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Determining the Risks of MRI at 1.5 Tesla for Patients with Pacemakers and Implantable Cardioverter Defibrillators (The MagnaSafe Registry)

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 death, generator/lead failure, induced arrhythmia, or loss of capture at the time of the MRI. Secondary endpoints were clinically-relevant device parameter changes.

Results: Between April 2009 and May 2013, 1189 non-thoracic MRI studies were performed (881 pacemakers, 308 ICD, 2293 leads) at 19 clinical sites. Pacemaker dependence was noted in 20% of cases; and MRI scan duration was 44 ± 20 min. No deaths, generator/lead failures, losses of capture, or ventricular arrhythmias occurred during the scan. Six episodes of self-terminating atrial fibrillation (all within 48 hr) and 5 cases of partial electrical reset were noted. A decrease in battery voltage ≥0.04V occurred in <1% of PMs and 9% of ICDs; pacing lead impedance change ≥50Ω in 3% of PMs and 4% of ICDs; and high-voltage impedance change ≥3Ω in 15% of ICDs. A decrease of ≥ 50% in P-wave amplitude occurred in 5 PMs and 1 ICD. A decrease of ≥25% in R-wave amplitude occurred in 4% of PMs and 2% of ICDs. A decrease in R-wave amplitude ≥50% was recorded in 1 ICD case. A pacing threshold increase ≥0.5V at 0.4 ms occurred in 1% of PM and 1% of ICD leads. Overall, one or more clinically-relevant device parameter changes occurred in 11% of PM and 26% of ICD cases. In 256 cases (22%), a previous MRI had been performed. The frequency of one or more device parameter change events was 16% in those with, and 14% in those without a previous MRI exam.

Conclusions: Preliminary results for the first 1189 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.