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Repeat MRI for Patients with Implanted Cardiac Devices Does Not Increase the Risk of Clinical Events or Parameter Changes: Preliminary Results from The MagnaSafe Registry

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Introduction: The MagnaSafe Registry is a multicenter, prospective study designed to determine the frequency of major adverse clinical events and device parameter changes for 1500 patients with standard implantable cardiac electronic devices who undergo clinically-indicated, non-thoracic MRI at 1.5T.

Methods: Device interrogation was performed pre- and post-MRI. Pacemaker-dependent subjects were programmed to an asynchronous pacing mode, and non-dependent subjects had pacing functions deactivated. For implantable cardioverter defibrillator (ICD) patients, all therapies were programmed to off for those not pacing-dependent; pacing-dependent ICD subjects were excluded. Primary study endpoints were device failure, generator/lead replacement, induced arrhythmia, loss of capture, or electrical reset. Secondary endpoints were clinically-relevant device parameter changes. No limits were placed on the number of repeat scans performed.

Results: Between April 2009 and November 2011, 431 MRI studies (324 pacemakers, 107 ICDs) were performed at 11 sites. In 325 patients (88%), only one MRI examination was performed in the MagnaSafe Registry, while in 43 patients (12%), more than one MRI study was performed. Two scans were performed in 32 patients (9%), 3 scans in 6 (2%), 4 scans in 3 (0.8%), 6 scans in 1 (0.3%), and 7 scans in 1 (0.3%). No deaths, device failures, generator/lead replacements, losses of capture, or ventricular arrhythmias occurred in either the Initial scan or Repeat scan groups. There was a decrease in battery voltage ≥0.04V in 4% of the Initial scan group and 0% of the Repeat scan group, and a pacing lead impedance change ≥50Ω in 7% of the Initial scan group, and 2% of Repeat scan group. No decrease of ≥ 50% in R-wave or P-wave amplitude occurred in either group. A pacing threshold increase ≥ 0.5V at 0.4 ms occurred in 2% in each group.

Conclusion: Preliminary results demonstrate no association between the number of MRI scans performed and the rate of clinical events or device parameter changes. No deaths, device failures, generator/lead replacements, or losses of capture were noted after clinically-indicated non-thoracic MRI at 1.5T.