Utilization and programming of an automatic MRI recognition feature for cardiac rhythm management devices

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BACKGROUND Cardiac implantable electronic devices (CIED)—ie, pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronization therapy devices—have recently been designed to allow for patients to safely undergo magnetic resonance imaging (MRI) when specific programming is implemented. MRI AutoDetect is a feature that automatically switches CIED's programming into and out of an MR safe mode when exposed to an MRI environment.

OBJECTIVE The purpose was to analyze de-identified daily remote transmission data to characterize the utilization of the MRI AutoDetect feature.

METHODS Home Monitoring transmission data collected from MRI AutoDetect–capable devices were retrospectively analyzed to determine the workflow and usage in patients experiencing an MRI using the MRI AutoDetect feature.

RESULTS Among 48,756 capable systems, 2197 devices underwent an MRI using the MRI AutoDetect feature. In these 2197 devices, the MRI AutoDetect feature was used a total of 2806 times with an average MRI exposure of 40.83 minutes. The majority (88.9%) of MRI exposures occurred on the same day as the MRI AutoDetect programming. A same day post-MRI exposure follow-up device interrogation was performed 8.6% of the time. A device-related complaint occurred within 30 days of the MRI exposure in 0.25% of MRI exposures using MRI AutoDetect but with no adverse clinical outcome.

CONCLUSION As a result of automation in device programming, the MRI AutoDetect feature eliminated post-MRI device reprogramming in 91.4% of MRI exposures and, while less frequent, allowed for pre-MRI interrogations prior to the day of the MRI exposure—reducing resource utilization and creating workflow flexibility.

KEYWORDS Automation; Defibrillator; Device programming; Magnetic resonance imaging; MRI-conditional; MRI detection; Pacemaker

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Introduction

Patients with permanently implanted cardiac pacemakers and implantable cardioverter-defibrillator (ICD) / cardiac resynchronization therapy defibrillators (CRT-D) have historically been contraindicated to magnetic resonance imaging (MRI). Strong static, gradient, and radiofrequency fields used to create the MR images can be detrimental to pacemaker and ICD function and potentially cause harm to patients undergoing MRI examinations.[1] Various studies have shown that MRI may be hazardous in patients with older generations of implanted pacemakers and ICD/CRT-Ds.[2,3] Recent design changes in pacemakers, ICD/CRT-Ds, and corresponding leads allow for MRIs to be performed safely under specific conditions.[4–6] Individual components and combined systems undergo rigorous testing before being approved as MRI conditional, and specific programming during MRI, including utilization of an MRI-specific pacing mode and temporary disabling of ICD therapies, is designed to reduce risks to patients and damage to the system components. Despite a growing list of MRI-conditional medical devices, barriers such as lack of training of medical personnel and logistical difficulties still exist.[7–9] Further advancements have been developed to reduce the burden of programming MRI-conditional devices into and out of an MRI safe mode. The MRI AutoDetect is one of these advancements.

The MRI AutoDetect feature, which received FDA approval on March 24, 2017 after extensive bench testing, allows for the patient's device to be programmed into an

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KEY FINDINGS

- An automatic magnetic resonance imaging (MRI) detecting feature, MRI AutoDetect, eliminated post-MRI device reprogramming in 91.4% of MRI exposures.
- MRI AutoDetect was programmed 71.3% of the time compared to traditional MRI programming.
- A device-related complaint occurred within 30 days of the MRI exposure in 0.25% of MRI exposures using MRI AutoDetect but with no adverse clinical outcome.

automatic MRI detecting mode at the preliminary examination up to 14 calendar days prior to the MRI scan. Traditionally, same-day interrogations, pre-MRI and post-MRI, are required for programming into and out of an MRI safe mode; whereas the MRI AutoDetect feature enables a sensor to automatically recognize an MRI field, converts the programming to a prespecified MRI safe mode when the patient enters an MRI field, and reverts the settings back to optimal therapy programming when the patient exits the MRI field. The prespecified MRI safe mode programming options available when using the MRI AutoDetect feature are identical to the programming options available when manually programming the device into an MRI safe mode without using MRI AutoDetect. These parameters include basic pacing rate, amplitude, and pulse widths for each lead; asynchronous pacing modes (recommended for pacing-dependent patients) or turning pacing off; and left ventricular pacing polarity (for CRT devices). For ICD/CRT-D devices, tachycardia therapy is disabled during MRI field detection, but is automatically re-enabled upon confirmation of MRI field exit. Patient prerequisites, such as contraindications as well as the MRI scanner conditions and restrictions, are the same as traditional manual MRI safe mode programming and need to be considered when using the MRI AutoDetect feature. A remote monitoring follow-up may be performed and transmitted following the MRI for patients with a registered and activated remote monitoring device.

This automation in programming removes the previous requirement of same-day pre-MRI and post-MRI in-office device interrogations (Figure 1). Same-day programming using MRI AutoDetect can still be performed, but eliminating the traditional requirement for same-day programming sessions helps alleviate logistical complexities, such as scheduling of qualified personnel required for programming these devices, and also reduces patient contact while still delivering the same level of patient care.

Data from the Home Monitoring system on utilization and programming in real-world clinical practice of the automatic MRI recognition feature, MRI AutoDetect, are presented here.

Methods

Study design

This retrospective analysis was conducted utilizing Real World Evidence methodology, which has been approved by an institutional review board granting waiver of informed consent and a full waiver of HIPAA authorization owing to the use of retrospective and de-identified data. Data for this analysis were collected through the Home Monitoring system

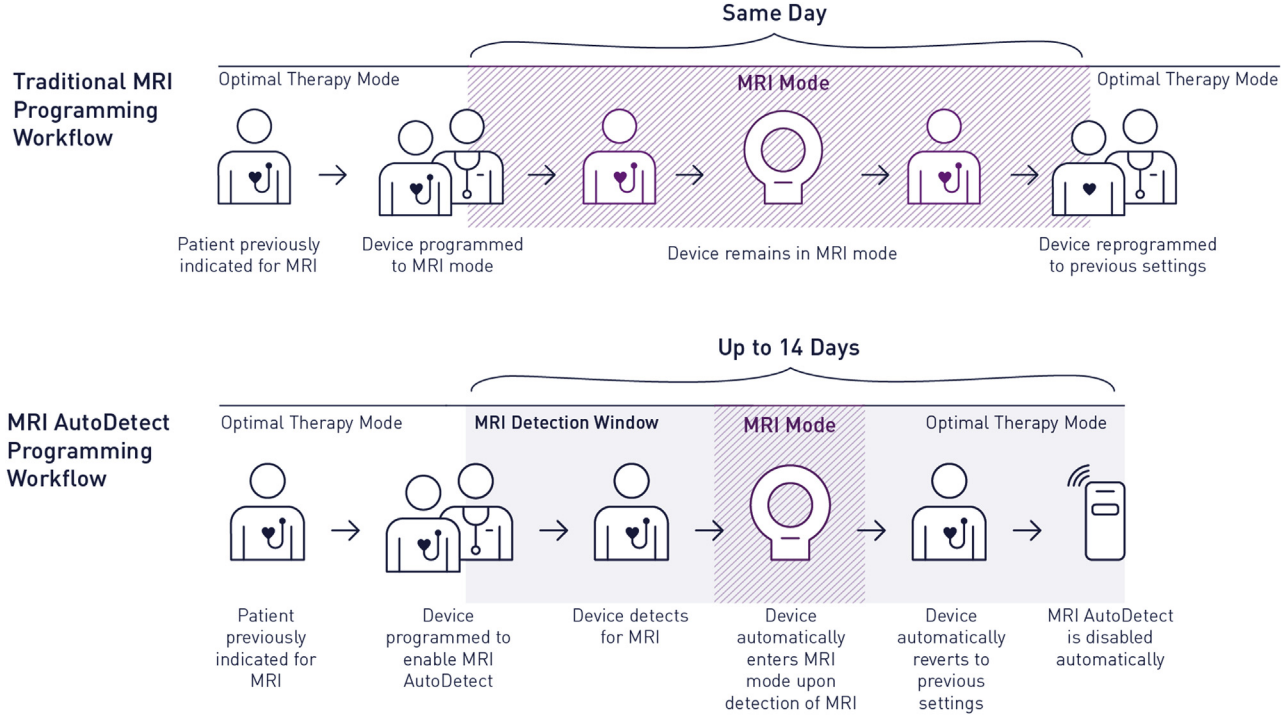

Figure 1 Comparison of traditional magnetic resonance imaging (MRI) programming workflow with the MRI AutoDetect programming workflow.

(BIOTRONIK SE & Co KG, Berlin, Germany) at time of first approval for approximately 2.5 years from March 24, 2017, to November 1, 2019 via transmissions sent by the MR conditional generators through an FDA-approved CardioMessenger II or CardioMessenger Smart. These transmissions included daily and event-triggered data from the patient's device. Specific data included the device status, programmed setting, diagnostics, and stored events, including the date and time the device entered and exited an MR field. In addition, the data transmitted via the Home Monitoring system included the permanent programmed settings during daily transmission as well as collected data such as dates of MRI AutoDetect activation and MR field detections.

Study population

The population analyzed consisted of all US market–released MRI-conditional systems capable of MRI AutoDetect (BIOTRONIK SE & Co KG, Berlin, Germany) and registered with Home Monitoring in the United States. To be considered an MRI-conditional system, a pulse generator labeled MR conditional must be connected with respective leads that are separately labeled MR conditional. This population was retrospectively assessed through a de-identified Home Monitoring database following an MRI mode, either manual or MRI AutoDetect, being programmed. Patients were characterized as potentially pacing dependent if they had a ventricular pacing percentage of 100% prior to the MRI scan.

Determination of MRI exposure

MR-conditional devices with the MRI AutoDetect function have a built-in sensor that recognizes the fields of an MRI scanner and switches automatically into the predefined MRI mode if the patient is in or near the MRI scanner. Typically, the magnetic sensor in MRI AutoDetect–capable devices will activate when the magnetic flux density exceeds 10 mT; therefore, patients are instructed to avoid close proximity to significantly larger than commonly observed magnetic fields of greater than 1 mT while the MRI AutoDetect feature is enabled. The device automatically switches back into the permanently programmed parameters following a 1-minute hysteresis period after the patient exits the MRI scanner. The MRI AutoDetect function is active for a maximum of 14 calendar days (programmable) from the day it is programmed and allows for multiple MRI scans during this period. The 14-calendar-day window was designed as a safety precaution to minimize risk while still allowing for workflow flexibility and will likely be less restrictive in future iterations. The programming expires at the end of the selected day, and therefore the device does not need to be reprogrammed after the MRI scan. Once the programmed time has expired, the device will no longer change to a predefined MRI program if it detects an MRI field (Figure 1). When a subject undergoes an MRI using the MRI AutoDetect feature, the date of the MRI exposure is logged into the device's memory and is sent during the next Home Monitoring transmission.

The combination of the MRI AutoDetect programmed settings and the dates of MRI field detections were used to distinguish subjects who had entered an MRI field using the MRI AutoDetect feature and those who were programmed into a manual MRI safe mode. Home Monitoring transmissions rely on patient compliance to transmit daily. If there was a Home Monitoring transmission gap post-MRI, the next successful Home Monitoring transmission was utilized for analysis. If a system had multiple MRI exposures during a continuous MRI AutoDetect activation, the first available MRI exposure date was used to calculate the mean duration from MRI AutoDetect activation to MRI exposure. When activated, the MRI AutoDetect feature remains on until 23:59h of the programmed expiration date unless the feature was manually programmed off during a device interrogation. In order to address potential gaps owing to patient noncompliance in Home Monitoring transmissions, MRI AutoDetect activations were considered to be deactivated automatically unless any device interrogations prior to the programmed MRI AutoDetect expiration date are known and subsequent Home Monitoring transmissions indicated the MRI AutoDetect feature is no longer active.

Statistical analysis

Continuous variables were reported as means with standard deviation, while categorical variables were presented as frequencies with percentages. All statistical analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC).

Results

Study population

Between March 24, 2017, and November 1, 2019, 48,756 capable systems in the United States were evaluated. An MRI mode was activated (programmed) in 3113 systems (6.4% of total systems), with the MRI AutoDetect feature used in 2291 (71.3% of systems activated) and manual activation in 822 (28.7%). In some of these 2291 systems, MRI AutoDetect was activated more than once, for a total of 2821 activations. A total of 2806 of the MRI AutoDetect activations resulted in at least 1 MRI exposure (Table 1). Of these patients, 316 (11.3%) exhibited a ventricular pacing percentage of 100% and were considered potentially pacing dependent.

MRI AutoDetect utilization

Of the 2291 systems with MRI AutoDetect activated, 2197 (95.9%) systems experienced an exposure to an MRI environment (447 ICD/CRT-D systems, 1750 pacemaker/CRT-P systems; Table 1). The mean programmed duration of all MRI AutoDetect activations is 12.8 days, indicating that most MRI activations are programmed to the maximum 14-calendar-day duration. Time from activation to MRI exposure is 0.46 days on average, as a majority (88.9%) were programmed to the MRI AutoDetect feature on the

Table 1 MRI AutoDetect utilization

MRI AutoDetect–capable ProMRI system		MRI AutoDetect activations, n (%)	Programmed duration of MRI AutoDetect, mean (SD), days	MRI exposures with MRI AutoDetect, n (%)	MRI AutoDetect activation to MRI exposure, mean (SD), days	MRI exposure time with MRI AutoDetect, mean (SD), min
ICD/CRT-D	Systems	476 (20.8)	12.65 (4.4)	447 (20.3)	0.35 (1.4)	37.12 (22.7)
	Exposures	561 (19.9)		539 (19.2)		
Pacemaker/CRT-P	Systems	1815 (79.2)	12.83 (4.2)	1750 (79.7)	0.49 (1.6)	41.65 (19.5)
	Exposures	2260 (80.1)		2267 (80.8)		
Total	Systems	2291 (100)	12.80 (4.2)	2197 (100)	0.46 (1.6)	41.2 (20.4)
	Exposures	2821 (100)		2806 (100)		

CRT-D = cardiac resynchronization therapy-defibrillator; CRT-P = cardiac resynchronization therapy-pacemaker; ICD = implantable cardioverter-defibrillator; MRI = magnetic resonance imaging.

same day as the MRI procedure. The mean MRI exposure time using MRI AutoDetect is 40.83 minutes.

Of the 2821 MRI AutoDetect activations, 101 (3.6%) resulted in manual deactivations while 96.4% of MRI AutoDetect activations remained programmed on for the programmed duration and allowed to automatically deactivate. Post-MRI exposure in-office follow-up device interrogations were not performed the same day as the MRI exposure 91.4% of the time (Figure 2). A total of 1966 (70.1%) of all MRI exposures using MRI AutoDetect had an in-office follow-up device interrogation greater than 30 days after the MRI exposure. Every patient had a successful remote monitoring transmission following an MRI, but in 5 cases (0.2%) an in-office interrogation following the MRI exposure had not been completed and therefore was considered ongoing at the time of the data cutoff.

MRI AutoDetect safety

Complaint data from Medical Device Reporting were reviewed for all 2197 systems that experienced an MRI with the MRI AutoDetect feature. A total of 7 non–infection generator–related complaints (incidence rate of 0.25%) occurring within 30 days of the MRI exposure were reported from a total of 2806 MRI exposures using the MRI AutoDetect feature. Of these, 4 complaints appear unrelated to the MRI AutoDetect feature, including a nonsustained ventricular tachycardia recording due to external noise near the same time as the MRI scan (n = 1); irregular pacing during laser lithotripsy procedure (n = 1); thoracic impedance trend no longer transmitting, requiring reset to statistics (n = 1); and active radiofrequency session during MRI scan (n = 1). The relation of MRI AutoDetect to the remaining 3 complaints was less clear. Upon review, it was determined that the following 2 complaints were most likely attributable to the post-MRI scan interrogation occurring prior to the device completing the 1-minute hysteresis period: MRI mode still active shortly after MRI completed (n = 1) and time and date stamp of MRI not populating immediately after MRI scan (n = 1). The remaining complaint (delay in MRI mode activating, n = 1) was considered to be possibly due to the MRI AutoDetect feature; however, the relation cannot be confirmed, as the device was not explanted and further analysis was not possible. There were no adverse clinical outcomes related to any of these 7 events.

Discussion

This analysis characterizes the usage rate and workflow of the automatic MRI recognition feature, MRI AutoDetect. The 71.3% usage rate of MRI AutoDetect compared to traditional MRI programming suggests that MRI

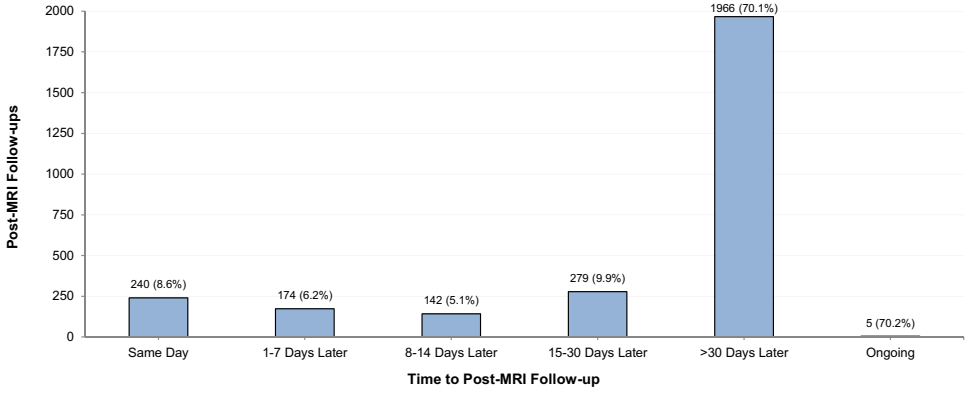

Figure 2 First follow-up post–magnetic resonance imaging (MRI) exposure using MRI AutoDetect. This graph displays the distribution of time (in calendar day changes) until the first in-office follow-up device interrogation occurs following an MRI using MRI AutoDetect. The category of "Ongoing" indicates that a follow-up interrogation did not occur before the data cutoff date.

AutoDetect is preferred by a majority of clinicians when given the option. In all but 15 cases, the programming of MRI AutoDetect resulted in an MRI exposure. Among 48,756 capable systems, the MRI AutoDetect feature was used a total of 2806 times with an average MRI exposure of 40.83 minutes, with 88.9% of MRI exposures occurring on the same day as the MRI AutoDetect programming. The high percentage of same-day MRI AutoDetect programming may suggest that MRI safe mode programming was not planned until the need for the patient's MRI occurred or that workflow adoption of the feature has yet to be fully realized. While the results indicate that the wider pre-MRI safe mode programming window was not taken advantage of, the feature did provide post-MRI programming relief, with a same-day post-MRI exposure follow-up device interrogation rate of 8.6% of the time. The low percentage of same-day post device interrogations suggests that remote monitoring follow-ups using the post-MRI automatic remote transmission were preferred to in-office interrogations in order to assess the device system for any potential adverse effects caused by the MRI scan. A device-related complaint occurring within 30 days of the MRI exposure presented in 0.25% of MRI exposures using MRI AutoDetect, of which none had a negative or adverse clinical outcome.

In standard MRI study protocols, before an MRI study can be scheduled, a radiologist must verify the patient has an MRI-conditional system with no contraindications (such as abandoned or fractured leads) and then a cardiologist must provide an order that the device be programmed to an MRI-conditional mode.[8] If the appropriateness of the MRI study request for the patient is met, the device will be interrogated by personnel with device expertise prior to the MRI, an MRI scan will be performed by an MRI technologist with a clinician monitoring the patient's heart rate throughout, and the device will be interrogated again by electrophysiology personnel after the MRI.[8] This division of responsibilities and tasks between multiple individuals complicates the MRI procedure.

Eliminating the need for 2 programming sessions on the day of MRI for MR-conditional pacemaker or ICD, 1 session to program MRI mode on and 1 to program the device out of MRI mode and back to original programmed settings, has many benefits not quantified in this study. For one, the feature reduces the burden and infrastructural requirements for medical centers by allowing the pre–MRI mode programming session to occur up to 14 calendar days prior to MRI and eliminating the need for a post-MRI interrogation session to program the device out of MRI mode.[6] This simplification and reduction in resources is expected to result in cost savings. MRI AutoDetect may also act as a safety net in eliminating the possibility of device personnel failing to program the patient out of MRI mode following the MRI exposure. This is especially true for ICD patients, as antitachycardia therapies are disabled during MRI mode. Furthermore, potential risks of MRI AutoDetect appear to be minimal owing to the low incidence of device complaints around the time of MRIs using the automation feature and the absence of any adverse clinical outcomes.

Limitations

Owing to the retrospective nature of this analysis, there was no ability to gain insight into reasons manual programming of an MRI mode was done instead of using MRI AutoDetect or why the device was manually programmed out of MRI AutoDetect vs letting the feature automatically expire on the programmed expiration date. Assessments from patients and of radiology personnel's comfort level with using the MRI AutoDetect feature were not feasible for this analysis. Although MRI data collected from the devices were stored and sent during the next Home Monitoring transmission, data from patients that did not transmit after an MRI could not be analyzed; and while most likely an infrequent occurrence, multiple MRIs occurring between Home Monitoring transmissions may not have been identified. The characterization of potential pacing-dependent patients was limited to pre-MRI ventricular pacing percentage and did not rule out presence of atrioventricular block, short atrioventricular programming by the clinician, or forced biventricular pacing for CRT devices. Owing to the European Union's General Data Protection Regulation law, analysis was restricted to United States data only. Lastly, identifying complications associated with the MRI AutoDetect feature was limited to reported complaints within 30 days of the MRI scan and therefore may be underreported.

Future directions

The MRI AutoDetect feature allows for patients to safely enter an MRI environment up to 14 calendar days of programming this feature on. As the MRI sensor is sensitive and sophisticated enough to prevent the device from switching into an MRI mode inappropriately in all but the most unique of environments, the feature itself acts as a fail-safe for inappropriate or negligent programming of an MRI mode prior to MRI exposure. The mean programmed duration of the feature was 12.8 days, indicating that the maximum 14-calendar-day detection window was programmed in the majority of cases. As the feature requires low power consumption (no recognizable reduction in lifetime of the device, according to bench testing), the next step would be to remove the 14-calendar-day window restraint. As noted above, this was originally put in place as a safety precaution, but with the proven safety and utility of the feature this time limitation will be reevaluated. This has the potential to relieve clinical centers of even more scheduling burden of device experts as well as increase safety and prevention of potential emergent MRI exposures without the need of reprogramming the device. It is expected that as MRI AutoDetect feature usage increases and education on the MRI AutoDetect feature is expanded, the number of same-day pre-MRI programming sessions will decrease and

traditional manual MRI programming will continue to decrease.

Conclusion

As a result of automation in device programming, the MRI AutoDetect feature eliminated post–MRI device reprogramming in 91.4% of MRI exposures and, though less frequent, allowed for pre-MRI interrogations to occur prior to the day of the MRI exposure. Additionally, only 0.25% of MRI exposures using the MRI AutoDetect feature had a device-related complaint within 30 days of the MRI, none of which resulted in adverse clinical outcomes. These results demonstrate a more flexible MRI workflow compared to same-day pre-MRI and post-MRI interrogations required for traditional MRI safe mode programming, while still providing the same level of patient care and safety, and presenting the opportunity for cost savings from the reduction in resources traditionally needed for a patient with a cardiac implantable electronic device to safely undergo an MRI scan.

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Disclosures

Steven Mullane, Crystal Miller, Camden Harrell, and Dr David Hayes are employed by BIOTRONIK Inc. Dr Kyle Michaelis has no conflict of interest to disclose. Dr Charles Henrikson and Dr Sei Iwai have been involved with BIOTRONIK clinical studies as principal investigators and clinical events committee members.

Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

The institutional review board granted waiver of informed consent and a full waiver of HIPAA authorization owing to the use of retrospective and de-identified data.

Ethics Statement

This retrospective analysis was conducted utilizing Real World Evidence methodology, which has been approved by an institutional review board. The research reported in this study adhered to the guidelines set forth by the Office of Human Research Protection that is supported by the U.S. Department of Health and Human Services.

References

1. Indik JH, Gimbel JR, Abe H, et al. 2017 HRS expert consensus statement on magnetic resonance imaging and radiation exposure in patients with cardiovascular implantable electronic devices. Heart Rhythm 2017;14:e97–e153.
2. Luechinger R, Duru F. Do we need MR conditional pacemakers? Kardiovaskuläre Medizin 2010;13:70–74.
3. Roguin A, Schwitter J, Vahlhaus C, et al. A Position Paper from European Heart Rhythm Association and working Group on Cardiovascular Magnetic Resonance of the European Society of Cardiology: Magnetic resonance imaging in individuals with cardiovascular implantable electronic devices. Europace 2008;10:336–346.
4. Gold MR, Sommer T, Schwitter J, et al. Evera MRI Study Investigators. Full-body MRI in patients with and implantable cardioverter-defibrillator: primary results of a randomized study. J Am Coll Cardiol 2015;65:2581–2588.
5. Gold MR, Kanal E, Schwitter J, et al. Preclinical evaluation of implantable cardioverter-defibrillator developed for magnetic resonance imaging use. Heart Rhythm 2015;12:631–638.
6. Bauer WR, Lau DH, Wollmann C, et al. Clinical safety of ProMRI implantable cardioverter-defibrillator systems during head and lower lumbar magnetic resonance imaging at 1.5 Tesla. Sci Rep 2019;9:18243.
7. Sabzevari K, Oldman J, Herrey AS, Moon JC, Kydd AC, Manisty C. Provision of magnetic resonance imaging for patients with 'MR-conditional' cardiac implantable electronic devices: an unmet clinical need. Europace 2017; 19:425–431.
8. Cunqueiro A, Lipton ML, Dym RJ, Jain VR, Sterman J, Scheinfeld MH. Performing MRI on patients with MRI-conditional and non-conditional cardiac implantable electronic devices: an update for radiologists. Clin Radiol 2019; 74:912–917.
9. Camacho JC, Moreno CC, Shah AD, et al. Safety and quality of 1.5-T MRI in patients with conventional and MRI-conditional cardiac implantable electronic devices after implementation of a standardized protocol. AJR Am J Roentgenol 2016;207:599–604.