Magnetically controlled capsule endoscopy in aging patients with cardiac implantable pacemakers: A retrospective pilot study

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INTRODUCTION

Magnetically controlled capsule endoscopy (MCE) is popular because of its non-invasiveness and excellent diagnostic performance, especially in patients in poor physical condition.

A cardiac implantable electronic device (CIED) is a contraindication for MCE. However, MR-labeled (MR-conditional) devices can complete magnetic resonance imaging (MRI) scans under strict protocols [1, 2]. Additionally, safety data support MR scanning in patients with CIEDs that do not have MR safety labels. A risk-benefit decision is required for both MR-labeled and MR-unlabeled devices [1].

The MCE capsule has a permanent magnet inside its dome; the adjustable magnetic field generated by the magnetic robot can reach a maximum of 0.5 Tesla [3]. This magnetic field is lower than that of MRI, which can reach 1.5–3.0 Tesla. Therefore, MCE is theoretically feasible and safe for patients with MRI-compatible medical implants [4]. However, to date, no studies have assessed the safety and gastric visualization of MCE for patients with CIEDs.

Thus, we aimed to analyze retrospectively the safety of elderly patients with CIEDs who underwent MCE examinations.

METHODS

This was a retrospective single-center study. Data from patients who underwent MCE at Peking University First Hospital between August 2017 and August 2023 were collected and divided into the CIED and non-CIED groups. The exclusion criteria were age <75 years and incomplete basic information or imaging data.

The MCE examination was performed using the NaviCam magnetic capsule guidance system (Ankon Technologies Co. Ltd., Wuhan, China). The magnetic robot reached a maximum of 0.2 Tesla.

Before MCE, electrocardiography (ECG) was performed on all patients with CIED. Doctors and operators identified the CIED MR labels, discussed the risk-benefit assessment with patients, and obtained patient consent before proceeding with MCE. During MCE examinations, patients with CIEDs were monitored using a pulse waveform monitor. One operator inspected the gastric images in real-time and communicated with patients regarding new symptoms. The other operator (a trained nurse or physician with basic life support accreditation) monitored heart rate changes. ECG was recommended where feasible. A doctor who could reprogram the CIED was available throughout the MCE examination. After the examinations, ECG was performed on the patients with CIEDs.

All patients were followed up to confirm capsule excretion in 2 weeks. In addition, the CIED group underwent telephone follow-up in August 2023 to establish the presence of significant long-term adverse events and device-related problems.

The primary outcome was the safety of MCE for patients with CIEDs. Safety assessments included adverse CIED and MCE events. CIED short-term adverse events included generator failure, reprogramming changes, battery depletion, cardiac arrhythmias, inhibition of pacing, and patient-reported discomfort, such as pain, heating, and palpitations [5]. CIED long-term adverse events

meant CIED-related dysrhythmias and death. MCE adverse events included abdominal pain, nausea, and capsule retention. Capsule retention was identified by detector scanning during 2-week follow-up.

The secondary outcomes of this study were gastric examination time, gastric visualization, and cleanliness, which were compared between the CIED and non-CIED groups.

Ethical considerations

This study was approved by the Medical Ethics Committee of Peking University First Hospital and was registered with chictr.org.cn (ChiCTR2300077975, 24 November 2023). Patient consent was waived because all identifiable personal information was removed from the datasets.

Statistical analysis

Categorical data were described as percentages. Continuous data with normal distribution were presented as means (standard deviations). Continuous data with a non-normal distribution were presented as medians with interquartile ranges (IQR). Categorical data were compared by a χ^2 test or Fisher's exact test. Continuous data with normal distribution were compared using independent sample t-tests. Continuous data with a non-normal distribution were compared using Mann–Whitney U tests. All statistical tests were two-sided and a *P*-value of less than 0.05 was considered significant. Statistical analyses were performed using IBM SPSS Statistics version 26 for Windows (IBM, Armonk, NY, US).

RESULTS AND DISCUSSION

In total, 212 patients (41 female, mean age 85.7 [6.2] years) were enrolled in the study and completed gastric examinations. Eleven were in the CIED group (3 females, mean age 87.1 [5.6] years), and 201 were in the non-CIED group (38 females, mean age 85.6 [6.2] years). The CIED group included 5 MR-labeled, 1 mismatched, and 5 MR-unlabeled CIEDs (Supplementary material, *Table S1*). The most common indication for MCE in this group was severe cardiovascular disease (8/11), followed by severe respiratory disease (2/11) and poor physical condition (1/11).

In the CIED group, the subjects completed the MCE examination without short-term discomfort. Only one patient with a mismatched pacemaker (an MR-labeled generator and MR-unlabeled leads) showed a transient magnet rate and recovered quickly (Figure 1). Although the magnetic field is 0.2 Tesla in this study, there were still disturbances. When a magnet is placed on the pacemaker, the pacing mode and frequency of the pacemaker can be changed. The pacing mode becomes a constant pacing mode, called magnet rate, which is used to quickly check the pacemaker battery status. After MCE, the mismatched patient underwent pacemaker programming, and no problems were detected with the device. We suggest that all patients with CIEDs should have their programming and battery status checked before MCE examination.

For all 11 patients with CIEDs, capsule retention did not occur after MCE examination. The median follow-up time in the CIED group was 30 months (IQR, 9.0–57.0). The patients had no long-term clinically significant adverse events or device-related problems.

The gastric examination time was 30.6 (5.7) min in the CIED group. The total visualization score was 16.0 (IQR, 15.8–18.0), and the total cleanliness score was 20.5 (IQR, 17.5–21.3) in the CIED group (Supplementary material, *Table S2*). The visualization and cleanliness were acceptable and clean enough to detect positive findings.

To our knowledge, our study is the first to show that MCE is safe for elderly patients with CIEDs. In our study, all CIEDs were pacemakers. The magnetic field in our study was 0.2 Tesla, which is much lower than that of MRI (1.5––3.0 Tesla). MR-labeled CIEDs have been shown to be safe for patients undergoing MRI, with various studies demonstrating no clinically significant adverse events in patients with MR-labeled CIEDs after randomization to MRI [6, 7].

The risks associated with MR-unlabeled CIEDs in MR fields include mechanical forces, heating, device malfunction, and unintended stimulation [1]. However, in testing and clinical data, CIED generators implanted after the year 2000 reduced the risk of electrical resetting, malfunction, and heating during MRI [8]. A prospective, non-randomized study included 1509 patients with MR-unlabeled CIEDs [5] and assessed the safety at a magnetic field strength of 1.5 Tesla. No long-term clinically significant adverse events were reported. Standardized programming and monitoring during MR examinations in a 1.5 Tesla magnetic field can optimize the safety of the procedure, reducing the risk of long-term clinically significant adverse effects [9, 10].

As for mismatched CIEDs, recent multicenter data have suggested no increased adverse effects of MRI with MR-unlabeled leads compared with MR-labeled leads, both in terms of safety and lead parameter changes [11]. Therefore, the clinical risk of MCE in patients with mismatched CIED was not increased.

Consistently with other published series, the use of CIEDs did not affect the quality of endoscopic images (loss of images or gaps in video) or capsule transit time [12].

Limitations

Our study has several limitations. First, the data were retrospective and acquired at a single center. It may not be generalized to other MCE facilities. Second, because this was a retrospective study, we were unable to obtain all patients' CIED programming results before and after MCE examination. In patients with CIEDs, we recommend an intricate protocol for both pre- and post-MCE.

CONCLUSIONS

In summary, MCE was performed safely in 11 patients with CIED and was not associated with long-term adverse cardiac events. Pacemakers did not appear to interfere with MCE imaging. Further multicenter studies are needed to

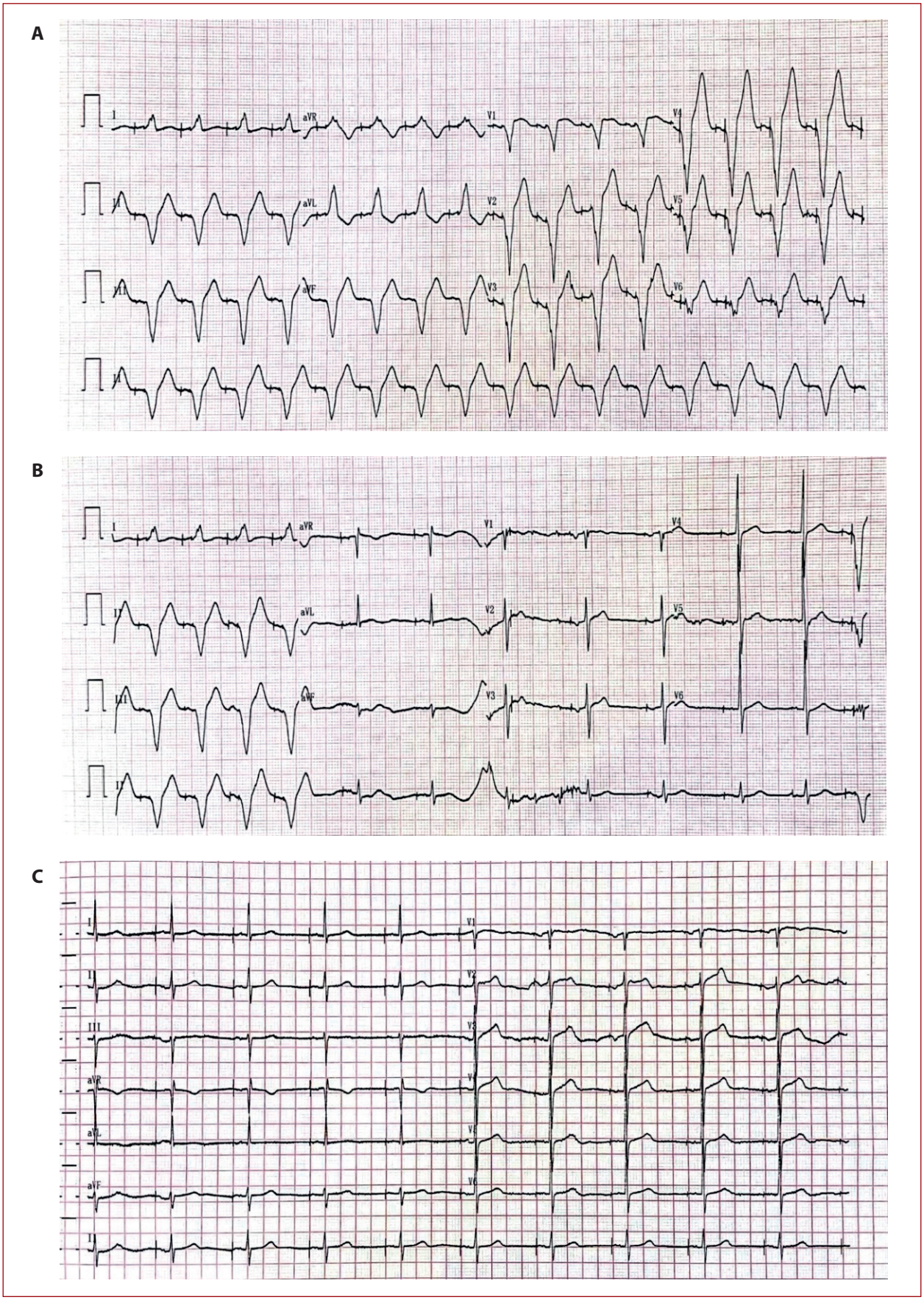

Figure 1. Magnet rate in a patient with mismatched cardiac implantable electronic devices. **A.** Magnet rate occurred when magnetic guidance moved to the chest. **B.** Pacing rhythm recovered when magnetic guidance moved away from the chest. **C.** Pacing rhythm after magnetically controlled capsule endoscopy examination

demonstrate the safety and feasibility of MCE in patients with CIEDs.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

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