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Author Block: Robert J. Russo, MD, PhD, Heather Costa, PhD, Debra Doud, MD, Edward T. Martin, MD, Christian Machado,MD, Seth Uretsky, MD, Steven D. Wolff, MD, PhD, Michael Porter, MD, Gail Tominaga, MD, Ulrika Birgersdotter-Green, MD,Raymond Schaerf, MD, Todd Florin, MD, Daniel C. Bloomgarden, MD, PhD, Rachel Lampert, MD and George Ponce, MD. Scripps Clinic, La Jolla, CA

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

Introduction: The MagnaSafe Registry is a multicenter study designed to evaluate 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 from the study. 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 November 2011, 454 clinically-indicated non-thoracic MRI studies involving 340 PM, 114 ICDs, and 875 leads were performed at 12 sites. Pacemaker dependence was noted in 20%. MRI duration was 41 ± 18 min; the MRI was performed 2.8 ± 2.0 yrs after generator implant. No deaths, device failures, generator/lead replacements, losses of capture, or ventricular arrhythmias occurred. Four episodes of self-terminating atrial fibrillation were noted. One case of partial electrical reset was observed. A decrease in battery voltage ≥0.04V occurred in 1% of PMs and 12% of ICDs, a pacing lead impedance change ≥50Ω in 3% of PMs and 4% of ICDs, and a high-voltage impedance change ≥3Ω in 18% of ICDs. A decrease of ≥ 25% in R-wave amplitude occurred in 3% of PMs and 3% of ICDs. No decreases in P- or R-wave amplitudes ≥ 50% were recorded. A pacing threshold increase ≥0.5V at 0.4 ms occurred in 1% of PM and 2% of ICD leads. One or more clinically-relevant device parameter changes occurred in 11% of PM and 32% of ICD studies. Two patients required device reprogramming. In a subset, the quality of one scan (1/229) was affected by a cardiac device imaging artifact.

Conclusions: Preliminary results of the MagnaSafe Registry demonstrate no deaths, device failures, generator/lead replacements, losses of capture, or electrical reset episodes after non-thoracic MRI at 1.5T, and a low rate of clinically-relevant device parameter changes.