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Automatic consultation system for patients with cardiac implantable electronic devices undergoing magnetic resonance imaging

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Abstract

Background: Safety evaluation for patients with cardiac implantable electronic devices (CIEDs) undergoing magnetic resonance imaging (MRI) scanning is often overlooked. We developed an automatic consultation system (ACS) to improve the screening rate in these patients.

Methods: ACS was developed by the Hospital Information System Development Department of Seoul National University Bundang Hospital. It was designed to automatically request pre-MRI cardiac evaluation in patients with CIED when MRI orders are issued. The proportion of the patients without pre-MRI cardiologic evaluation was evaluated before and after the ACS application.

Results: From January 2016 to June 2018, a total of 157 patients with CIEDs [pacemaker 136 (86.6%), ICD or CRT-D 21 (13.4%), MR-conditional 117 (74.5%)] visited the MRI facility. Before the ACS application, 23 out of 84 patients (27.4%) did not have adequate pre-MRI cardiologic evaluation. Despite urgent request for pre-MRI cardiac evaluation, MRI examination was postponed or cancelled in 14 (60.8%) cases. After the ACS application, all 73 patients underwent proper cardiologic evaluation before their MRI examinations (P < 0.001). The proportion of immediate request for pre-MRI evaluation at the moment of MRI order also improved with the ACS application (before ACS 57.1%, after ACS 100%, P < 0.001).

Conclusions: The newly developed ACS helped the patients with CIED receive MRI scan safely on the schedule, improving the quality of care in this population.

Keywords: Hospital information system, Automatic consultation system, Cardiac implantable electronic device, Magnetic resonance imaging

Introduction

The number of patients with cardiac implantable electronic devices (CIEDs) is increasing, and many of these patients have various comorbidities [1, 2]. A previous study reported that these patients have an approximately

75% chance of being indicated for a magnetic resonance imaging (MRI) scan over the lifetime of the device [3]. The prerequisite of the protocols for safe MRI scans in these patients [4, 5] is that the patient should be evaluated by experts in cardiology department before MRI scanning, which is often overlooked in daily clinical situations. To address this problem, we developed a new feature in our hospital information system (HIS) which provides automatic consultation to the cardiology department at the moment of issuing an MRI scan order in patients with CIED and investigated its beneficial effect.

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Han et al. Int J Arrhythm (2020) 21:2 Page 2 of 6

Materials and methods

Study population

The patients with pacemakers or implantable cardioverter defibrillators who visited the MRI facility for MRI scan between January 2016 and June 2018 in Seoul National University Bundang Hospital (SNUBH) were consecutively enrolled. This study period consists of two parts: (1) before the application of the new automatic consultation system (ACS) (January 2016 to April 27, 2017) and (2) after the application of the ACS (from April 28, 2017, to June 2018). The development of the new system for patients with CIED undergoing MRI scan was one of the hospital's innovative projects, and during this period, patients with CIED who visited the MRI facility were prospectively listed up at both the MRI facility and the CIED analysis laboratory to evaluate the effects of the new system. Patients having either MR-conditional or conventional CIED who visited the MRI facility were enrolled in this study. This study protocol was approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-1809-493-107) and was performed in accordance with the tenets of the Declaration of Helsinki.

Automatic consultation system in the hospital information system

The SNUBH developed its own hospital information system (HIS) named BESTCare, "Bundang hospital

Electronic System for Total Care" and upgraded it to the next-generation HIS, BESTCare 2.0 in 2013 [6, 7]. The project team consisting of cardiologists, nurses from cardiology department, MRI technicians and HIS department of SNUBH designed and developed an automatic consultation process into the HIS to improve quality and safety of the patients with CIEDs undergoing MRI scan on 2016. The hospital HIS department which had developed BESTCare 2.0 also developed this new ACS.

The scheme of the newly developed ACS is presented in Figs. 1 and 2. On the patient information window of the HIS, a new alert icon, "Device", was added to reveal information regarding implanted devices of the patient. Inside the "Device" alert icon, "CIED" checkbox was designed to be checked automatically when the orders regarding CIED implantation surgery or interrogation were detected in the SNUBH HIS (BESTCare 2.0). In patients with activated "CIED" checkbox, a red shoulder badge appears on "Device" alert icon (Fig. 1). This alert sign can be activated manually, for exceptional cases such as a patient who implanted CIED elsewhere and visits our hospital for an MRI evaluation. When an MRI order is issued in a patient with an activated "Device" alert, a warning pop-up window automatically opens. This warning window not only notifies the ordering physician that the patient needs to be checked for the MRI safety of the CIED, but also asks whether to make a consultation request to a cardiologist. Simply clicking "yes" opens a



Fig. 1 New alert system for cardiac implantable electronic devices (CIEDs). a A new alert icon, "Device", was added to reveal information regarding implanted devices of the patient (green box). b Clicking this "Device" icon displays a pop-up registration window for implantable devices. "CIED" checkbox (yellow box) was designed to be checked automatically when the orders related to implantation surgery or interrogation of CIEDs were detected in the SNUBH hospital information system (BESTCare 2.0). Manual check is also allowed. c In patients with activated "CIED" checkbox, a red shoulder badge appears on "Device" alert icon (green box). CIED cardiac implantable electronic device

Han et al. Int J Arrhythm (2020) 21:2 Page 3 of 6



Fig. 2 Process of the automatic consultation system. An MRI order for a patient with an activated "Device" alert automatically opens a warning pop-up window, which notifies the necessity of pre-MRI evaluation for the patient and asks whether to make a consultation request to a cardiologist. Clicking "yes" issues a pre-written consultation request for pre-MRI cardiologic evaluation. Medical personnel at the MRI facility can also identify this patient by additional "D" mark in the receptionist list. *MRI* magnetic resonance imaging

consultation request window with a pre-written request for a safety check of CIEDs under MRI scan. Then, a visit to the cardiology department would be arranged on the day of MRI, allowing the patient to perform device interrogation and required changes in CIED modes before and after MRI scan. In the MRI room, "Device" alert mark also can be screened on the patient's registration window, warning the radiologists and technicians to monitor the patients with caution (Fig. 2). After examination, 1-month follow-up visit to cardiology department is reserved. We completed development of this system and applied it in the clinical field on April 28, 2017.

Effects of the automatic consultation system

We evaluated the beneficial effects of the ACS as the proportion of the adequate cardiology consultation before the patients with CIED visit the MRI facility. In addition, it was investigated whether pre-MRI consultation to cardiology department was requested immediately at the time of MRI order or later after being screened by medical personnel in the MRI room. For this purpose, pre-MRI evaluation was considered to be requested immediately after MRI order if the consultation request was issued on the same day as the MRI order. In addition, cancellation rate was compared among the periods.

Statistical analysis

The Student's t test and Chi-square (or Fisher's exact) test were used to compare means and proportion of baseline clinical characteristics between the groups. All of the statistical analyses were performed using R version 3.6.0, and P < 0.05 was considered statistically significant.

Results

Characteristics of the study population

A total of 157 patients with CIEDs visited the MRI facility during the study period. There were 84 cases before and 74 cases after the ACS application. Clinical characteristics of the study population are presented in Table 1. The mean age was 73.8 ± 10.8 before ACS and 75.1 ± 10.2 after ACS (P=0.414). The proportion of MR-conditional devices, which are known to pose no known hazards in a specific MRI environment under specific MRI scanner condition [8], was not significantly different [before ACS 58/83 (70.7%), after ACS 59/73 (80.8%), P = 0.204]. The proportions of high-voltage devices such as implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) were 12/84 (14.3%) and 9/73 (12.3%), before and after ACS, respectively (P=0.901). Among them, 9/12 (75.0%) and 8/9 (88.9%) were MR-conditional devices, respectively (P = 0.810).

Han et al. Int J Arrhythm (2020) 21:2 Page 4 of 6

Table 1 Characteristics of the study population

	Before ACS (n = 84)	After ACS (n = 73)	P value
Age (years)	73.8 ± 10.8	75.1 ± 10.2	0.414
Male	49 (58.3)	35 (47.9)	0.254
MR-conditional	58 (70.7)	59 (80.8)	0.204
Pacemaker	72 (85.7)	64 (87.7)	0.901
MR-conditional	49 (70.0)	51 (79.7)	0.276
Indications			0.327
AV block	32 (44.4)	36 (56.3)	
SSS	40 (55.6)	28 (43.7)	
ICD or CRT-D	12 (14.3)	9 (12.3)	0.901
MR-conditional	9 (75.0)	8 (88.9)	0.810
Indications			0.331
Primary prevention	9 (75.0)	4 (44.4)	
Secondary prevention	3 (25.0)	5 (55.6)	
MRI scan site ^a			0.014
Brain	48 (73.8)	37 (50.7)	
Spine	9 (13.8)	24 (32.9)	
Others	8 (12.3)	12 (16.4)	
Emergency room	12 (14.5)	8 (11.0)	0.680

Data are expressed as n (%) or mean \pm SD

ACS automatic consultation system, MRI magnetic resonance imaging, AV atrioventricular, ICD implantable cardioverter–defibrillator, CRT-D cardiac resynchronization therapy defibrillator, SSS sick sinus syndrome

The most frequent MRI scan site was the brain in both groups. MRI was ordered in the setting of emergency in 20/157 (12.7%) cases.

Pre-MRI cardiology consultation

The proportion of patients visiting the MRI facility with cardiologic evaluation before and after the ACS application is presented in Table 2. Before the setting of the ACS, the rates of adequate screening consultation to cardiology department before visiting MRI facility in patients with CIED were 72.6%. After the ACS application, all 73 patients underwent pre-MRI cardiologic evaluation before MRI examination (P<0.001). Regarding the timing of the request for pre-MRI evaluation, more patients were immediately referred to the cardiology department after the application of the new ACS (P<0.001).

Patients without pre-MRI cardiology evaluation were screened at the MRI facility at the day of the examination and were sent to a cardiologist for screening evaluation, which resulted in postponing or cancellation of MRI examination in 14/23 (60.8%) cases. With urgent requests, 9/23 (29.2%) patients were able to be evaluated by a cardiologist and underwent MRI scan on the scheduled day. There was no patient with CIED visiting the MRI facility without pre-MRI cardiac evaluation.

Table 2 Changes in the proportion of patients with pre-MRI cardiologic evaluation after the application of ACS

	Before ACS (n = 84)	After ACS (n = 73)	P value
MRI visit with cardiologic evalu- ation	61 (72.6)	73 (100)	< 0.001
Evaluation requested immediately after MRI order	48 (57.1)	73 (100)	< 0.001
MRI visit without cardiologic evaluation	23 (27.4)	0 (0)	< 0.001
MRI as scheduled after urgent evaluation	9 (39.1)	-	_
MRI rescheduled	1 (4.4)	-	-
MRI cancelled after evaluation	13 (56.5)	-	_
1-month follow-up interrogation	52 (61.9)	73 (100)	< 0.001

Data are expressed as n (%)

ACS automatic consultation system, MRI magnetic resonance imaging

After the ACS application, all patients underwent follow-up CIED interrogation 1 month after the MRI examination, and there was no evidence of MRI-related complications.

Discussion

MRI has become the imaging modality of choice in various clinical situations, and the use of MRI scans has markedly increased [9]. Also the number of patients with CIEDs is increasing [10]; thus, the patients with pacemakers and ICDs are often indicated for an MRI scan over the lifetime of the device [1-3]. Nazarian et al. [11]reported that more than 36% of patients with ICDs would require an MRI scan within 4 years of device implantation. Despite the potential risks of the interactions between the MRI environment and conventional CIEDs, the evidences supporting the safety of MRI in patients with conventional CIEDs are recently growing [12]. Several protocols were suggested to perform MRI scan safely, at least in the selected patients with selected CIEDs [4, 13–17]. Similarly, we have previously reported that MRI examinations could be performed without adverse events or significant parameter changes in both the MR-conditional and the conventional CIED groups [18]. Since the first FDA approval for the MR-conditional pacing devices in 2011, MR-conditional CIEDs have been rapidly replaced conventional non-MR-conditional devices in the market, reducing the concerns regarding the safety issues of MRI in patients with CIEDs. Nevertheless, to perform MRI safely, MR-conditional devices still require specific device programming, imaging protocols and also continuous monitoring during the MRI, similarly as conventional devices [19–22]. Therefore, pre-MRI evaluation by cardiologists is crucial for safe MRI examination in

^a Numbers may not sum to total due to cancellation of the examination after visiting the MRI facility or scanning of multiple sites

Han et al. Int J Arrhythm (2020) 21:2 Page 5 of 6

patients with CIEDs, regardless of whether their CIEDs are MR-conditional or not. This study introduces the newly developed automatic consultation system incorporated in the HIS, for patients with CIEDs undergoing MRI scan. The results suggest that this new system could improve the safety of MRI scans in this population.

Increased utilization of MRI in patients with CIEDs may be partly from expansion of MR-conditional CIEDs. During the past 5 years, the number of patients with CIEDs having MRI scanning in SNUBH has increased, mainly attributed by the increase in MRI cases with MRconditional CIEDs (Fig. 3). However, it should be empathized that high prevalence of MR-conditional CIEDs by itself cannot translate into better quality of care. In this study, more than one-fourth of the patients with CIED visited the MRI facility without adequate pre-MRI cardiac evaluation before the ACS application. MRI orders are frequently placed by non-cardiologists, and some physicians' misunderstanding that "MR-conditional" devices do not require any evaluations or changes in device programming before MRI scan may have led to this negligence of pre-MRI cardiologic screening. It is noteworthy because we promoted pre-MRI cardiology consultation to the medical personnel during this ACS developmental period. Therefore, this result also suggests that promotion and education alone would not be sufficient in achieving the safety of patients with CIED

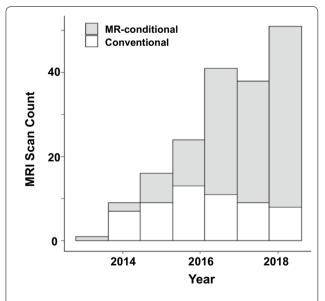


Fig. 3 Trend of MRI scan in the patients with CIEDs in the Seoul National University Bundang Hospital. The number of MRI scan in patients with CIED has gradually increased. The proportion of MR-conditional CIEDs among the patients underwent MRI scan has also increased. *CIED* cardiac implantable electronic device, *MRI* magnetic resonance imaging

undergoing MRI. In this respect, systematic approach such as our new ACS may improve the quality of care in these populations.

Before a patient with CIED has an MRI scan, there are several points in time when the patient can be screened. A patient can be screened first when the MRI order is placed, when MRI examination is scheduled, when obtaining written consent for the examination and lastly when the MRI scan is actually performed. The first step, at the moment of issuing MRI scan order, was considered to be a good target to intervene, not only to improve the rate of pre-MRI cardiologic evaluation, but also to decrease the dissatisfaction of patients as a consequence of cancellation or postponing of the examination. Therefore, the main feature of this ACS was to generate an automatic consultation request at the moment of the MRI order placement. As an additional screening filter for these patients, the ACS was designed to alert medical personnel with activated alert icons that can be seen from the patient list of the MRI room, notifying that this patient has CIED. This feature provided another safety net to ensure appropriate preparation and monitoring before and during MRI examinations.

After adoption of the new ACS, all patients received MRI scan after adequate cardiology consultation, device interrogation and devices reprogramming. Moreover, all patients revisited the cardiology department for follow-up analysis of their implanted devices, and all patients received MRI scan on the schedule, without delays. Therefore, it is suggested that the application of the ACS has improved the patients' satisfaction, the safety of MRI examination and the quality of care in the study population.

This study is underpowered to assess the actual clinical effect following the increase in pre-MRI cardiologic consultations. There were no reports of significant MRI-related adverse events during the study period regardless of ACS application, though it might have been underreported because some patients missed follow-up CIED interrogation before the ACS application period. Nevertheless, this study showed that the addition of a new alert process in the electronic hospital records system significantly increased the quality of care and helped avoid nearmiss events which may potentially lead to harmful results.

Conclusions

The newly developed ACS helped patients with pace-makers or implantable cardioverter defibrillators receive their MRI scan safely on schedule and visit the cardiology department for 1-month follow-up analysis of the devices. Utilization of this system could help improve the quality of care in patients with CIEDs undergoing MRI examinations.

Han et al. Int J Arrhythm (2020) 21:2 Page 6 of 6

Abbreviations

ACS: automatic consultation system; CIED: cardiac implantable electronic device; CRT-D: cardiac resynchronization therapy defibrillator; HIS: hospital information system; ICD: implantable cardioverter–defibrillator; MRI: magnetic resonance imaging.

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Authors' contributions

DH acquired and analysed the data and drafted the manuscript. JHL analysed the data and substantively revised the manuscript. IYO contributed to the conception of the work and revised the manuscript. IC contributed the design of the work and revised the manuscript. HYL created an automatic consultation system used in the study. YC designed the work, analysed the data and revised the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analysed during this study are included in this published article.

Ethics approval and consent to participate

This study protocol was approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-1809-493-107) and was performed in accordance with the tenets of the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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