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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:

Objective: The MagnaSafe Registry is a multicenter study designed 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. Pacemaker non-dependent patients had pacing functions deactivated; dependent patients had the device programmed to an asynchronous pacing mode. Tachyarrhythmia therapies were disabled in non-pacemaker-dependent ICD patients; dependent ICD patients were excluded. 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: Between April 2009 and May 2012, 600 non-thoracic MRI studies were performed (447 pacemakers, 153 ICD, 1161 leads) at 12 sites. Pacemaker dependence was noted in 20% of cases; and MRI scan duration was 42 ± 20 min. No deaths, device failures, generator/lead replacements, losses of capture, or ventricular arrhythmias occurred. Four episodes of self-terminating atrial fibrillation (within 48 hours) were noted, and three cases of partial electrical reset. A decrease in battery voltage $\geq 0.04V$ occurred in 1% of PMs and 10% of ICDs; pacing lead impedance change $\geq 50\Omega$ in 4% of PMs and 4% of ICDs; and high-voltage impedance change $\geq 3\Omega$ in 18% of ICDs. A decrease of $\geq 50\%$ in P-wave amplitude occurred in 1 PM and 1 ICD. A decrease of $\geq 25\%$ in R-wave amplitude occurred in 4% of PMs and 3% of ICDs. No decreases in R-wave amplitudes $\geq 50\%$ were recorded. A pacing threshold increase $\geq 0.5V$ at 0.4 ms occurred in 1% of PM and 2% of ICD leads. Overall, one or more clinically-relevant device parameter changes occurred in 13% of PM and 31% of ICD cases. In 136 cases (23%), a previous MRI had been performed. The frequency of one or more device parameter change events was 15% in those with, and 18% in those without a previous MRI exam.

Conclusions: Preliminary results for the first 600 cases enrolled in the MagnaSafe Registry demonstrate no deaths, device failures, generator/lead replacements, ventricular arrhythmias, or losses of capture during non-thoracic MRI at 1.5T.