



## Abstract Accepted for Presentation at the American College of Cardiology 2013

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**Abstract Title: Determining the Risks of Magnetic Resonance Imaging at 1.5 Tesla for Patients with Pacemakers and Implantable Cardioverter Defibrillators (The MagnaSafe Registry)**

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*Abstract:*

**Background:** The MagnaSafe Registry is a multicenter prospective study to determine the risk of MRI at 1.5T in 1500 patients with pacemakers (PM) and implantable cardioverter-defibrillators (ICD) who undergo clinically indicated non-thoracic imaging.

**Methods:** Device interrogation was performed pre- and post-MRI using a standardized protocol. Primary endpoints were device failure, generator/lead replacement, induced arrhythmia, loss of capture, or electrical reset. Secondary endpoints were clinically relevant device parameter changes.

**Results:** From April 2009 to October 2012, 829 non-thoracic MRI studies were performed (617 PM, 212 ICD, 1620 leads) at 16 sites. No deaths, device failures, generator/lead replacements, losses of capture, or ventricular arrhythmias occurred. A decrease in battery voltage  $\geq 0.04V$  occurred in 1% of PMs and 9% of ICDs; pacing lead impedance change  $\geq 50\Omega$  in 3% of PMs and 4% of ICDs. A decrease of  $\geq 50\%$  in P-wave amplitude occurred in 0.4% PM and 0.7% ICD leads. A decrease of  $\geq 25\%$  in R-wave amplitude occurred in 5% of PMs and 2% of ICDs. A decrease in R-wave amplitude  $\geq 50\%$  occurred in 1 ICD patient. A pacing threshold increase  $\geq 0.5V$  at 0.4 ms occurred in 1% of PM leads and 2% of ICD leads. One or more clinically relevant device parameter changes occurred in 13% of PM and 28% of ICD cases, and 3% had  $>1$  parameter change event. The frequency of a device parameter change event was 17% in those with and without a previous MRI. For PM cases, 1% had multiple parameter change events exclusive of battery voltage changes. In 9 PM cases with an impedance increase  $\geq 50\Omega$ , 1 (11%) had an additional change event, while in 29 cases with an impedance decrease  $\geq 50\Omega$ , 5 (17%) had an additional change event. However, a change in pacing lead impedance was not associated with changes in P/R wave voltage, pacing threshold or body mass index. In addition, right ventricular pacing lead age did not correlate with an increased risk of impedance change events.

**Conclusion:** Preliminary results for the first 829 cases in MagnaSafe demonstrate no deaths, device failures, generator/lead replacements, ventricular arrhythmias, or losses of capture during non-thoracic MRI at 1.5T, and multiple parameter changes were infrequent.