Magnetic resonance imaging safety in nonconditional pacemaker and defibrillator recipients: A meta-analysis and systematic review

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BACKGROUND Recommendations regarding performance of magnetic resonance imaging (MRI) in non-MRI conditional pacemaker and defibrillator recipients are evolving. Previous studies have suggested low adverse event rates with MRI in nonconditional cardiac implantable electronic device (CIED) recipients, but low power limits optimal characterization of risk.

OBJECTIVE The purpose of this study was to perform a systematic review and meta-analysis to characterize the clinical risk associated with MRI in CIED recipients in order to improve power.

METHODS PubMed and CINAHL indexed articles from 1990 to 2017 were queried. A random effects model was used for meta-analysis of continuous variables. Safety outcomes were evaluated with descriptive statistics.

RESULTS Seventy studies of non-MRI conditional devices undergoing MRI were identified, allowing for analysis of 5099 patients who underwent a total of 5908 MRI studies. Heterogeneity in lead parameter changes was observed within studies, although smaller variances were noted between studies. All lead characteristics and battery voltages showed very small, clinically insignificant changes when assessed as a pooled cohort, although cases of clinically relevant outcomes were also noted (lead failure 3, implantable cardioverter–defibrillator shock 1, electrical reset 94). Electrical resets were found only in older devices. Defibrillator function was unchanged, and inappropriate shocks were avoided with pre-MRI programming changes.

CONCLUSION This review demonstrated low lead failure and clinical event rates in non-MRI conditional pacemaker and defibrillator recipients undergoing MRI. Observed changes were small and interstudy variance was low, suggesting that the composite event rates offer a reasonable estimate of true effect. The observed adverse events reinforce the need for ongoing vigilance and caution, particularly with older devices.

KEYWORDS Defibrillator; Electromagnetic interference; Magnetic resonance imaging; Pacemaker; Reset

(Heart Rhythm 2018;■:1–8)

Introduction

An implanted, non-magnetic resonance imaging (non-MRI) conditional pacemaker or defibrillator system (cardiac implantable electronic device [CIED]) is considered a relative contraindication to performance of an MRI study.[1] Lead malfunction, battery voltage depletion, unexpected pacing behavior, inhibition of pacing output, and inappropriate shocks thought to be secondary to MRI-related CIED malfunction have been reported, and death secondary to ventricular fibrillation was postulated as a cause of death after inadvertent MRI performance in patients with pacemakers.[2] Several phantom models have demonstrated considerable

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1547-5271/$-see front matter https://doi.org/10.1016/j.hrthm.2018.02.019

lead tip heating, approaching 30°C for abandoned leads.[3] Regulatory and reimbursement policy has significantly limited the availability of MRI for CIED recipients.[4] Despite this, several protocols exist detailing methods of monitored MRI scanning in selected CIED patients.[5–9] The Heart Rhythm Society recently offered an expert consensus statement with a Class IIA, Level of Evidence B recommendation for performing MRI in the setting of non-MRI conditional CIED.[10] These recommendations are supported by results of a large registry study demonstrating low safety events among 1500 patients undergoing MRI in the presence of nonconditional CIEDs.[11] Permutations in study methodology and definitions, devices and leads studied, locations scanned, and MRI scanners used lead to difficulty in generalizing results.[12] Citing safety and efficacy concerns, the Centers for Medicare and Medicaid Services has not recommended coverage for MRI in CIED patients.[13] Thus, safety and clinically oriented outcomes reporting seems important to furthering possible regulatory change. We present a systematic review and meta-analysis of outcomes from case reports, series, and prospective studies in order to characterize the risks associated with MRI in non-MRI conditional CIED recipients.

Methods

The MOOSE (Meta-analysis Of Observational Studies in Epidemiology) guidelines for meta-analysis of observational studies were used for study design (Supplemental Table 1).[14] A search query of the terms "MRI and pacemaker" and "MRI and defibrillator" was performed for the time period from January 1990 to October 2017 using the PubMed and CINAHL databases by 2 of the authors (AS, AP). All studies detailing results of MRI in the presence of a non-MRI conditional CIED were included for analysis. Duplicate cohorts were removed.

In order to homogenize outcomes reporting, the following clinically oriented definitions were created for outcomes adjudication:

Unintended programming changes were defined as any changes in the mode of the CIED compared to the mode that the device was programmed immediately before entry into the MRI suite. These changes were suggested by unexpected pacing or failure of pacing and typically confirmed by CIED interrogation after MRI completion/termination.

Lead failure was defined as the need for lead replacement or revision. The need for such procedure was determined per the original author's recommendation/report and within 30 days of the scan in each case encountered.

Electrical resets were pulse generator events defined as reversion to a set of manufacturer-specified parameters (indicated in product manuals as Safety Mode, Reset Parameters, or Back-Up mode). Generally, these modes are indicated by ventricular inhibited (VVI) pacing at a rate of 65–72.5 bpm with high outputs and occasionally with altered lead polarities.[15] In an implantable cardioverter–defibrillator (ICD), ventricular tachycardia detection and therapies are activated in a singe-tier fashion. An indicator is displayed at interrogation. For this analysis, all resets (partial and full electrical reset) were combined.

Inappropriate antitachycardia therapies were defined as antitachycardia pacing or internal defibrillation shocks secondary to noise/electromagnetic interference (EMI) during the scan or attributable to the MRI environment.

Symptoms were most commonly obtained by patient query or verbalization of complaint during the scan and further classified as clinically significant if they required termination of the scan.

A composite of safety events was the sum of all the previously defined events. Meta-analysis was performed in R version 3.2.4 with, and descriptive statistics were performed using Prism version 7.0c (Graphpad Software, La Jolla, CA).[16] Data extraction and endpoint adjudication were performed independently by 2 authors (AS, ML). Scan-related information (MRI isocenter, Tesla [T], specific adsorption rate), CIED information, and clinical and safety events were extracted. For the purposes of analysis, Vitatron devices were recorded as Medtronic devices; Pacesetter, Siemens, and Telectronic devices as St. Jude Medical; Guidant, CPI, and Intermedics devices as Boston Scientific; and ELA as Sorin.

Statistical analysis

Meta-analysis of lead parameters (capture threshold, sensing, impedance), high-voltage ICD lead impedance, and battery voltage change was performed using the random effects model of DerSimonian and Laird. Only trials reporting data as a mean change or with pre- and postscan measures were included in meta-analyses, but all safety and clinical outcomes were collected for systematic review. Studies reporting sensing change as a percentage of pre-MRI value could not be meta-analyzed. For studies reporting data with interquartile ranges, a conversion factor of 1/1.35 was used to convert to standard deviation, which was derived assuming symmetric distribution of results. Studies that reported pre- and postscan measures were converted to mean change assuming a correlation of 0.75 between pre- and postscan measures. Studies that reported a standard deviation or interquartile range of 0 were assumed to have a standard deviation <0.05 or 0.005 depending on the number of significant figures reported. Bias was assessed using a funnel plot.

Nominal outcomes, such as device corruption, power on reset, and patient-reported complaints, were assessed via by χ^2 analysis or Fisher exact test. Safety events were considered per MRI performed. Nominal outcomes were aggregated for systematic review. $P < .05$ was considered significant.

Results

Study cohort and characteristics

The search yielded 1324 records for review. After applying limitations and reviewing abstracts and manuscripts, a total