Original Article

Safety of Patients with Conventional Pacemaker System and MRI-Conditional Pacemaker System Undergo Magnetic Resonance Imaging [MRI] at Ramathibodi Hospital

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Background: MRI-conditional pacemaker system has been safely used in clinical practice worldwide. However, there are many patients with conventional pacemaker system need magnetic resonance imaging [MRI] evaluation with strong clinical indication that benefit of MRI outweighs the risks.

Objective: To investigate the safety of conventional pacemaker system and MRI-conditional pacemaker system in MRI scanning in term of the adverse occurrence such as a) a significant change in pacing capture threshold [PCT] of any leads, b) abnormal pacemaker function, and c) major adverse clinical event.

Materials and Methods: A retrospective study of consecutive pacemaker patients that underwent MRI at 1.5 Tesla and estimated specific absorption rate [SAR] of less than 2.0 W/kg, under institution safety protocol, between August 2012 and June 2014, was done.

Results: Sixteen patients (mean age 77.6 years old, 50% male) with a total of 32 leads and 16 pulse generators underwent MRI between August 2012 and June 2014 were included. Of all patients, eight (50%) were MRI-conditional pacemaker system, and five (31%) were pacemaker-dependent. The majority of MRI scanning position was brain (8, 50%), followed by spine (6, 37.5%) and others (2, 12.5%), which included upper abdomen and lower limb. Unintended cardiac stimulation induced by magnet occurred in one patient with conventional pacemaker system without significant clinical consequences. There was no other MRI-related complication during and after the scan. At six months follow-up, 12 patients had their pacemaker evaluated. There was no occurrence of significant change in PCT or abnormal pacemaker function found at six months follow-up.

Conclusion: Patients with conventional pacemaker system who have strong clinical indication for MRI may safely undergo the scan with close and continuous monitoring strategy.

Keywords: Permanent pacemaker and MRI, Safety of pacemaker patients and MRI

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Magnetic resonance imaging [MRI] examination in pacemaker implanted patients is discouraged due to potential hazardous interaction between the MRI and pacemaker system except in the case with strong clinical indication where benefit clearly outweighs the risks and should be done in experienced center under safety protocol[1,2]. Recently, in 2008, an MRI-conditional pacemaker system has been developed and safely used in clinical practice worldwide[3-5]. However, there are many patients with conventional pacemaker system who need MRI. In Thailand, there was limited information in this group of patients. The present study was conducted to investigate the safety of conventional pacemaker system and MRI-conditional pacemaker system in MRI scan at 1.5 Tesla in term of the occurrence of a) a significant change in pacing capture threshold [PCT], defined as increasing in the PCT by 1.0 V or more at 0.4 milliseconds pulse duration, b) abnormal pacemaker function, and c) major adverse clinical event.

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Materials and Methods

Study population and methods

All consecutive pacemaker implanted patients underwent MRI evaluation of any clinical indication in Ramathibodi Hospital between August 2012 and June 2014 were identified. The patients' medical records were retrieved and retrospectively reviewed. Variables extracted from patients' medical records included

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patient's demographic data, baseline clinical conditions that indicated if the patients had a pacemaker, clinical conditions that relate to indication for MRI, duration from implantation of the pacemaker to the time of MRI, part and duration of the scan. Current pacemaker data were collected included percentage of ventricular pacing, lead impedance, and PCT. The patients had to have at least three months clinical follow-up and/or pacemaker interrogation after the MRI.

Institution protocol for permanent pacemaker patient who undergoing MRI evaluation

All pacemaker implanted patients who have strong clinical indication for MRI have to be informed by their attending physicians and electrophysiologist team regarding their clinical indication for MRI and risks of interaction between the MRI and pacemaker system (including death) as part of the informed consent process.

Immediate pre-MRI evaluation

On the day of the MRI, immediately pre-MRI, the patients' pacemaker will be interrogated. Data regarding pacemaker mode, percentage of ventricular pacing, PCT, sensing, lead impedance, and battery status will be obtained. The pacemaker will be programmed to asynchronous mode, so it will generate fixed and regular discharge from the generator if the patient is pacemaker dependent or demonstrate unstable intrinsic rhythm during a short period of pacing inhibition on interrogation before MRI. For MRI-conditional pacemaker system, the device will be programmed according to manufacturer instructions. All patients will be required to report their symptoms during the MRI.

During MRI evaluation

During the scan, patients will be continuously monitored using electrocardiogram [ECG] and pulse oximetry monitoring system INVIVO 3150. The patient can report their symptoms through voice contact via an intercom. An electrophysiologist, cardiologist, or ACLS' certified personnel will be present throughout each study. Resuscitation equipment are readily available outside MRI room.

Immediate-post MRI evaluation

The patients will be asked about their symptoms and feeling of torque or warmness over the device pocket. The patients' pacemaker will be immediately interrogated afterward. Measured parameters include PCT, sensing, lead impedance, battery status, and device alert episodes.

The patients are routinely scheduled for clinical follow-ups and pacemaker interrogation at three and six months after the scan.

All MRI evaluations were performed using PHILIPS MR system Achieva 1.5 T, release 3.2.3.1, or GE 1.5 T HDxt, release 15.0_0947a, estimated specific absorption rate [SAR] was limited to less than 2.0 W/kg. No limitation in part and duration of MRI were placed in the present study.

Definitions

Pacemaker dependent patient was defined as the patient who have risk of serious injury or death from sudden pacemaker failure, an event more dangerous than progressive rate decrease[6,7]. In the present study, pacemaker dependent patient was defined as patient who had ventricular pacing percentage of 40% or more.

Significant change of PCT was defined as increasing in PCT 1.0 V or more at 0.4 milliseconds pulse duration.

Significant change of pacing lead impedance was defined as increasing or decreasing of lead impedance to greater than 2,000 Ω or less than 200 Ω.

Statistical analysis

Data were presented using median, minimum and maximum for continuous variables, and percentage for categorical variables. Statistical analyses were performed using SPSS version 15.0.

Results

Study population, pacemaker related clinical conditions, and MRI data

Between August 2012 and June 2014, there were 16 pacemaker implanted patients with 32 leads and 16 pulse generators that underwent 16 strong clinical indicated MRI at 1.5 Tesla (estimated SAR of less than 2.0 W/kg) in Ramathibodi Hospital. All patients' medical records were available for review. Baseline clinical characteristics, pacemaker related clinical conditions, and MRI data are shown in Table 1. The mean age (± SD) of the patients was 77±7.6 years old. Of these, eight (50%) were male. The major bradycardia indication was sick sinus syndrome (11/16, 68.8%), followed by atrioventricular block (3/16, 18.8%), and other indications such as cardio-inhibitory type syncope that accounted for 12.5% (2/16 patients). There were five (31.3%) pacemaker-dependent patients. Of sixteen pulse generators, eight (50%) were MRI-conditional pacemaker system. Most

Table 1. Baseline clinical characteristics, pacemaker related clinical condition, and MRI data

	Number (n = 16) n (%)
Age (years), mean (± SD)	77.6 (±7.6)
Gender	
Male	8 (50.0)
Female	8 (50.0)
Pacing indication	
Sick sinus syndrome	11 (68.8)
AV block	3 (18.8)
Others	2 (12.5)
VP	
<40%	11 (68.8)
≥40%	5 (31.3)
Pacemaker system	
MRI-conditional	8 (50.0)
Conventional	8 (50.0)
Part of MRI	
Brain	8 (50.0)
Spine	6 (37.5)
Others	2 (12.5)
Setting during MRI	
Synchronous	4 (28.6)
Asynchronous	10 (71.4)
Duration of MRI (minute), median (min, max)	45.30 (40, 103)
Complication	
Yes	1 (6.3)
No	15 (93.8)
Significant threshold change (pacing capture threshold increase ≥1 V)	
Yes	0 (0.0)
No	16 (100)

AV = atrioventricular; VP = ventricular pacing; MRI = magnetic resonance imaging

of the MRI scanning position was brain (8/16, 50%), followed by spine (6/16, 37.5%), and others (2/16, 12.5%) included upper abdomen and lower limb. The median (min, max) duration of the scanning was 45.30 (40, 103) minutes. Ten (71.4%) pulse generators were programmed to asynchronous mode during MRI. No patients were sedated during the scan. Table 2 provided details regarding the pulse generator, lead model, and duration from implantation to the time of MRI scan. The pulse generators were not restricted to a single company. The minimum duration after implantation of pulse generator to the time of the scanning was 11 days.

Incidence of significant change of PCT

All devices (16/16, 100%) could be interrogated immediately after MRI. Three atrial leads were unable to evaluate the PCT due to AF rhythm. There was no incidence of rising of the PCT more than 1.0 V at 0.4 milliseconds pulse duration. No incidence of change of the impedance to more than 2,000 Ω or less than 200 Ω was noted. At six months after MRI, only 75% (12/16) of the devices were interrogated. However, no occurrence of significant change of the PCT was observed.

Pacemaker malfunction and major adverse clinical events during MRI scan

All patients safely completed the MRI scans. No abnormal symptoms were reported from the patients, especially any torque or warm sensation at the device site during or immediately after the

Table 2. Pacemaker and leads' data

Patient No.	Generator model	Lead model	Duration after implantation (month)
1	Medtronic SENSIA SEDR01	Medtronic 4076-52, 58	37.1
2	Medtronic Advisa DRMRI A3DR01	Medtronic 5086-52, 58	5.4
3	Medtronic Advisa DRMRI A3DR01	Medtronic 5086-52, 58	11.8
4	SJM Identity ADxXL DR 5386	SJM 1688-52, 58	84.2
5	SJM Victory XLDR	SJM 1688-52, 58	43.1
6	Guidant 1296	Guidant 4470-4471	100.7
7	Medtronic Advisa DRMRI A3DR01	Medtronic 5086-52, 58	23.6
8	Medtronic Ensura EN1DR01	Medtronic 5086-52, 58	1.7
9	Medtronic Advisa DRMRI A3DR01	Medtronic 5086-52, 58	20.9
10	Medtronic Ensura EN1DR01	Medtronic 5086-52, 58	20.9
11	BSC Adventio DR MRI J066	Guidant 4470-4471	0.4
12	Guidant S502	Guidant 4470-4471	25.1
13	Guidant Insignia	Guidant 4470-4471	82.5
14	BSC Adventio DR MRI J066	Guidant 4470-4471	5.6
15	SJM Victory XLDR	SJM 1688-52, 58	14.2
16	Medtronic SENSIA SEDR01	Medtronic 4076-52, 58	88.9

scanning. There was no clinical evidence of pacemaker malfunction in the pacemaker dependent patients with asynchronous mode during the scan. No incidence of sustained hemodynamically unstable atrial or ventricular arrhythmias were observed during any scan. Immediately post MRI, interrogation could be performed without difficulties in all cases and showed no incidence of alteration of the pre-MRI device's programmed setting or a power on reset in any devices. However, unintended cardiac stimulation induced by magnet occurred in one patient with conventional pacemaker system but without significant clinical consequence and no need for device reprogramming.

Discussion

In the present study, a retrospective single center study of sixteen consecutive pacemaker implanted patients who underwent their compelling indicated MRI (1.5 Tesla with estimated SAR of less than 2.0 W/kg) were investigated to determine whether the patients can safely undergo the MRI scan and the safety of conventional pacemaker system and MRI-conditional pacemaker system in MRI scan.

Findings in the present study showed that all patients could safely undergo the MRI under closed monitoring protocol, which the patients were continuously monitored using ECG, pulse oximetry, and could report their symptoms through voice contact via an intercom during the scan. No major adverse cardiac conditions related to the MRI occurred. There was no significant change of the PCT from immediate before and post MRI and at six months follow-up. There was one unintended cardiac stimulation with conventional pacemaker system but without significant clinical consequences. No incidence of power-on-reset was observed.

Overall findings showed similar results as several studies conducted before regarding the safety of patients with permanent pacemaker undergoing MRI of 1.5 T magnetic strength. Variety of magnetic field strength (0.2, 0.5, 1.5, 2.0, 3.0 T) have also been evaluated and published. They showed that each strength could be safely performed[8-12] in patients with permanent pacemaker. However, problems that might be potential risks on the function of the devices include reed switch activation[9,11], continuous pacing in the static field[9], decrease in battery voltage[11,13], and significant increase or alteration in pacing threshold[13-16]. Furthermore, the occurrence of power-on-reset have been reported as primary clinically significant event attributed to MRI in up to 1.5% of device recipients[17]. Although, there was no incidence of power-on-reset, there was an incidence of unintended cardiac stimulation induced by magnet (programmed lower rate was increase to magnet rate). The event occurred in an 83 years old female patient with very thin chest wall over her conventional pacemaker pocket during the scanning, but without significant clinical consequences or need for device reprogramming.

There was one MRI scan done successfully in an urgency examination of a patient who had a very short period (11 days) between the time of patient's device implantation and the time of the MRI without any difficulties or major adverse clinical events. A point that had been concerned in case of MRI scanning during early period of device implantation was the movement of pacemaker generators or leads[12] which in fact that lead tips do not possess ferromagnetic materials[18,19]. Therefore, they should never be moved magnetically. However, according to general recommendation, the time period from device implantation to the time of MRI scan should be at least six weeks[1].

Five (30%) patients were pacemaker dependent. Using safety protocol that have been used in several studies about utilities and safety of specific protocol performing MRI in patient with permanent pacemaker[16,20-22], devices of pacemaker dependent patients and patients who had unstable rhythm demonstrated during a short period of interruption of pacing function at pre-MRI interrogation were set to asynchronous mode. Closed monitoring strategy was used in all MRI examinations. Asynchronous pacing was also used in patients with MRI-conditional system according to manufacturer's instructions. For other patients, synchronous mode was used. In the current study, MRI could safely be performed in all patients whether they were pacemaker dependent or not.

Eight (50%) devices were MRI-conditional pacemaker system and the remaining were conventional pacemaker system. However, under closed monitoring protocol as described above, neither groups showed any incidence of significant change in the PCT between before and post-MRI and at six months follow-up and patients of both groups could safely undergo the scan. These findings showed that whether the device was MRI-conditional or conventional pacemaker system, MRI performing under the closed monitoring safety protocol is essential and safe.

Limitation

The principle limitation of the present study are the retrospective design and the small sample

size. At six months after MRI, only 75% (12/16) of the devices were interrogated and some data were missing. Not all available products were evaluated. The study did not include some anatomic parts, for example, cardiothoracic scan. Use of MRI scanners on pacemaker patients were specifically limited to only 1.5 T and estimated SAR of less than 2.0 W/kg under well-defined conditions according to institutional closed monitoring safety protocol. Therefore, safe use outside of these conditions has not been demonstrated.

Conclusion

Patients with conventional pacemaker system who have compelling indication for MRI may safely undergo the scan with close and continuous monitoring strategy.

What is already known on this topic?

Before 2010, pacemakers available around the world were labeled as MR unsafe. Previous expert consensus document on MRI examination in pacemaker implanted patients was discouraged due to potential hazardous interaction between the MRI and the pacemaker system except in case of strong clinical indication that outweighs the risks. Furthermore, those should only be done in experienced center.

Even though MRI-conditional pacemaker system has been developed and safely used in clinical practice worldwide, conventional pacemaker system have been used in most patients who undergone implantation before MRI-conditional system has been approved. However, there are a number of patients with conventional pacemaker system indicated for MRI. Recently, more clinical trials have been conducted to assess conditions and strategy that MRI in these older device system could be safely performed.

Recently, the 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy[23] have recommended that MR at 1.5 T can be performed with a low risk of complications in patients with conventional pacemaker system if appropriate precautions are taken, and following manufacturer instructions with MRI-conditional pacemaker systems.

What this study adds?

The findings in the present study support the latest recommendation on MRI examination in pacemaker implanted patients. However, it should be recognized that, the conventional pacemaker system does not constitute a list of MR-safe or MRI-conditional whether or not the patient is pacemaker dependent. The MRI-conditional pacemaker system is now available from all product manufacturers.

The authors would like to encourage the implanters to seek for possible conditions that could indicate the patients to have a chance of undergoing MRI after device implantation and consider using MRI-conditional pacemaker system for these group of patients.

Potential conflicts of interest

The authors declare no conflict of interest.

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