NEUROLOGIA I NEUROCHIRURGIA POLSKA 49 (2015) 16–23

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.elsevier.com/locate/pjnns

Original research article

The use of 1.5 T magnetic resonance imaging for therapeutic decisions in patients with cardiac implantable electronic devices and significant neurological, neurosurgical and neuro-oncology diagnostic indications

Łukasz Hawryluk [a,*], *Maciej Sterliński* [a,1], *Magdalena Marczak* [b,2], *Jolanta Miśko* [b,2], *Jan Krzysztof Podgórski* [c,3], *Hanna Szwed* [a,1]

[a] *The Second Department of Coronary Artery Disease, The Cardinal Stefan Wyszynski Institute of Cardiology, Warsaw, Poland*

[b] *Magnetic Resonance Unit, Department of Radiology, Institute of Cardiology, Warsaw, Poland*

[c] *Department of Neurosurgery, Military Medical Institute, Warsaw, Poland*

ARTICLE INFO

Article history:
Received 23 June 2014
Accepted 9 December 2014
Available online 18 December 2014

Keywords:
Cardiac implantable electronic device
Magnetic resonance imaging
Therapeutic decision

ABSTRACT

Between September 2009 and May 2014 the classification of 36 patients with cardiac implantable electronic devices (CIEDs) in terms of the feasibility of MRI scanning due to strong clinical indications was carried out. Finally MRI examinations were performed in 20 patients, of whom 27 studies were conducted and a total number of 35 anatomical regions were scanned. Neurological, neurosurgical and neuro-oncology indications for MRI were reported in 19 patients (95%) in whom 26 MRI studies (96.3%) were performed, and 34 anatomical regions (97.1%) were scanned. One patient had indications for MRI in the field of cardiology.

Medical information obtained from 27 MRI studies allowed decisions to be made regarding the treatment in all patients. After 8 studies (29.6%), patients were classified into 9 different neurosurgical procedures. In the case of the remaining 19 studies (70.4%), there were no indications for surgical treatment and the decisions to implement conservative treatment were made.

There were no complications related to the implanted CIEDs observed: neither immediate nor in the follow-up.

* *Corresponding author at*: The Second Department of Coronary Artery Disease, The Cardinal Stefan Wyszynski Institute of Cardiology, Spartańska 1 Street, 02-637 Warsaw, Poland. Tel.: +48 22 343 40 50; fax: +48 22 343 38 19; mobile +48 601 086 680.

E-mail addresses: lucas.hawryluk@gmail.com (L. Hawryluk), msterlinski@poczta.onet.pl (M. Sterliński), magmarczak@wp.pl (M. Marczak), jmisko@wp.pl (J. Miśko), jkpodg@gmail.com (J.K. Podgórski), s_kchw@ikard.pl (H. Szwed).

[1] Tel.: +48 22 343 40 50; fax: +48 22 343 38 19.

[2] Tel.: +48 22 343 46 57.

[3] Tel.: +48 22 810 47 91.

http://dx.doi.org/10.1016/j.pjnns.2014.12.005

Conclusions:

(1) Magnetic resonance imaging studies in patients with non-MRI-conditional CIEDs in the vast majority are performed because of significant neurological, neurosurgical and neuro-oncology clinical indications.
(2) Careful determination of the indications for MRI in each case allows the data necessary to be obtained to make definitive treatment decisions.
(3) The adherence to examination protocol and device controlling procedures after MRI allows a very high safety profile of the method to be achieved.

1. Introduction

Magnetic resonance imaging (MRI) in patients with cardiac implantable electronic devices (CIEDs) may be considered when there are significant clinical indications but in practice it is usually avoided.

Magnetic resonance imaging is used in an increasing number of indications, particularly when other imaging techniques are insufficient to help reach final therapeutic decisions. It is the method of choice in diagnosing many disorders of the central nervous system. There is non-ionizing radiation during the MRI scans so it is a preferable method in patients who have indications for multiple MRI scanning.

In general awareness, cardiac implantable electronic devices (CIEDs) are considered a strong contraindication to conduct MRI examination.

The American Heart Association (AHA) and the American College of Radiology (ACR) developed in 2007 the position regarding the conditional execution of MRI in patients with CIEDs and emphasized that the eligibility of a patient with the implanted device must be always determined to estimate the risk–benefit ratio, and the presence of CIED is therefore a relative contraindication to MRI [1]. The Recommendations of The European Society of Cardiology (ESC) on Cardiac Pacing and Cardiac Resynchronization Therapy published in 2013 and created in collaboration with the European Heart Rhythm Association (EHRA) allow the possibility of MRI scan execution in patients with implanted devices [2]. In the case of ''traditional pacemakers'' [not certified for MRI or MRI (–)] the recommendation is class level IIb and has level of evidence: C, if there is a presence of significant clinical indications for MRI. However, in the case of the newer types of devices with a safety profile, certified for the MRI environment [MRI (+)], the recommendation is class level IIa and has level of evidence: C, assuming compliance with recommendations of the device manufacturer. Classes of Recommendations and the Levels of Evidence are shown in Tables 1 and 2.

The vast majority of patients in Poland and throughout the world, have traditional devices [MRI (–)] and as such are still excluded from the benefits arising from the MRI. At the same time statistics show that up to 50–75% of patients after CIED implantation will develop the indications for MRI scanning in their lifetimes [3]. Physicians may need MRI examination for 17% of their patients within twelve months after pacemaker implantation [4]. Due to the increasing number of patients with implanted CIED, this situation constitutes a very serious diagnostic limitation.

MRI scans in patients with CIED and with significant clinical indications were initiated in our department in 2009.

We are showing our own experience in the conducting of MRI examination in patients with CIED, analysis of indications spectrum and the utility of MRI results in making final therapeutic decisions.

2. Aim of the study

Evaluation of the possibility to take the definitive therapeutic decisions based on the result of MRI 1.5 T in patients with cardiac implantable electronic devices and with significant indications for MRI.

Table 1 – Classes of recommendations.

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure	
Class IIa	Weight of evidence/opinion is in favor of usefulness/efficacy	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful	Is not recommended

Table 2 – Levels of evidence.

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

3. Patients

In the years 2009–2014 examinations using MRI were performed in 20 patients with CIED (12 men, 8 women), with the mean age of 69.5 years (from 52 to 88 years). All patients had significant clinical indications for testing by means of magnetic resonance imaging and other diagnostic methods were not sufficient to make the final therapeutic decision.

4. Methods

Patients for MRI studies were mostly referred to our department by neurologists, neurosurgeons and oncologists. Then a consultation carried out by a cardiologist and radiologist (CIED MRI Team – CMT) was done. Only on the basis of such a consultation was the final qualification for MRI made. In some doubtful cases direct consultations between CMT and a neurologist, neurosurgeon or oncologist as a referring physician were needed. Each negative decision was discussed with a referring physician. In the process of qualification for the MRI examination the clinical relevance of the proposed examination and the possibilities of alternative diagnostic techniques were determined by the CMT. The comparison of the predictable benefits and the potential risks arising from the presence of the implanted system in the electromagnetic field was discussed. In order to guarantee safety during the implementation of the MRI, the patients were hospitalized for three days. During hospitalization electrocardiogram, echocardiogram, at least 3 controls of the device and basic laboratory tests were performed.

The types of CIEDs owned by patients are shown in Table 3. All patients' devices belonged to the category of non-approved for the use in the electromagnetic environment [MRI (–)], except for one pacemaker approved for the use in the electromagnetic environment [MRI (+)]. But this pacemaker was connected to the leads MRI (–) and due to that fact this whole device was regarded as the MRI (–).

Table 3 – Types of devices implanted in studied patients.

Pacemaker	17 (85%)
VVI	4 (20%)
AAI	2 (10%)
DDD	11 (55%)
Included pacemaker dependent patients	4 (20%)
Implantable cardioverter defibrillator	1 (5%)
Implantable loop recorder	2 (10%)

Abbreviations: VVI, ventricular pacemaker; AAI, atrial pacemaker; DDD, atrio-ventricular sequential pacemaker.

Immediately before performing the MRI scans, CIEDs were suitably, temporarily programmed. The basic parameters such as: battery impedance, battery voltage, level of battery charge, lead impedance, pacing threshold and sensing were checked. If a patient had his own rhythm the AAI, VVI or DDI mode was programmed. If a patient was pacemaker dependent, the AOO, VOO or DOO mode was programmed. MRI examinations were performed on a Siemens Avanto 1.5 T MRI scanner. Specific absorption rate (SAR) was limited to <2.0 W/kg. SAR is a measure of the rate at which energy is absorbed by the body when exposed to a radio-frequency electromagnetic field. It is defined as the power absorbed per mass of tissue and has units of watts per kilogram (W/kg). The time of each study was not limited. The patient's safety and the proper conduct of MRI examination were supervised by CMT. While conducting the MRI scan, the heart rate, blood pressure, ECG and blood oxygen saturation were monitored by means of a camera approved for use in the electromagnetic environment.

When MRI scanning was finished, the implanted devices were carefully checked and reprogrammed according to settings present before the MRI. If there were no irregularities in the functioning of the implanted device directly after the MRI and for the following 24 h, and if there were no other complications, patients were discharged from the hospital to continue routine device checking as before as an outpatient. MRI data were sent to the physician who referred the patient to the test.

We analyzed the final form of the therapy based on the data from the MRI studies.

5. Results

Between September 2009 and May 2014, 36 patients with CIEDs were consulted in terms of the possibility to undergo magnetic resonance imaging. Finally, 20 patients who had important indications were qualified for MRI. Sixteen patients were not qualified for MRI. The main reason was that patients after being informed about the possible risk decided not to undergo MRI scanning (11 patients). In 4 cases there were alternative imaging techniques suggested (Computed Tomography). In the case of one patient with epicardial leads, in our opinion, the risk of MRI scanning was too high. The patients who qualified for MRI underwent a total number of 27 MRI studies (4 patients had 2 studies and 1 patient had 4 studies), during which 35 anatomical body regions were examined. The indications for MRI in the field of neurology, neurosurgery and neuro-oncology were reported in 19 patients (95%) in whom 26 MRI studies (96.3%) were conducted and 34 body regions (97.1%) were scanned. The types of indications, number of patients and number of studies are shown in Table 4.

Among the performed tests the majority were those relating to one body area. The following were also performed: 3 studies of 2 anatomical regions (spine Th and LS regions), one study involving 3 anatomical regions (spine C, Th and LS regions) and one study involving 4 body areas (head, spine C, Th and LS regions). The number of anatomical areas is summarized in Table 5.

Table 4 – Indications for MRI, number of patients, number of examinations for each indication.

Indications for MRI	Patients	MRI examination
Movement/sensory disorders of upper limbs	3	3
Movement/sensory disorders of lower limbs	9	9
Brain tumor	3	9
Encephalitis	1	1
Cerebral aneurysm	1	2
Motor aphasia	1	1
Syncopies of unknown, probable central origin	1	1
Acute heart failure aggravation in previously healthy young subject	1	1
Total	20	27

Table 5 – MRI studies detailing anatomical areas scanned.

Anatomical areas scanned	*n*
MRI of head	15
MRI of spinal column	
Cervical	6
Thoracic	5
Lumbosacral	7
MRI of heart	1
MRI of pelvis	1
Total	35

MRI results were evaluated in terms of their usefulness in determining the causes of the diseases as well as the possibility of making a final decision.

It was found, as a result of all independent MRI studies, that it was possible to clearly establish the kind of therapeutic treatment.

Twenty-seven of the MRI studies were performed, out of which 26 (96.3%) were related to the issues on the borderline of neurology, neurosurgery and neuro-oncology and one (3.7%) study was done because of cardiology reasons (cardiac MRI in a 52-year-old woman with an acute heart failure). On the basis of 8 MRI studies (29.6%) 6 patients (30%) were classified into 9 different surgical procedures:

1. In the case of 3 patients, only once was a neurosurgical treatment introduced. These were the procedures concerning: brain tumor, herniated nucleus pulposus of intervertebral disc of the cervical spine and herniated nucleus pulposus of intervertebral disc of the lumbar spine.
2. Two patients were directed to double-surgical treatment on the basis of two separate MRI scans.
   a. The first patient had two incidents of paraplegia caused by herniations of the nucleus pulposus at different levels of the thoracic spine, which appeared one by one at an interval of 18 months.
   b. The second patient, with a brain tumor, after the first MRI examination was qualified for neurosurgical treatment. The control MRI examination showed the incomplete resection of the tumor and re-surgical treatment was planned.
3. Moreover, one patient was selected for two different surgical procedures on the basis of one anatomical region MRI scanning. Firstly, the treatment of vertebral angioma Th 11 was performed. Secondly, the treatment of disc herniation at spine level L5 – S1 was conducted.

Lastly, thanks to the data obtained in 19 studies (70.4%), patients were eligible for medical management: observation of changes, drug treatment, rehabilitation, and, in one case, biological treatment of encephalitis. These proceedings concerned 14 patients (70%). The distribution of therapeutic decisions is shown in Fig. 1.

In Fig. 2, the MRI scan demonstrates the hyperintense signal in the medial right temporal lobe and part of the right insula in a man with limbic encephalitis and epilepsy. In Fig. 3, the MRI scan demonstrates the hyperintense signal in the medial right temporal lobe and hippocampus in the same patient.

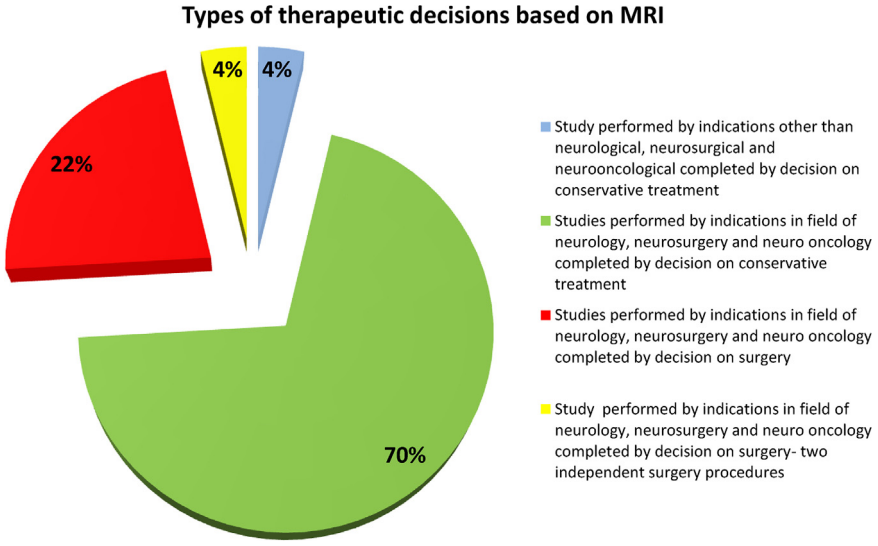

Fig. 1 – Types of therapeutic decisions based on MRI. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

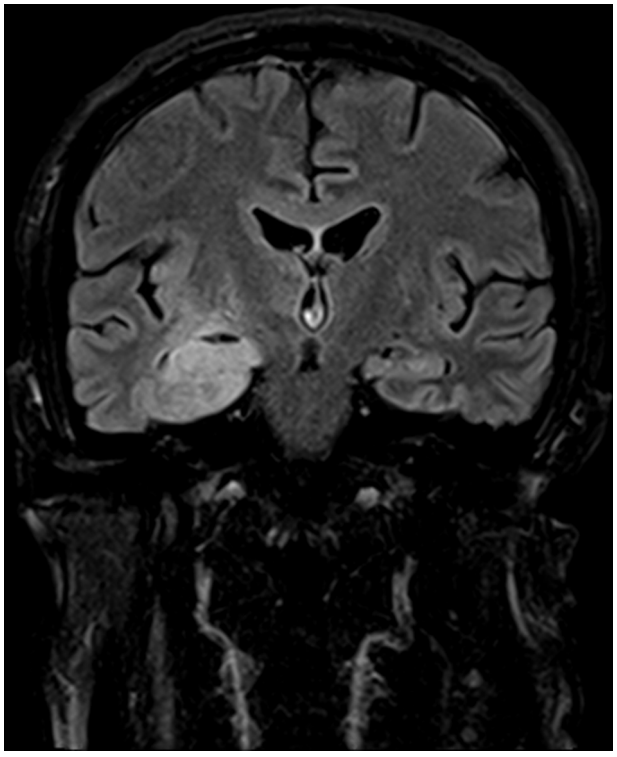

Fig. 2 – Coronal image from Fluid-Attenuated Inversion Recovery (FLAIR) MRI. MRI scan demonstrates the hyperintense signal in the medial right temporal lobe and part of the right insula in a man with limbic encephalitis and epilepsy.

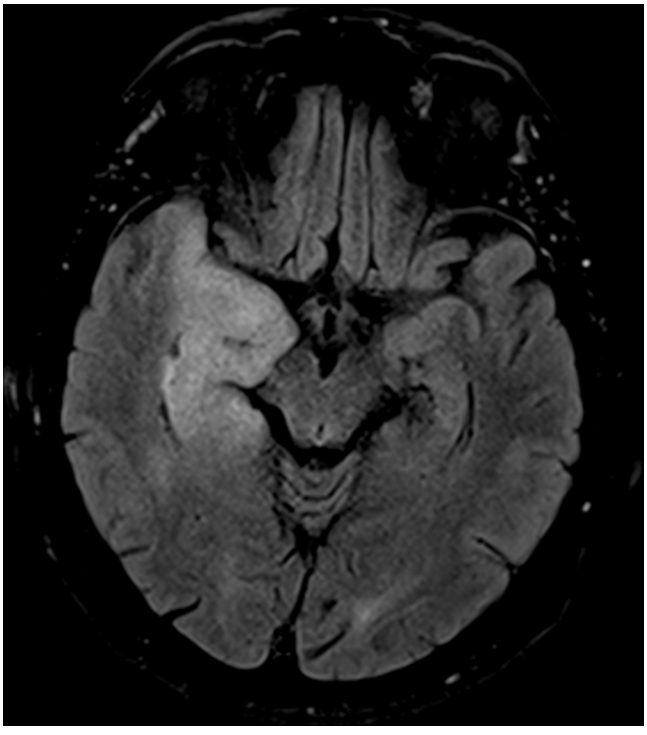

Fig. 3 – Axial image from Fluid-Attenuated Inversion Recovery (FLAIR) MRI. MRI scan demonstrates the hyperintense signal in the medial right temporal lobe and hippocampus in a man with limbic encephalitis and epilepsy.

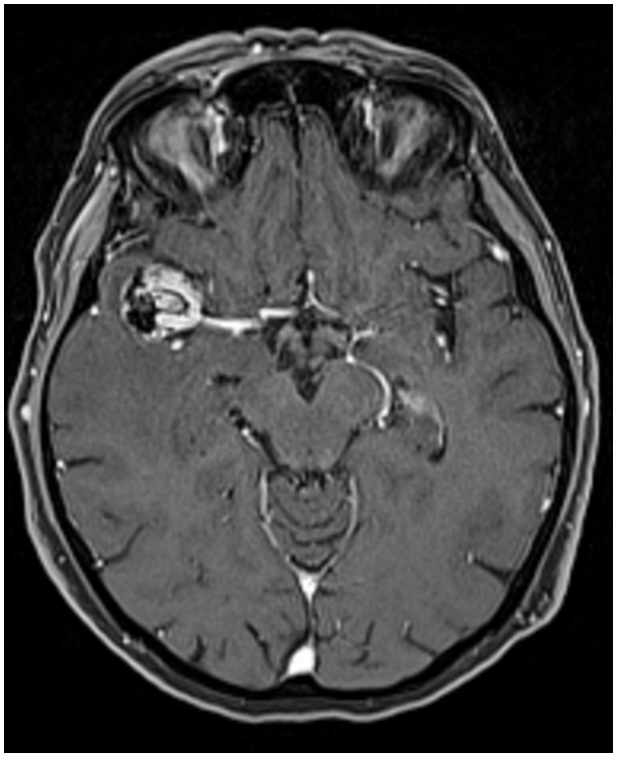

Fig. 4 – Axial image from a contrast-enhanced MRI follow-up of coiled aneurysm of the right middle cerebral artery. MRI scan demonstrates partial central recanalization of the aneurysm and the thin linear rim of peripheral/ circumferential contrast enhancement around the coil mass, which is not representative of recanalization but more likely of mural enhancement as a sequela of the in-growth of granulation tissue.

The results of the MRI examination of two patients, in whom as a new finding, brain tumors not shown previously in other imaging studies were detected, should be given additional attention. In the first patient meningioma was detected on MRI. The patient had an MRI taken as a control study after embolization of the middle cerebral artery aneurysm. As the first step computed tomography was conducted but it was disrupted by a large halo effect, so a decision regarding MRI examination was made. The MRI test result proved to be diagnostic for the assessment of aneurysm treatment and additionally a meningioma was detected. In this case the conservative treatment and observation of changes were proposed. In the control MRI examination, after 18 months, there was no tumor growth observed. The MRI scans of this patient are shown in Figs. 4–7.

The second patient had a tumor in the cererebellopontine angle as a new finding. It was invisible in computed tomography. This tumor was selected for surgical treatment by the Cyber-Knife method. Six months later, the second MRI study showed that the tumor was the same size as before the cyber-knife surgery. After the second MRI no more surgical treatment was implemented. Conservative treatment and observation of changes were proposed.

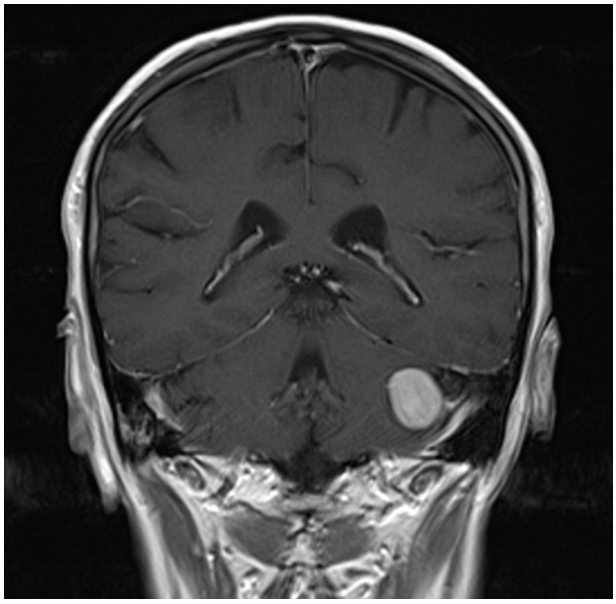

Fig. 5 – Coronal image from a T1WI contrast-enhanced MRI. MRI scan demonstrates infratentorially, well-circumscribed, homogeneous enhanced mass, shaping left cerebellar hemisphere. MR image is typical for meningioma.

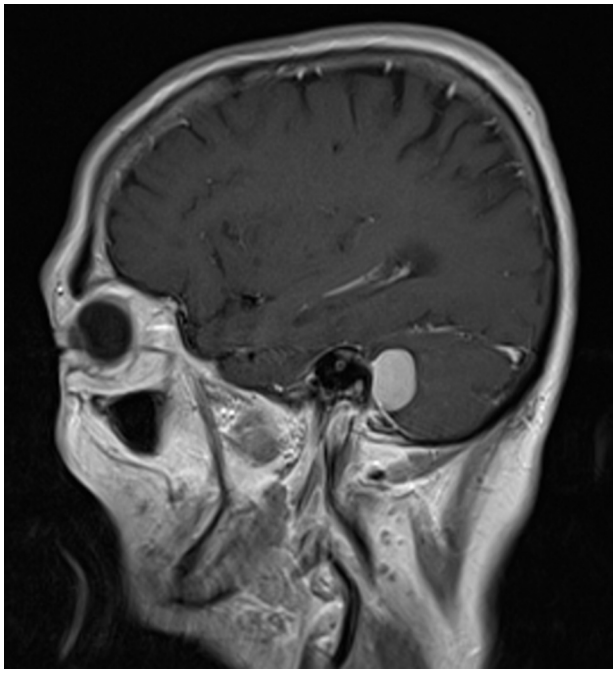

Fig. 6 – Sagittal image from a T1 weighted image (T1WI) contrast-enhanced MRI. MRI scan demonstrates well-circumscribed, homogeneous enhanced subtentorial mass with a broad dural base. MR image was described to be typical for meningioma.

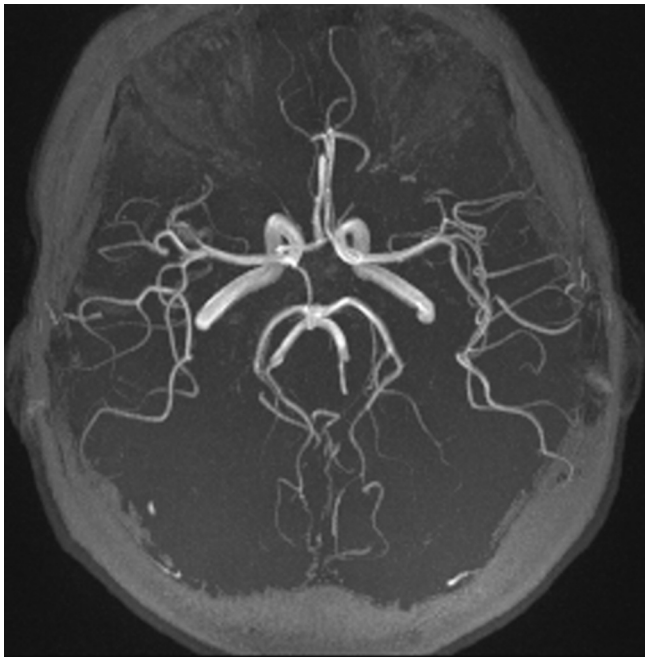

Fig. 7 – Three-dimensional time of flight (TOF)-MRI source image demonstrates partial recanalization of the of the right middle cerebral artery aneurysm, treated using a coil embolization technique.

There were no reported complications related to the CIEDs presence under the influence of electromagnetic field.

6. Discussion

The presented data show that the indications for MRI in the field of neurology, neurosurgery and neuro-oncology are in the vast majority. All patients eligible to scanning had significant clinical indications for MRI, and other previously conducted imaging tests had not revealed the cause of ailments. The CIEDs owned by these patients met safety requirements to justify taking the risk connected with a MRI examination.

In the cases of all patients it was possible to identify the cause of therapeutic problems and to take appropriate treatment on the basis of MRI examinations.

Patients not eligible for MRI scanning in the majority did not agree to examination because of the possible risks. Such situations mostly appeared at the beginning of our program, in the years 2009–2011, when our experience was not extensive enough and there was little information from other sources about performing MRI scans in patients with CIEDs.

We believe that taking well-considered risks of procedure for the implementation of MRI in patients with CIEDs is justified to achieve the therapeutic target.

It should be emphasized that the qualifying of patients for MRI examination more than once was caused each time by a new clinical situation or by the progression of the disease. In such a situation, patients were subjected to a new, independent qualification for the MRI procedure. Qualification for the MRI in the same patients did not result from the inability to

determine the proceedings on the basis of the results of previous MRI. Other qualifications were always caused by the progression of the disease or the need to monitor the results of treatment.

It is very important that a team consisting of a cardiologist and radiologist who are in contact with a referring physician should evaluate on each occasion the clinical relevance of the proposed research, the possibility of using the alternative diagnostic techniques, and should always define potential risks associated with the implanted device undergoing MRI scans. In the present work, the lack of qualifications for MRI in 16 patients, out of 36 originally reported to consider the MRI study, was due to the lack of patients' consent, the possibility of using alternative imaging methods, not sufficiently strong indications or significantly increased risk associated with the device (for example the presence of epicardial leads).

More and more centers perform MRI studies in patients with CIEDs. Both, patients with pacemakers [5–13] and implantable cardioverter-defibrillators [14–19] underwent MRI examinations. This phenomenon is inevitable. The main reason is that year-by-year more patients are treated by using CIEDs. Indications for MRI are still multiplying and probably this trend will continue. Such a situation requires searching for new solutions. One of the best solutions is a device certified for MRI. But in our population this rarely occurs. We have to learn how to help patients with CIEDs non-certified for MRI.

As regards patients with CIEDs, the information gained from MRI is very valuable, because the indications were well considered. We believe that MRI studies in patients with CIEDs are probably more diagnostic than in patients without pacemakers. This is because indications for MRI in patients without CIEDs are sometimes borderline.

At present, the CIEDs certified for MRI [MRI (+)] are increasingly available. These new pacemakers and ICDs were tested in the MRI environment [20–25]. In the group described in the article only one patient had an MRI (+) pacemaker implanted but it was connected to the non-MRI certified leads and the entire system was also considered as non-certified for MRI [MRI (–)]. Patients with a complete device system certified for MRI (device and leads) have a reduced risk of complications during MRI, but there is no guarantee of complete security. Therefore, the calculation of anticipated benefits and potential risks arising from the implementation of MRI regardless of the device type [MRI (+), MRI (–)] is always necessary and the detailed analysis of the manufacturers' instructions should not be neglected. It should be mentioned that there is a possibility of extraction of non-MRI Conditional CIED to facilitate scanning. According to The Heart Rhythm Society Consensus on Lead Extraction, this kind of procedure is in Class IIb of recommendations and has level of evidence: C [26].

The results of this study relate only to patients with ''classic'' CIEDs that are not certified for performing MRI. Not all manufacturers of CIEDs and not all types of devices were represented. It should be noted that all manufacturers are emphasizing contraindications to MRI. These are included in the instruction manuals of traditional CIEDs. Therefore, the increasing use of MRI-compatible devices is indicated and probably in the next few years it should become the ''gold standard'' for this method of treatment. It should be noted that regardless of the CIED type [MRI (+) or MRI (–)], performing of MRI may be considered in every case, as far as the health and life of the patient requires it, but only after the exact calculation of benefits and risks.

7. Conclusions

(1) Magnetic resonance imaging studies in patients with cardiac implantable electronic devices not certified for MRI are performed in the vast majority because of significant clinical indications in the field of neurology, neurosurgery and neuro-oncology.
(2) Careful determination of the indications for MRI in each case allows to obtain the data necessary to make definitive treatment decisions.
(3) The adherence to examination protocol and device controlling procedures after MRI allows to achieve a very high safety profile of the method.

Conflict of interest

None declared.

Acknowledgement and financial support

None declared.

Ethics

The work described in this article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

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