Original Article

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# Cardiac Implantable Electronic Device Safety during Magnetic Resonance Imaging

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**Background and Objectives:** Although magnetic resonance imaging (MRI) conditional cardiac implantable electronic devices (CIEDs) have become recently available, non-MRI conditional devices and the presence of epicardial and abandoned leads remain a contraindication for MRIs.

**Subjects and Methods:** This was a single center retrospective study, evaluating the clinical outcomes and device parameter changes in patients with CIEDs who underwent an MRI from June 1992 to March 2015. Clinical and device related information was acquired by a thorough chart review.

**Results:** A total of 40 patients, 38 with a pacemaker (including epicardially located pacemaker leads) and 2 with implantable cardioverter defibrillators, underwent 50 MRI examinations. Among the patients, 11 had MRI conditional CIEDs, while the remaining had non-MRI conditional devices. Among these patients, 23 patients had traditional contraindications for an MRI: (1) nonfunctional leads (n=1, 2.5%), (2) epicardially located leads (n=9, 22.5%), (3) scanning area in proximity to a device (n=9, 22.5%), (4) devices implanted within 6 weeks (n=2, 5%), and (5) MRI field strength at 3.0 Tesla (n=6, 15%). All patients underwent a satisfactory MRI examination with no adverse events during or after the procedure. There were no significant changes in parameters or malfunctioning devices in any patients with CIEDs.

**Conclusion:** Under careful monitoring, MRI is safe to perform on patients with non-MRI conditional CIEDs, remnant leads, and epicardially located leads, as well as MRI-conditional devices. **(Korean Circ J 2016;46(6):804-810)**

**KEY WORDS:** Magnetic resonance imaging; Pacemaker, artificial; Defibrillators, implantable.

## Introduction

Magnetic resonance imaging (MRI) is currently a common and useful diagnostic tool in various clinical fields. MRI has been previously deferred by physicians in patients with a cardiovascular implantable electronic device (CIED), mostly because of a concern for a device malfunction from electromagnetic interference (EMI) and lead heating that may cause serious harm to the patient.[1] For decades, there have been debates about MRI safety issues in implanted cardiac electrical devices. Although MRI-conditional CIEDs are now widely available[2-5] patients with non-MRI conditional devices and specific contraindications may require an MRI examination. The aim of this study was to evaluate the safety of conducting an MRI on patients with CIEDs in variable conditions, including cases with a previously known contraindication for this procedure.[6-8]

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## Subjects and Methods

### Patients

We identified patients who underwent an MRI examination after a CIED implantation by searching our electronic medical record system and CIED implantation registry. We also identified 54 patients with epicardially located pacemaker leads, whether the pacemaker generator was connected or not, by searching the cardiac surgery database. From June 1992 to August 2015, 2161 patients underwent a CIED implantation including surgical lead implantation at Asan Medical Center. Of these cases, 711 patients underwent an MRI examination also at our institution. The majority (n=650) of these patients had the MRI examination before the CIED implantation, and the remaining 61 patients received an MRI after the CIED implantation. Among these 61 patients, 19 patients who had a CIED extraction (due to infection in four cases, and a heart transplantation in the remaining cases) before the MRI examination; two patients who underwent an MRI in another hospital were excluded from the analysis. Ultimately, 40 patients with a CIED in whom 50 MRI examinations were performed were included in this study. Among the 40 patients, 9 patients had epicardially located leads. Four patients had epicardial leads; four 4968 CapSure Epi leads (Medtronic, Minneapolis, MN, USA). While in 5 prophylactic lead implanted patients, endocardial leads (Tendril® ST Optim®, St. Jude Medical, St. Paul, MN, USA) were screwed directly on the ventricle or was screwed or surgically sutured directly into the right ventricle through the atrium and tunneled into the abdominal pocket without a generator connection and were also classified as epicardially located leads. Clinical and device-related information was acquired by a thorough chart review. Device-related data included the type and mode of the device, manufacturer, generator model, lead model, and lead parameter before, immediately after, and 3 months after the index MRI. MRI-related data included the anatomical region, device indwelling days until the index MRI, and the Tesla of the MRI. Patient-related data included the underlying disease indicator for device implantation and pacemaker dependency. Any adverse clinical event or device malfunction after the MRI was checked within 48 hours and again 3 months later. Informed consent was obtained from all the study patients before the index MRI. Our study protocol was approved by the Institutional Review Board of the Asan Medical Center (Seoul, Korea; IRB No. S2015-1547-0001).

### Device interrogation and programming

With physician supervision, nurses certified to test cardiac devices examining each device immediately before and immediately after the MRI (within 48 hours), as well as during follow-up clinic visits from 3 to 6 months after the procedure. The technical and functional status of the pacemaker system was evaluated using battery voltage, pacing mode, lead capture thresholds, sensing signal amplitudes, and lead impedance. Pacemaker dependence was determined by a review of the medical records and an electrocardiogram (ECG) without pacing prior to the MRI. Pacemaker-dependency was defined by an intrinsic escape rhythm of <40 bpm and a percentage of pacing >80%. Pacemaker settings were then reprogrammed to a pacing-only mode (DOO, VOO), and all atrial anti-tachycardia functions of the device were turned off during the procedure. Implantable cardioverter-defibrillator (ICD) settings were programmed to a pacing-only mode (DOO, VOO) in pacemaker-dependent patients, and ventricular anti-tachycardia pacing and low- and high-voltage shocks were turned off. Patients were monitored for at least 10 minutes with the pacemaker in the passive mode before entering the MRI scanner. Following the MRI, all devices were re-examined and reprogrammed to their original settings, including re-initiation of all anti-tachycardia functions.

### Patient monitoring during the MRI

A cardiologist was present throughout the entire MRI. Heart rate and oxygen saturation were monitored continuously with an ECG and a pulse oximeter. Audio contact between the patient and physicians was maintained via an intercom system in non-sedated patients. Patients were asked to inform the physician of any discomfort during the procedure.

### Contraindications for an MRI

We defined contraindication for an MRI based on previous reports.[6-8] This group in our current study included patients with (1) an abandoned lead, (2) epicardially located leads, (3) a scanning area in proximity to the device (such as thorax area), (4) devices implanted within the previous 6 weeks, or (5) individuals who were subjected to an MRI field strength >1.5 Tesla.

### Statistical analysis

Statistical analysis was performed using R 3.1.1 statistical software (R Development Core Team Vienna, Austria). Categorical variables were described using frequencies, and continuous variables were reported as medians and inter-quartile ranges. A paired t-test and an analysis of variance (ANOVA) were used to compare continuous variables of the measured device's parameters (at baseline, immediately after the MRI, and 3 to 6 months later).

## Results

### Patient characteristics

A total number of 40 patients (20 women and 20 men) with a CIED who underwent 50 MRIs at our hospital were analyzed. These patients ranged in age from 17 to 83 years at the time of the MRI.


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The median device indwelling time was 936 days (range, 1-5550 days). The type of device was a permanent pacemaker in 34 patients, an ICD in 2 patients and a lead without a generator connection in 6 cases (5 prophylactic epicardially located leads and 1 remnant lead). Eleven devices (27.5%) were MRI conditional, while the remaining were non-MRI conditional devices. Thirty-four patients underwent a 1.5 T MRI, and the remaining 6 patients underwent a 3.0 T MRI. A brain MRI was the most frequently performed (21 patients, 25 MRIs), followed by a spine MRI (9 patients, 9 MRIs). The indication for a CIED implant was sick sinus syndrome, including preoperative tachycardia bradycardia syndrome in 20 patients (50%), complete degree atrioventricular (AV) block in 18 (45%) cases, and secondary prevention for ventricular arrhythmia in 2 patients (5%). Pacemaker dependency was observed in 15 patients (37.5%). In 38 (95%) patients, bipolar leads were implanted, and 75% were active fixation leads (Table 1).

**Table 1.** Baseline characteristics of the study population

| Baseline characteristics | Value |
|---|---|
| Total number of patients | 40 |
| Age (years) | 64 (17-83) |
| Types of cardiac arrhythmia | |
| Complete AV block | 18 (45%) |
| Sick sinus syndrome | 20 (50%) |
| Ventricular arrhythmia | 2 (5%) |
| Implanted mode of device | |
| DDD (R) | 21 (52.5%) |
| ICD | 2 (5%) |
| VDD | 3 (7.5%) |
| VVI (R) | 9 (22.5%) |
| Lead only | 6 (15%) |
| Epicardially located lead | 9 (22.5%) |
| Active fixation lead* | 30 (75%) |
| Remnant ventricular lead | 1 (2.5%) |
| Device indwelling time (days) | 936 (1-5550) |
| Polarity of the lead* (bipolar) | 38 (95%) |
| Pacemaker dependent, n | 15 (37.5%) |
| MR conditional device (leads), n | 11 (27.5%) |

*Denotes the number of the patients not the number of leads, because in a single patient leads of the same character were implanted. AV: atrioventricular, DDD: atrium & ventricle can both be paced; atrium & ventricle both sensed; pacing triggered in each, ICD: implantable cardioverter-defibrillator, VVI: ventricle paced, ventricle sensed; pacing inhibited, MR: magnetic resonance

### MRI examination of patients with an MRI-conditional pacemaker

Eleven MRIs were performed in 11 patients with an MRI-conditional pacemaker (9 Advisa MRI DR pacemakers [Medtronic, Minneapolis, MN, USA] and two Accent MRI pacemakers [St. Jude Medical, St. Paul, MN, USA]). None of the patients experienced an adverse clinical event, and no device or lead parameter change occurred either immediately after the MRI or three months later.

### MRI examination of patients with non-MR conditional pacemaker/ICD

In 23 patients with 21 pacemakers and 2 ICDs, 25 MRIs were performed. Among the 21 patients with a pacemaker, a pacemaker-dependent patient with an epicardial pacemaker underwent a brain MRI three times without any adverse event or parameter change. The remaining 20 patients with pacemakers underwent 12 brain MRIs, 3 spine MRIs, a pelvic MRI and 2 lower extremity MRIs. Two patients with an ICD underwent a brain MRI and a spine MRI, respectively. None of these patients experienced an adverse clinical event, and no device or lead parameter change occurred either immediately after the MRI or during follow up.

### MRI examination of patients with a known contraindication for this procedure

There were five contraindications against a MRI in 28 of our study patients, and in this group, 36 MRIs were performed overall, (Table 2) as described below.

*(1) Abandoned lead*

A patient with a remnant RV lead received a total of 8 MRIs (4 ankle MRIs and 4 brain MRIs) with no adverse clinical event. This patient had a remnant ventricular lead after a failed surgical and transvenous lead extraction due to infective endocarditis.

*(2) Epicardially located leads*

Four of the 9 patients with epicardially located leads were pacemaker-dependent and had epicardial leads. The other 5 patients had prophylactic pacemaker leads as described in method section that were implanted during tricuspid valve replacement and maze operation because of a high risk of pacemaker implantation based on preoperative tachycardia bradycardia syndrome. However, none of these patients required a pacemaker generator implantation after the surgery.

*(3) Scanning area in proximity to the device (such as the thorax area)*

Nine MRIs were performed in proximity to the device in 9 patients, including 5 thoracic spine MRIs and 4 heart MRIs. Three heart MRIs were performed in 3 patients, implanted with prophylactic epicardially

**Table 2.** Contraindicated cases for MRI in the study population

| | No. of cases | Organs for MRI | Description | Events |
|---|---|---|---|---|
| Abandoned lead | 1 | Ankle (4) | 8 MRI exam in one patient | None |
| | | Brain (4) | | |
| Epicardially located leads | 9* | Brain (7) | 5 prophylactic | None |
| | | Heart (3) | 1 case Brain ×3 | |
| MRI on trunk | 10* | Heart (4) | 3 prophylactic | None |
| | | T-spine (6) | | |
| 3.0 T MRI | 6 | Heart (1) | MRI-conditional device | None |
| | | Brain (4) | | |
| | | Knee (1) | | |
| <6 weeks implantation | 2 | Brain (2) | 1 prophylactic, both acute CVA, 1 MRI-conditional device | None |

*Overlapping contraindication cases (e.g., heart MRI in epicardially located leads). MRI: magnetic resonance imaging, T: Tesla, CVA: cerebrovascular accident

**Table 3.** Characteristics of 3.0 Tesla MRI cases

| No | Implanted Age/Sex | Diagnosis | Days from implant to MRI | Device | MRI |
|---|---|---|---|---|---|
| 1 | 8/M | CAVB | 4005 | Epicardial VVI<br>lead: 4968 CapSure Epi leads (Medtronic, Minneapolis, MN, USA)<br>Generator: Identity XL (St. Jude Medical, St. Paul, MN, USA) | Brain |
| 2 | 58/M | SSS (TBS) | 3013 | VVI (Thera DR, Medtronic, Minneapolis, MN, USA) | Knee |
| 3 | 54/F | SSS (TBS) | 3236 | VVIR (Regency SR, St. Jude Medical, St. Paul, MN, USA) | Brain |
| 4 | 72/F | SSS | 59 | VVI (Accent MRI, St. Jude Medical, St. Paul, MN, USA) | Heart |
| 5 | 52/F | Epicardially located lead | 67 | Tendril® ST Optim® (St. Jude Medical, St. Paul, MN, USA) | Brain |
| 6 | 72/M | Epicardially located lead | 3 | Tendril® ST Optim® (St. Jude Medical, St. Paul, MN, USA) | Brain |

MRI: magnetic resonance imaging, CAVB: complete atrioventricular block, SSS: sick sinus syndrome, TBS: tachycardia-bradycardia syndrome

located leads, and one of the patients underwent a 3.0 Tesla MRI.

*(4) Devices implanted within 6 weeks*

In 2 patients, MRIs were performed less than 6 weeks of implantation, because of an acute cerebrovascular attack that occurred within 3 days of device implantation (1 day and 3 days after each implantation, respectively).

*(5) MRI field strength >1.5 Tesla*

In 6 patients, a 3.0 Tesla MRI was performed: 4 brain MRIs, one heart MRI, and one knee MRI (Table 3). Among them, one patient with prior mitral valve replacement and MRI-conditional pacemaker underwent heart MRI.

### Safety and device functions

There was a single minor device-related event recorded in one of our current patients with a non-MRI conditional pacemaker, which was a non-sustained ventricular tachycardia (which turned out to be noise) during a brain MRI. However, there was no adverse clinical outcome in this patient. There were no immediate or delayed adverse clinical events in any of the study patients. There were also no parameter changes or malfunctions of the implanted devices (Table 4). Even in patients with a contraindication for MRI, such as (1) an abandoned lead, (2) epicardially located leads, (3) scanning area in proximity to the device (such as the thorax area), (4) devices implanted within 6 weeks, or (5) underwent an MRI field strength >1.5 Tesla, no clinically adverse events or device parameter fluctuations occurred.

## Discussion

The findings of our current study demonstrated that (1) MRI studies in patients with CIEDs, including both non-MRI conditional

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**Table 4.** Changes in device parameters

| | Pre-MRI | Immediately Post-MRI | 3 months Post-MRI | p |
|---|---|---|---|---|
| Battery voltage (V) | 2.88 (2.60-3.10) | 2.80 (2.63-3.09) | 2.84 (2.67-3.00) | 0.48 |
| P wave amplitude (mV) | 2.50 (0.4-5.8) | 2.5 (0.2-5.0) | 2.80 (0.4-6.0) | 0.53 |
| Atrial capture threshold at 0.40 ms (V) | 0.75 (0.4-2.5) | 0.7 (0.3-2.5) | 0.75 (0.5-2.0) | 0.45 |
| Atrial lead impedance (Ω) | 437 (290-909) | 436 (318-532) | 443 (324-534) | 0.18 |
| R wave amplitude (mV) | 8.75 (3.0-20) | 9.8 (2.5-22.4) | 10.1 (2.8-22.4) | 0.84 |
| Ventricular capture threshold at 0.40 ms (V) | 1.0 (0.5-3.8) | 0.8 (0.5-2.8) | 1.0 (0.5-1.75) | 0.19 |
| Ventricular lead impedance (Ω) | 571 (241-1175) | 547 (257-1547) | 527 (157-1177) | 0.50 |

MRI: magnetic resonance imaging

**Table 5.** Reported studies of MRI in cardiac implantable electronic device

| Publication | Design | No. of patients | Main findings |
|---|---|---|---|
| MRI with MRI-unsafe pacemakers | | | |
| Sommer et al.[10] | Single-centre prospective | 82 | Increased capture threshold post MRI at 1.5 T. |
| Gimbel et al.[9] | Single-centre retrospective | 5 | There was no adverse events associated with MRI. |
| Pulver et al.[15] (+epicardial leads) | Single-centre retrospective | 8 | Minimal changes (not felt to be clinically important) in device parmeters without clinical significance. |
| Nazarian et al.[8] | Single-centre prospective | 31 | No abnormalities during 1.5-T MRI or 99 days' follow-up. |
| MRI with MRI-conditional pacemakers | | | |
| Gimbel et al.[16] | Multicentre prospective | 263 | No MRI-related complications were reported during or after MRI. |
| MRI with ICD devices | | | |
| Nazarian et al.[8] | Single-centre prospective | 24 | No abnormalities during 1.5-T MRI or 99 days' follow-up. |
| Mollerus et al.[17] | Single-centre prospective | 22 | MRI at 1.5 T was associated with decreased sensing amplitudes and pace impedances. |
| Keller et al.[2] n (S-ICD) | Single-centre prospective | 15 | No evidence of device malfunction was observed. |
| Bailey et al.[4] | Multicentre prospective | 226 | No adverse events occurred, resulting in an SADE-free rate of 100.0%. |
| Kypta et al.[5] | Single-centre prospective | 18 | Lead impedances after the MRI scan were significantly lower as compared with baseline values without clinical significance. |
| Wollmann et al.[18] | Single-centre prospective | 36 | In seven patients, a >100% increase in ventricular PCT was measured, this was maintained till the end of 15-month follow-up in only two patients. |
| MRI with abandoned leads | | | |
| Higgins et al.[19] (+ICD leads) | Single-centre retrospective study | 19 | There was no adverse events associated with MRI. |
| MRI with CRT (LV) leads | | | |
| Sheldon et al.[20] | Multicentre prospective | 40 | There were no overall differences in pre- and post-MRI interrogation of LV lead. |

MRI: magnetic resonance imaging, ICD: implantable cardioverter-defibrillator, CRT: cardiac resynchronization therapy, LV: left ventricular, PCT: pacing capture threshold, SADE: serious adverse device effect

and MRI conditional devices, were safe under close medical supervision during the examination; and (2) 57.5% of the patients we analyzed with a contraindication to an MRI had no adverse events during the procedure or after the 3-month follow-up.

Several studies regarding the safety of an MRI in CIED patients have been performed (Table 5),[8-12] though many concerns still remain about performing an MRI in this particular group of patients, based on the reports of fatalities from late 1980s to the 2000s with older devices.[1,13,14] However, as in Table 5, MRIs were performed safely without serious adverse effects in various conditions of CIED; MRI-unsafe pacemakers,[8-10,15] MRI-conditional pacemakers,[16] ICD devices,[2,4,5,8,17,18] abandoned leads,[19] and CRT devices.[20]

Disturbances in the CIED circuitry or behavior attributable to electromagnetic radiation emitted from an external source are known as EMI.[21] EMI might lead to transient oversensing, thus pacemaker inhibition, or cause asynchronous pacing and inhibit tachycardia therapies in ICDs.[22]

There is no definite safety guideline to perform a 3.0 Tesla MRI in CIED patients, but experts recommend MRI performance at a lower SAR (2 W/kg). Investigations support a linear relationship between SAR and heating within a given type of MRI system. A key variable in determining the patient heating potential in an MRI scanner is the power absorbed per unit mass of tissue, which is the SAR. Mollerus et al.[17] reported the outcome of scanning CIED patients without limitations on the peak SAR. However, it remains to be validated by further by a large number of patients.

Even though EMI and adjacent tissue heating during an MRI remains a concern in patients with epicardial leads, there were no untoward clinical events in our study as in the study by Pulvar et al.[15] who reported a safe performance of MRIs in patients with congenital heart disease and predominantly epicardial leads.

Nine patients in our study received an MRI close to the CIED implanted site without experiencing an adverse event. In our current study patients, the MRI field included the heart and thoracic spine. Although there have been promising results in some earlier reports,[8,18] the safety of performing an MRI in proximity to a CIED has still not been clarified, especially with older leads and devices.

While the changes in functional lead performance *in vivo* can be measured, the effect and degree of nearby tissue heating along with the non-functioning lead might not be examined objectively, as was done in our current study. Higgins et al.[19] have also reported a safe MRI performance in patients with non-functioning leads. As mentioned in other previous studies, there are various heating effects among leads in diverse conditions.[6,23] Even at the same lead length, varied lead heating responses have been noted. *In vitro*, the lead tip temperature increment is profound in bipolar leads with active fixed leads. However, this may not be the same *in vivo* where the lead tip heating response based on the lead configuration is an intricate issue that it is hard to predict.

Whether the patient is pacemaker-dependent or not is also a critical issue in terms of the safety of conducting an MRI. Defining pacemaker dependency is arbitrary depending on studies.[22,23] We here defined a patient as pacemaker-dependent if the intrinsic escape rhythm was <30 bpm with the percentage of pacing between interrogation periods being >80%.

Our CIED follow-up and programming protocol prior to an MRI was basically similar to previous reported protocols:[24,25] 1) a baseline measurement of all device- and lead-related parameters; 2) in pacemaker-dependent patients, we changed the mode to (AOO, VOO, or DOO); and 3) in ICD patients, we turned off the therapy mode and changed to the VOO mode. During the MRI, a cardiologist performed continuous patient monitoring. After the MRI, we measured the device and lead parameters along with an event check. If no significant change or event occurred, the program was restored to the pre-MRI condition. With this protocol, an MRI was safe and feasible in CIED patients.

Currently, an increasing number of cardiovascular devices have been approved for an MRI by regulatory authorities. The main device-specific considerations are concerned with the field strength of the scanner (mostly 1.5 T), the permitted scan zone (no thoracic exclusion zone), scan duration (<30 to 40 minutes), and specific SAR (<2.0 W/kg). In November 2011, an ICD system was approved for the first time as MRI-conditional for a 1.5 T. Today, even a 3.0 T MRI is possible with several devices, and the first cardiac resynchronization therapy with defibrillation systems have gained approval for use with a MRI in Europe and the United States.[5,20,26]

### Limitations

This study had several limitations of note. First, this was a single center retrospective study. Second, we studied a relatively small number of patients and generalized our findings to all CIED implanted patients. Third, in the same vein, our patients showed a diversity that also reflects the limitations of a retrospective study, but, we believe this is also a strength of the study reflecting the reality in practice. Fourth, in patients with prophylactic epicardially located leads, lead-related complications or heating-related variables could not be assessed. Cardiac biomarkers, which represent cardiac injury were not measured in this study population.

### Conclusions

Traditional contraindications for MRI include an ICD, non-MRI conditional CIED, or remnant lead, proximity of the MRI to the CIED position, a device implanted within 6 weeks, and epicardially located leads. However, even in traditional contraindicated patients, performing an MRI without adverse clinical events is feasible. MRIs did not affect the function of devices, and no lead-induced injuries occurred. Although it is cautious to conclude that performance of an MRI in CIED is safe, but we have learned from our own experiences in conducting MRIs on patients with various CIEDs that the procedure can generally be performed safely under interrogation with careful monitoring, whether the device is MRI conditional or not.


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