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【 ORIGINAL ARTICLE 】

Current Status and Issues Concerning Magnetic Resonance Imaging in Patients with a Magnetic Resonance Conditional Cardiac Implantable Electrical Device: A Single-center Study

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Abstract:

Objective Following the introduction of magnetic resonance (MR)-conditional cardiac implantable electrical devices (CIEDs), patients with CIEDs have undergone MRI scanning more frequently. As the required settings of MRI equipment for scanning patients with a CIED vary by device, a number of precautions should be taken to allow safe examinations, including the confirmation of conditions and selection of MRI modes appropriate for pacing status in individual patients. In this study, we examined the current status and issues concerning the performance of MRI examinations in patients with an MRI-conditional CIED.

Method and Results We reviewed a total of 262 MRI scans. The most common site of MRI scanning was the head, followed by the spine, abdomen, and heart in order. Regarding the MRI mode, DOO was most often used, followed by OFF, AOO, and finally VOO mode, to maintain atrioventricular synchrony. Although no obvious adverse events were observed related to MRI scanning, there were several cases encountered that might have been predisposed to a significant incident or in which the patient's intrinsic pulse rates or subjective symptoms changed before and during scanning.

Conclusion As MRI is a very useful diagnostic tool for cerebrovascular diseases and orthopedic disorders, the demand for MRI scanning is high when treating these areas. Although MRI scanning in patients with MR-conditional devices was performed without any adverse events, there were incidents that could have potentially led to major harm. This highlights the importance of confirming the appropriate MRI mode is being used before scanning and monitoring patients during scanning.

Key words: MRI (magnetic resonance imaging), MR conditional device, arrhythmia

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Introduction

While magnetic resonance imaging (MRI) is less invasive than other modalities and lacks radiation exposure, it still requires caution, as it uses strong static magnetic fields, gradient magnetic fields, and radio frequency (RF) (1). Although MRI examinations were previously contraindicated in patients with cardiac implantable electrical devices (CIEDs), the introduction of magnetic resonance (MR)-conditional CIEDs has allowed relatively safe imaging (2-9).

MR-conditional pacemakers became available in Japan in October 2012, and MR-conditional models of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices are also now available. Following the introduction of MR-conditional CIEDs, patients with CIEDs have undergone MRI scanning more frequently. Kalin et al. reported that 50% to 75% of patients with devices required an MRI examination at some point in their lifetime (1). MRI in patients with devices is somewhat complicated because of the need to confirm the MRI scanner settings, which vary by device. A joint statement from the Ja-

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Table. Patients, Devices, and Device Settings for MRI Examination.

variable	
Total MRI scans/patients	262/162
Age (years)	74±12
Sex ratio (man:female)	109:53
Pacemaker indication (n=162 patients)	
Sick sinus syndrome	73
Atrioventricular block	64
Other (CHF, DCM, VF)	25
Pacing mode during MRI (n=262 scans)	
DOO	88 (34%)
OFF/ODO	76 (29%)
AOO	59 (23%)
VOO	36 (14%)
No MRI mode programming	3

Number of patients is shown unless otherwise indicated.
MRI: magnetic resonance imaging, CHF: chronic heart failure, DCM: dilated cardiomyopathy, VF: ventricular fibrillation

pan Radiology Society, the Japanese Society for Magnetic Resonance in Medicine, and the Japanese Heart Rhythm Society established the guidelines for MRI scanning (10), which differ markedly from those used in Western countries. However, MRI has been performed more frequently in Japan than in other countries, and the same tendency is consequently seen in patients with a device.

In addition, in contrast to patients without CIEDs, patients with CIEDs require the selection of an appropriate, individualized MRI mode. For example, pacing is OFF in patients with a stable intrinsic heart rate and stable circulatory dynamics, whereas asynchronous pacing (AOO, VOO, DOO) at a slightly higher rate than the intrinsic heart rate is used in patients without stable intrinsic heartbeats who are highly pacing-dependent. As an MRI examination has to be performed in patients with an ICD with the defibrillator function deactivated, adequate preparation and careful monitoring are necessary in patients at high risk of developing ventricular tachyarrhythmia in order to ensure that immediate treatment can be instituted at any time during scanning.

In this study, we examined the current status of MRI examinations and issues with scanning in patients with an MR-conditional CIED.

Materials and Methods

We reviewed a total of 262 MRI scans performed between June 2013 and April 2020 in 162 patients (109 men) with an MR-conditional CIED. All MRI scans were performed under the conditions recommended for the relevant devices using an actively shielded 1.5-T MR system (Achieva 1.5T Nova; Philips, Amsterdam, the Netherlands/ MAGNETOM Symphony; Siemens, Munich, Germany).

MRI scanning was performed under observation by a cardiologist, a clinical technician, and a radiological technologist. We examined the devices in all patients immediately before MRI scanning and programmed the devices to the MRI mode, setting them to OFF or an asynchronous pacing mode, according to the patient's pacing dependency. We prepared defibrillators for any unexpected life-threatening arrhythmia and monitored pulse rates with a pulse oximeter during MRI. Any problems occurring during the examination were recorded.

Results

Frequency and sites of MRI scanning

A total of 162 patients with CIEDs underwent MRI examinations between June 2013 and April 2020 at our hospital, with a total of 262 scans performed. Of these patients, 126 had a device implanted at our hospital, and 36 patients had a device implanted at other hospitals. Of the 126 patients who had a device implanted at our hospital, 117 had a newly implanted, MR-conditional CIED, while 9 had originally been implanted with a non-MR-conditional device but later switched to an MR-conditional device at the time of battery replacement. Since October 2012, when the use of MR-conditional pacemakers was approved in Japan, a total of 696 patients had been implanted with a new MR-conditional device at our hospital as of March 2020, and of these patients, 117 underwent MRI scanning in our hospital, accounting for 16.8% of all patients. A total of 44 patients underwent MRI scanning within 1 year of implantation of an MR-conditional device, accounting for 7.2% of the 609 patients who had an MR-conditional device newly implanted as of April 2019. The patient characteristics, indications for CIED implantation, and pacing modes during scanning are shown in Table.

The number of MRI scans performed in individual patients is shown in Fig. 1, and the scanning sites are shown in Fig. 2. The largest number of patients (110 patients), had a single MRI scan, and 27 patients had 2 scans, with 3 patients having the greatest number of scans (7 scans). The head was the most common site of the first MRI scan performed after device implantation, followed by the spine, abdomen, heart, and pelvis.

MRI mode selection

There are four types of MRI modes that can safely be used to avoid damage resulting from magnetic fields: DOO, OFF, AOO, and VOO. In our 162 patients, the MRI mode used most often was DOO, followed by OFF, AOO, and VOO (Table). As we describe in Case 2 below, some patients complained of discomfort when VOO mode was used; we therefore tried to use DOO or AOO modes instead to maintain physiological actuation with AV-synchronized pacing. In CRT patients, we tried to maintain biventricular pacing and avoided reversion to an intrinsic, wide QRS, in order to maintain the patient's usual treatment.

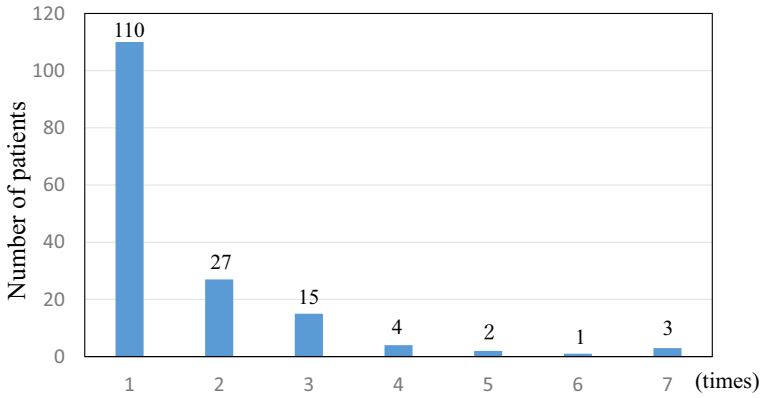

Figure 1. **Number of MRI scans per patient. Most patients underwent a single MRI examination, but 30% of the patients required ≥2 scans.**

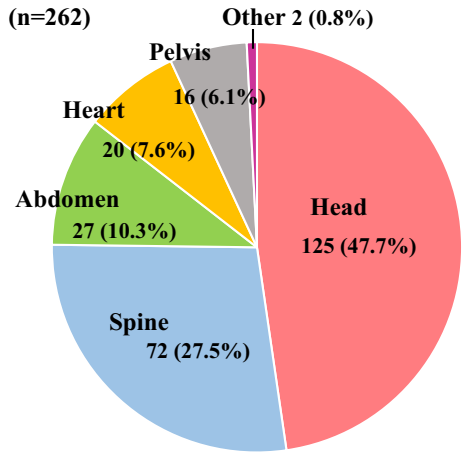

Figure 2. **Anatomical areas of MRI scan. Disposition of the sites subjected to MRI scanning. The head was the most common site, accounting for about a half of the total, followed by the spine (27.5%) and abdomen (10.3%).**

Problematic cases

Among the 262 MRI scans included in this study, there were 3 cases in which the scan was mistakenly performed without the device setting being changed to MRI mode. There were no life-threatening events related to MRI examinations in any of the patients included in this study. At subsequent pacemaker clinical visits, no data were acquired that suggested any worsening of thresholds or impedances. Below, we report two cases in which problems related to scanning settings arose.

Cases with issues

Case 1

We herein report one of the three cases in which an MRI scan was acquired without setting the device to its proper MRI mode.

The patient had a pacemaker (DDD) implanted for advanced atrioventricular block and was scheduled to undergo brain MRI as ordered by the Department of Neurosurgery. On the day of the examination, the patient checked into the hospital much earlier than the scheduled time and underwent the examination before the appointment time. Ordinarily, the cardiologist or clinical technician assigned on the day of the examination would have been present during the examination, but the patient underwent the examination directly due to the large deviation from the scheduled time and inadequate confirmation at the reception desk. The patient experienced no major physical health problems during or after MRI scanning and completed the examination without issue.

The attending clinical technician contacted the MRI department at the appointed time, and the patient, who had completed the examination and returned home, was called back for a device check. This check identified no problems with measurements, including impedances, sensing, and thresholds, but an automatic mode switch (AMS) event had been recorded, with the timing matching with that of MRI scanning (Fig. 3). The A-pace V-pace mode before the MRI examination had been switched to A-sense V-pace mode during the MRI examination when atrial noise began to be detected, finally switching to V-pace mode at a constant rate with atrial noise being falsely recognized as Af, activating the AMS. Fortunately, V-pace was not suppressed because ventricular noise was not over-sensed. Device checks at subsequent regular clinic visits revealed no abnormalities in impedances, sensing, or thresholds.

We encouraged the staff at the reception desk to perform reconfirmation and advised the patient to take precautions during future examinations.

Case 2

A patient had a pacemaker (DDD) implanted for complete atrioventricular block and underwent MRI scanning of the abdomen. The device check before the examination showed that the usual percentage of pacing was 100% V-pacing and 64% A-pacing. Due to a moderately high intrinsic atrial rate of about 80 bpm, the device was initially set to the VOO mode at 75 bpm, whereupon the patient complained of symptoms of chest discomfort and palpitations. Despite the rate being based on pulse rates for V-pacing alone, discomfort seemed to have occurred due to a lack of synchronization with the atrium. When the device was reset to DOO

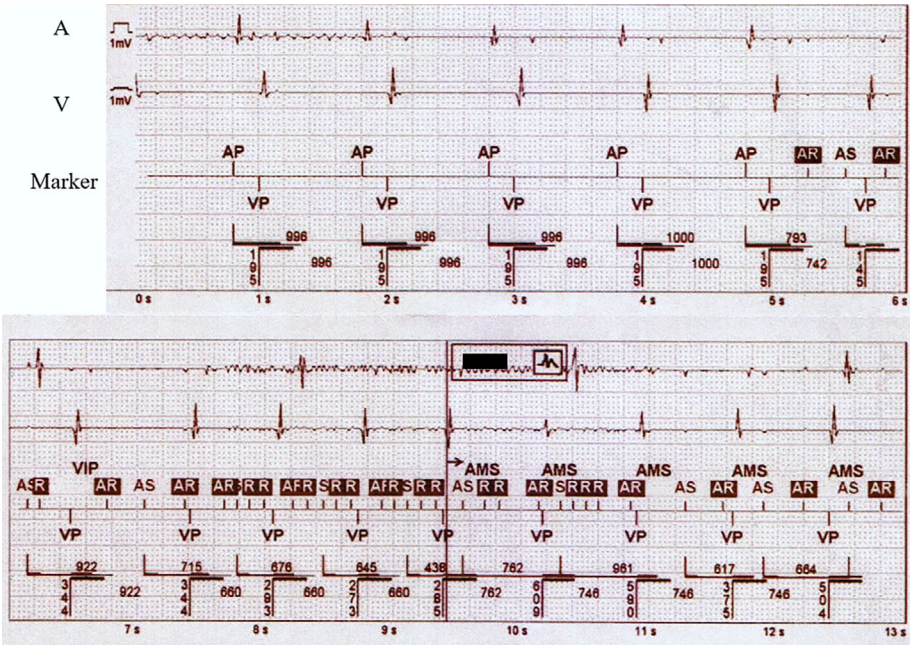

Figure 3. **Report of interrogation after MRI scanning (Case 1). Intracardiac electrogram revealed the inhibition of atrial pacing due to oversensing of atrial lead b caused by the magnetic field. Recorded events are shown matched to the scanning time. The A-pace V-pace mode was switched to automatic mode switch (AMS) due to the device sensing atrial noise.**

mode at 80 bpm to avoid asynchrony, the subjective symptoms disappeared, and the patient completed the examination without further problems.

Discussion

MRI scanning was conventionally contraindicated in patients with CIEDs. This is because strong static magnetic fields, gradient magnetic fields, and RF might interfere with the metal device body or leads, causing inappropriate activation or heat generation (11, 12). MRI in some patients with CIEDs was described as being feasible under certain conditions even before the introduction of MR-conditional devices but was not generally recommended, and in some medical settings, negative sentiments about MRI scanning persisted even after the introduction of MR-conditional devices (13-15). In patients with currently available MR-conditional devices, a prior device check remains essential. Caution should be exercised, including avoiding the risk of competition between the asynchronous mode and intrinsic pulse rates (16). Furthermore, monitoring with an electrocardiogram or pulse oximeter should be performed during MRI, and provisions for unforeseeable circumstances should be made, including ensuring the availability of a defibrillator.

The present review of MRI scans performed during the period of this study found that MRI scans were performed without setting the device to its MRI mode in 3 of 262 total MRI scans. The examination was started with the implanted device being overlooked in two of the three cases, and the remaining single case represents an operational error at the time of setting. Among the problem cases, Case 1 was one in which MRI was performed without setting the device to its MRI mode. In this case, the only change was switching to AMS in response to atrial noise; however, oversensing of ventricular noise might have caused a serious event, such as cardiac arrest. Although it was fortunate that no adverse event occurred during the examination or subsequent device checks in patients who underwent MRI without setting the device to the MRI mode, it seems necessary before the examination to not only ask the patient or his/her family verbal questions and to complete a questionnaire but also to reconfirm the physical findings and previous images/records wherever possible, as the responses obtained may not be accurate.

During the MRI examination, the intrinsic pulse rate may accelerate in some cases compared with that at the time of the device check prior to the examination due to development of paroxysmal atrial fibrillation or transient recovery of atrioventricular conduction, reaffirming the need for careful observation during the examination. Although one report claimed that a relatively safe examination can be performed in patients with CIEDs without monitoring during MRI where there are compelling reasons, such as in an emergency (17), monitoring should ideally still be performed in accordance with the recommendations of the Japanese Heart Rhythm Society, Japan Radiological Society, and Japanese Society for Magnetic Resonance in Medicine. Case 2 was one of the problematic cases. The patient was switched from VOO to DOO due to a complaint of discomfort with asynchronous pacing, without life-threatening consequences. This underscore the need to check with patients for subjective

symptoms when changing a setting prior to scanning.

The head was the most common site of scanning, followed by the spine. CIEDs are more frequently implanted in older people in Japan (average age of the subjects included in this study: 74±12 years old), suggesting that demand for MRI remains high for patients with cerebrovascular diseases, including stroke and orthopedic disorders. MRI has already been shown in previous reports to be more useful than computed tomography in many respects, especially for diseases involving the brain or spine (18). In addition to the head and spine, MRI of the heart, which was the fourth-most common site of scanning in this study, is also an examination that may be preferred for evaluating patients with cardiac dysfunction or cardiac sarcoidosis, and MRI is useful for predicting the prognosis of patients with non-ischemic cardiomyopathy (19, 20). The demand for MRI among patients with MR-conditional CIEDs will continue to grow. With the advent of MRI-conditional devices, many patients will likely continue to undergo MRI examinations following device implantation. Prior checks, configuration, monitoring, and responses should be individualized so that the examination can proceed safely.

Limitations

Several limitations associated with the present study warrant mention. This study was a single-center, retrospective study, and the number and range of cases included in the study were limited. At our hospital, there were several cases that were ineligible for MRI due to the lack of previous experience with emergency MRI examinations being performed in patients with a device combined with the use of MRI-conditional atrial and ventricular leads from different manufacturers. MRI scanning was consequently abandoned in some cases. Thus, the total number of MRI scans requested in patients with a device may be slightly smaller than expected.

Future issues

This review found that the percentage of patients who underwent device implantation at another hospital and were referred to our hospital for MRI alone was relatively high (22%; 36 of 162 patients). Given the convenience for patients, it is unfortunate that some implanting hospitals have MRI equipment in place but do not meet the requirements to be recognized as certified facilities for MRI examinations and thus cannot provide MRI examinations. For a facility to be certified to perform MRI examinations, full-time cardiologists and radiologists must be available on staff. The presence of cardiologists during scanning and coordination with other staff are important for ensuring safety. It is important to raise awareness about the need for coordination between cardiologists and other personnel and to ensure that the personnel assigned for the day are actually present during scanning, rather than tightening facility requirements for full-time personnel.

As a precaution for patient eligibility, scanning is currently not allowed if MR-conditional leads or devices from different manufacturers are used. This is because manufacturers test MRI scanning using combinations of their own leads and batteries and not in combination with other manufacturers' products. Therefore, when previously implanted atrial and ventricular leads have different manufacturers, MRI remains contraindicated regardless of replacement with MRI-conditional devices. As MRI may be absolutely essential to allow patients to make decisions about the treatment of their disease, a more flexible approach is desired in the future. The presence of leads that are no longer used or residual leads that are broken also makes MRI scanning unfeasible, as old leads remaining in the body but unconnected to batteries may produce heat during MRI. The safety of MRI in such situations has not been established, so it should be avoided (21).

Taken together, the above factors complicated decision-making for both patients and healthcare providers. At present, MRI examinations in patients with MRI-conditional devices can be performed only at certified facilities. If implanting facilities have MRI equipment in place but do not meet various requirements, they cannot obtain certification and therefore cannot provide MRI examinations. Thus, the situation in Japan differs greatly from that in Western countries. In the study conducted at our hospital, the risk due to human error during scanning and the need for measures to ensure the correct mode setting is used were recognized. However, it seems unlikely that potentially life-threatening events due to malfunction of the device could occur in cases where general procedures for scanning are followed. Flexible approaches with regard to eligible patients or eligible facilities are desirable, making patient wellbeing the highest priority. This should narrow the gap between Japan and Western countries, even if the reduction is only slight.

Conclusion

Our review of patients implanted with MR-conditional CIEDs did not identify any problematic cases that resulted in actual, significant harm, but incidents did occur that potentially could have led to major harm due to MRI scanning with the settings mistakenly remaining unchanged. A patient's intrinsic pulse rate or subjective symptoms may change before and during scanning, even if there are no problems with settings before scanning. Monitoring the patient with an electrocardiogram or pulse oximeter during MRI is therefore desirable.

The most common site of MRI scanning in patients with an MR-conditional CIED was the head, followed by the spine, abdomen, and heart in order. There will continue to be a high demand for MRI in cases of cardiovascular disease as well as orthopedic disorders where this modality is considered more useful than computed tomography.

Author's disclosure of potential Conflicts of Interest (COI).
Toshiko Nakai: Honoraria, Abbott Medical and Medtronic Japan.

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