to this main current contraindication to MRI. Since Magnetic Resonance imaging at 3 T is more and more frequently applied, in many centers being the only MR option, MR conditional and contemporary legacy CIEDs most likely will undergo a precise evaluation in this environment as well [17].

Conflict of interest

None declared.

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