Effect of thoracic Magnetic Resonance Imaging (tMRI) scan on Implantable Cardioverter Defibrillator (ICD) System - The ASIA MRI ICD Study Update.

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Introduction: Patients implanted with Implantable Cardioverter-Defibrillator (ICD) system may require a thoracic MRI (tMRI). However, performance of tMRI raises potential safety concerns since direct exposure of radiofrequency (RF) to ICD can possibly result in tissue heating, arrhythmia induction, or device damage. The purpose of this study is to evaluate safety of ICD system in patients from Asia undergoing an elective tMRI scan.

Methods: The ASIA MRI ICD study (Clinicaltrials.gov: NCT02877693) is currently enrolling up to 198 subjects across 16 sites from India, Malaysia, and South Korea. All enrolled subjects consented for study participation, were previously implanted with a St. Jude Medical MR Conditional ICD system for at least 60 days and had no contraindications for undergoing tMRI. At 30 days post-enrollment, subjects underwent a non-diagnostic, RF intensive, pre-defined, study specific 1.5 Tesla tMRI sequence, designed to reach a whole-body specific absorption rate (SAR) of 1.8 to 2.0 W/Kg. Device interrogation was conducted pre-/post and 1-month post-tMRI follow-up visit (1-M FU).

Result: To date 194 subjects [average age 58 years, 163 male, Single Chamber ICD: 143; Dual-Chamber ICD: 51], have been enrolled. The majority of subjects (162) were enrolled in India, 28 in South Korea, followed by 4 in Malaysia. One hundred sixty-four (164) subjects had tMRI scan performed at 30 days of post-study enrollment (26 subjects withdrew from the study prior to tMRI scan). The average scan duration was 24min 40sec and average SAR was 1.8W/kg. One hundred fifty (150) subjects completed the 1-M FU visit. There was no change in lead capture threshold (average 0.75V@0.5ms), sensing amplitude (average 10.9mV) & pacing/high voltage impedance (471/65 and 469/67 ohms) reported between pre-tMRI and 1-M FU visit in 93% (140/150) of the subjects. No clinically significant detection delays for non-sustained VT/VF episodes have been reported. There were 2 SAEs (1 death and 1 hospitalization due to ventricular tachycardia storm) reported prior to tMRI scan. 1 ADE was reported for loss of capture prior to tMRI. 2 SAEs were reported post-tMRI (1 death due to hypertension and acute pulmonary edema and 1 hospitalization due to breathless). None of the SAEs
were related to the MRI scan, or MRI scan procedure. (Results will be updated before publication)

**Conclusion**: The data reported so far in ASIA MRI ICD Study of subjects undergoing 1.5 T tMRI is consistent with other 1.5T MRI studies, with no significant MRI related complications or impact on lead electrical performance.