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# Safety of Magnetic Resonance Imaging in Patients with Cardiac Devices

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# Abstract


## Background:

Patients who have pacemakers or defibrillators are often denied the opportunity to undergo magnetic resonance imaging (MRI) because of safety concerns, unless the devices meet certain criteria specified by the Food and Drug Administration (termed "MRI-conditional" devices).

## Methods:

We performed a prospective, nonrandomized study to assess the safety of MRI at a magnetic field strength of 1.5 Tesla in 1509 patients who had a pacemaker (58%) or an implantable cardioverter-defibrillator (42%) that was not considered to be MRI-conditional (termed a "legacy" device). Overall, the patients underwent 2103 thoracic and nonthoracic MRI examinations that were deemed to be clinically necessary. The pacing mode was changed to asynchronous mode for pacing-dependent patients and to demand mode for other patients. Tachyarrhythmia functions were disabled. Outcome assessments included adverse events and changes in the variables that indicate lead and generator function and interaction with surrounding tissue (device parameters).

## Results:

No long-term clinically significant adverse events were reported. In nine MRI examinations (0.4%; 95% confidence interval, 0.2 to 0.7), the patient's device reset to a backup mode. The reset was transient in eight of the nine examinations. In one case, a pacemaker with less than 1 month left of battery life reset to ventricular inhibited pacing and could not be reprogrammed; the device was subsequently replaced. The most common notable change in device parameters (>50% change from baseline) immediately after MRI was a decrease in P-wave amplitude, which occurred in 1% of the patients. At long-term follow-up (results of which were available for 63% of the patients), the most common notable changes from baseline were decreases in P-wave amplitude (in 4% of the patients), increases in atrial capture threshold (4%), increases in right ventricular capture threshold (4%), and increases in left ventricular capture threshold (3%). The observed changes in lead parameters were not clinically significant and did not require device revision or reprogramming.

## Conclusions:

We evaluated the safety of MRI, performed with the use of a prespecified safety protocol, in 1509 patients who had a legacy pacemaker or a legacy implantable cardioverter-defibrillator system. No long-term clinically significant adverse events were reported. (Funded by Johns Hopkins University and the National Institutes of Health; ClinicalTrials.gov number, NCT01130896 .).

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