

Determining the Risks of Magnetic Resonance Imaging at 1.5 Tesla for Patients with Non-MRI Conditional Pacemakers and Implantable Cardioverter Defibrillators: Final Results of The MagnaSafe Registry

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

Methods: Device interrogation was performed pre-/post-MRI using a standardized protocol. Pacemaker non-dependent patients had pacing functions deactivated; dependent patients had the device programmed to an asynchronous mode. For ICD patients all therapies were disabled if non-pacemaker dependent; dependent ICD patients were excluded. Primary endpoints included death, generator/lead failure, or induced arrhythmia. Secondary endpoints were clinically-relevant device parameter changes.

Results: Between April 2009 and April 2014, 1500 clinically-indicated non-thoracic MRI studies (spine 41%; brain 35%) were performed at 21 sites (1000 PMs, 500 ICDs, 2923 leads). No deaths, generator/lead failures, losses of capture, or ventricular arrhythmias occurred during the scan. One ICD generator later required replacement when tachytherapy was inappropriately active during the exam. Six episodes of self-terminating atrial fibrillation (<49 hr) and 6 cases of partial electrical reset were noted. A decrease in battery voltage =0.04V occurred in 0.5% of PMs and 7% of ICDs; pacing lead impedance change =500 in 3% of PMs and 4% of ICDs; and high-voltage impedance change =30 in 17% 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, and a decrease of =50% in 1 ICD. A pacing threshold increase =0.5V at 0.4 ms occurred in 1% of PM and ICD leads. Overall, one or more clinically-relevant device parameter changes occurred in 12% of PM and 29% of ICD cases. A previous MRI had been performed in 312 cases (21%), and the frequency of a device parameter change event was 20% in those with, and 17% in those without a previous MRI (p=0.3). At 6-month follow up no clinically- significant durable device parameter changes were noted.

Conclusions: Final results of the MagnaSafe Registry demonstrate that clinically-indicated non-thoracic MRI at 1.5T may be performed for patients with non-conditional devices at no detectable clinical risk when the device is appropriately programmed.

Disclosure:

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