Peripheral MR Angiography with Gadobenate Dimeglumine: Results of a Large-scale Multi-institutional Experience

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Purpose: A previous crossover study showed that 0.1 mmol/kg gadobenate dimeglumine provided better signal to noise and vessel delineation in peripheral arteries than a similar dose of gadopentetate dimeglumine (1). The present study was undertaken to assess the accuracy of contrast-enhanced-MR angiography (CE-MRA) with gadobenate dimeglumine relative to unenhanced 2D Time-of-Flight (2D-TOF) MRA for detecting peripheral artery disease using DSA as the gold standard.

Methods: A total of 287 patients with peripheral arterial occlusive disease (Fontain's stage IIa to IV) were enrolled in the study. Of these, 272 patients underwent both MRA and DSA within a 30 day period. MRA was performed at 1.5T using a 2D-TOF sequence before and a 3D-SPGRE sequence after the administration of 0.1 mmol/kg gadobenate dimeglumine (MultiHance, Bracco Diagnostics Inc.). Both exams covered from the aortic bifurcation to the trifurcation. Three independent experienced radiologists blinded to all patient information evaluated the MRA images, while one expert reader evaluated the DSA exams. The technical failure rate (TFR) of both MRA techniques was calculated and compared to that of DSA using a chi-square test. Sensitivity, specificity, accuracy, and inter-reader agreement for detection of significant disease ($\geq$ 50%) using DSA as gold standard were calculated for both TOF and CE-MRA and compared using McNemar's test. Patient safety assessments include vital signs, ECGs, laboratory tests, and 24 hour monitoring of subjects for adverse events (AE).

Results: The technical failure rate of TOF-MRA was 6.2%-18%. The TFR was significant lower ($p< 0.001$) on the CE-MRA exam (2.5%-3.4%), a rate approaching that of DSA (1.4%). A total of 983 vessels with significant disease (597 stenoses and 386 occlusions) were identified by the DSA reader. Sensitivity for detection of significant disease ranged from 33.2% to 62.8% and from 54% to 80.9% for TOF-MRA and CE-MRA, respectively. Significant increases ($p< 0.001$). in specificity (from 74.3-88.9% to 89.7-95.3%) and accuracy (from 68-77.3% to 85-87.5) were noted when comparing CE-MRA results to those of unenhanced MRA. Significantly better reproducibility ($p< 0.00001$) was also demonstrated for CE-MRA (82% agreement, k-value: 0.66) compared to TOF MRA (65.2% agreement; k-value: 0.47). A total of 7.7% of subjects dosed experience one or more mild or moderate AE considered possibly related to injection of gadobenate dimeglumine, the most common being injection site warmth. Other safety findings were unremarkable.

Conclusions: Significant increases in diagnostic performance and reproducibility were demonstrated for gadobenate dimeglumine-enhanced MRA of peripheral vessels in comparison with TOF MRA.

(1) Knopp MV, Giesel FL, Von Tengg-Kobligk H, et al. Contrast-enhanced MR angiography of the run-off vasculature: intraindividual comparison of gadobenate dimeglumine with gadopentetate dimeglumine. JMRI J Magn Reson Imaging 2003;17(6):694-702.