**Results of Four Multicenter, Phase III, Magnetic Resonance Angiography Trials with MS-325, a Blood Pool Contrast Agent, for Detection of Vascular Disease in the Aortoiliac, Renal, and Pedal Regions**

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**Purpose:** To evaluate the safety and efficacy of MS-325 for contrast-enhanced (CE-) MRA in the Aortoiliac, Renal, and Pedal arteries compared to non-contrast 2D-TOF MRA, in patients with known or suspected vascular disease.

**Materials and Methods:** A 0.03 mmol/kg IV bolus of MS-325, an investigational MRI blood pool contrast agent, was administered. A consensus diagnosis of presence/absence of clinically significant (≥50%) stenoses by two independent blinded readers of catheter angiography (XRA), and a third adjudicator when necessary, established the standard of reference (SOR). Three additional readers separately diagnosed using 2D-TOF and CE-MRA images. Sensitivity, specificity, and accuracy of diagnosis were determined. Vessels deemed uninterpretable in MRA were considered inaccurate. Inter-reader XRA agreement was calculated by comparing XRA diagnoses. Patients were monitored for 72-96 hours post injection.

**Results:** In total, 3404 vessels in 641 patients were evaluated by twelve MRA readers. Average absolute increases in sensitivity, specificity, and accuracy with MS-325 application were 16.4%, 14.6%, and 13.9%, respectively. All readers showed statistically significant ($p<.005$) specificity improvements; accuracy improved significantly in 11/12 readers; sensitivity in 9/12 readers. Accuracies in MS-325-enhanced MRA were comparable to XRA inter-reader agreements. Generalized kappa-analysis showed improvements in reproducibility with MS-325. Rates of uninterpretable vessels were 1.6% in CE-MRA, 15.1% for TOF-MRA, and 9.5% for XRA. Studies yielded consistent safety results: related adverse events were mild and transient in nature, no adverse trends in labs or ECGs.

**Conclusion:** In 4 Phase III studies, MS-325 appears safe and effective for MRA assessment of vascular disease in multiple vascular territories.