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Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator

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Abstract

Background:

The presence of a cardiovascular implantable electronic device has long been a contraindication for the performance of magnetic resonance imaging (MRI). We established a prospective registry to determine the risks associated with MRI at a magnetic field strength of 1.5 tesla for patients who had a pacemaker or implantable cardioverter-defibrillator (ICD) that was "non-MRI-conditional" (i.e., not approved by the Food and Drug Administration for MRI scanning).

Methods:

Patients in the registry were referred for clinically indicated nonthoracic MRI at field strength of 1.5 tesla. Devices were interrogated before and after MRI with the use of a standardized protocol and were appropriately reprogrammed before the scanning. The primary end points were death, generator or lead failure, induced arrhythmia, loss of capture, or electrical reset during the scanning. The secondary end points were changes in device settings.

Results:

MRI was performed in 1000 cases in which patients had a pacemaker and in 500 cases in which patients had an ICD. No deaths, lead

failures, losses of capture, or ventricular arrhythmias occurred during MRI. One ICD generator could not be interrogated after MRI and required immediate replacement; the device had not been appropriately programmed per protocol before the MRI. We observed six cases of self-terminating atrial fibrillation or flutter and six cases of partial electrical reset. Changes in lead impedance, pacing threshold, battery voltage, and P-wave and R-wave amplitude exceeded prespecified thresholds in a small number of cases. Repeat MRI was not associated with an increase in adverse events.

Conclusions:

In this study, device or lead failure did not occur in any patient with a non-MRI-conditional pacemaker or ICD who underwent clinically indicated nonthoracic MRI at 1.5 tesla, was appropriately screened, and had the device reprogrammed in accordance with the prespecified protocol. (Funded by St. Jude Medical and others; MagnaSafe ClinicalTrials.gov number, NCT00907361 .).

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Multicenter Study

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