

Accuracy of Gadobenate dimeglumine-enhanced MR Angiography in the Evaluation of Renal Artery Stenosis: Comparison with Unenhanced Time-of-Flight MR Angiography versus Digital Subtraction Angiography (DSA)

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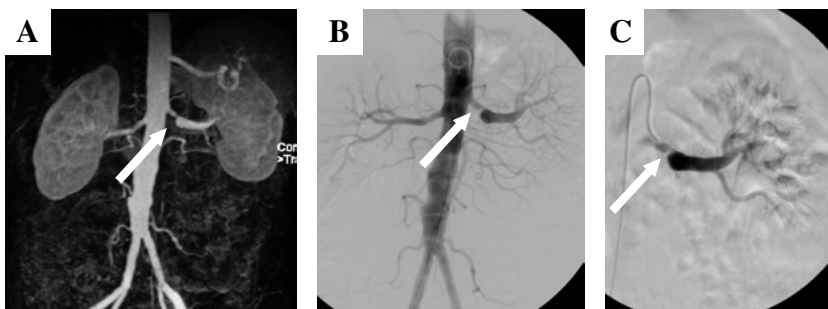
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Purpose: To determine the diagnostic accuracy of contrast-enhanced MR angiography (CE-MRA) with gadobenate dimeglumine for detection of significant steno-occlusive disease of the renal arteries using digital subtraction angiography (DSA) as reference standard, and to compare findings for CE-MRA with those for unenhanced time-of-flight [TOF] MRA.

Methods and Materials: A total of 293 patients (154 M, 139 F; mean age: 61.0±14.5 years; range: 18–93 years) with severe hypertension refractory to therapy (82.2%), progressive renal failure (11.3%), or suspected renal artery stenosis (RAS) were enrolled. Magnetic resonance angiograms were acquired using a 2D TOF sequence before and a 3D spoiled gradient-echo CE-MRA sequence after the administration of 0.1 mmol/kg gadobenate dimeglumine (MultiHance) at 2 ml/sec. DSA was performed in 268 subjects. Anteroposterior and oblique projections for the renal arteries were obtained at DSA. Image evaluation was performed by three blinded reviewers for MRA images and one blinded reviewer for DSA images. Sensitivity, specificity and accuracy of TOF MRA and CE-MRA for detection of clinically significant (>50%) stenoses were calculated using DSA as reference standard and were compared statistically using McNemars' test. Additional determinations were made of positive and negative predictive values, of interobserver agreement for the detection of significant stenoses (kappa analysis), and of the technical adequacy of TOF MRA, CE-MRA and DSA. Finally, determinations were made of the detection of accessory renal arteries and of the safety of gadobenate dimeglumine for use in CE-MRA of the renal arteries.

Results: The technical failure rates for CE-MRA, TOF MRA and DSA of the main renal arteries ranged from 1.9%–2.8% for CE-MRA, 14.1%–29% for TOF MRA and ~1% for DSA. Of the 268 subjects to undergo both MRA and DSA, 178 (66.4%) subjects had significant (>50%) steno-occlusive disease of the renal arteries determined by DSA. The sensitivity, specificity and accuracy for detection of significant disease ranged from 28.2%–42.2%, 67.5%–87.1% and 52.5%–66.3%, respectively, for TOF MRA and from 60.1%–74.5%, 89.4%–94.7% and 80.4%–86.9%, respectively, for CE-MRA. The increases from TOF MRA to CE-MRA were statistically significant ($p<0.001$) for all readers. Better positive and negative predictive values were also obtained for CE-MRA (81.2%–89.8% and 78.9%–85.6%, respectively) compared to TOF MRA (78.9%–85.6% and 66.5%–69.3%, respectively). A statistically significant ($P<0.0001$) increase in interobserver agreement was determined for CE-MRA (87.9% agreement) compared to TOF MRA (57.0%), with Kappa values increasing from 0.43 to 0.69 for agreement between all three blinded MRA readers. A total of 113 accessory renal arteries were detected on DSA. Of these the blinded MRA readers detected 66%–76% on CE-MRA compared with 6%–14% on TOF MRA. Adverse events considered of probable, possible, unknown or missing relationship to gadobenate dimeglumine were determined for 27/293 (9.2%) subjects. These events were mild in intensity in 26/27 patients and moderate in 1/27 patients. No clinically meaningful trends in vital signs, ECG or laboratory parameters were observed.

Conclusion: MRA performed with 0.1 mmol/kg gadobenate dimeglumine compares well with results from DSA in patients with RAS, with significant increases in diagnostic performance and test reproducibility compared to TOF MRA.



A 39-year-old patient with known coronary artery disease and HBP. (A) CE-MRA of abdominal aorta shows a high-grade stenosis of the main left RA with poststenotic vessel dilatation. (B, C) Corresponding catheter angiograms depict an eccentric stenosis estimated at >80% with plaque formation (arrow) just before the dilated vessel segment.