Multicenter Intraindividual Comparison of Gadobenate Dimeglumine and Gadofosveset Trisodium for MR Angiography of the Renal Arteries

G. Schneider[1], M. Pasowicz[2], J. Vymazal[3], Z. Seidl[4], M. Aschauer[5], D. Bilecen[6], R. Iezzi[7], and C. E. Ballarati[8]
[1]Radiology, University Hospital Hamburg, Hamburg/Saar, Germany, [2]Diagnostics and Rehabilitation, John Paul II Hospital, Krakow, Poland, [3]Radiology, Na Homolce Hospital, Prague, Czech Republic, [4]Radiology, Lékarská Fakulta Neurologicka Klinika, Prague, Czech Republic, [5]Medical University of Graz, Graz, Austria, [6]Radiology, University Hospital Basel, Switzerland, [7]Radiology, Università G. D'Annunzio, Chieti, Italy, [8]Radiology, Hospital Valduce, Como, Italy

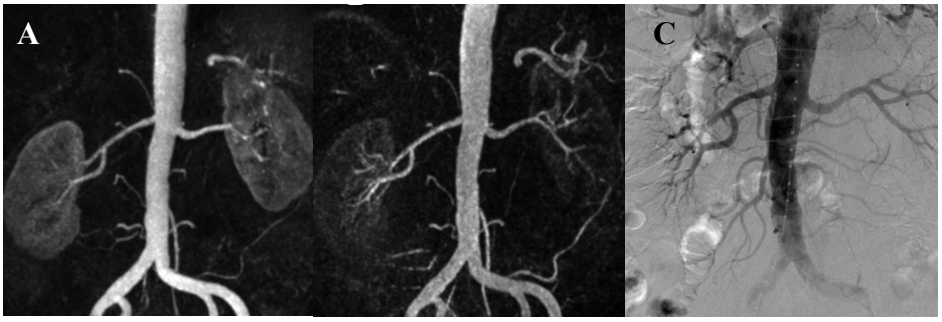
Purpose: To prospectively compare efficacy and safety of gadobenate dimeglumine and gadofosveset trisodium for contrast-enhanced MR angiography (CE-MRA) of the renal arteries.
Materials and Methods: Thirty-eight subjects with renal vascular disease underwent 2 CE-MRA examinations, the first with 0.1 mmol/kg bw gadobenate dimeglumine and the second, 3-12 days later, with 0.03 mmol/kg bw of the intravascular blood pool agent gadofosveset. For both examinations, identical T1-w SPGR sequences were used to acquire first-pass (FP) coronal images during breath-hold. In a subset of patients (16/38), additional steady-state (SS) sagittal and axial images were acquired with gadofosveset. Thirty-four patients underwent digital subtraction angiography (DSA). Three experienced blinded radiologists evaluated the MRA image sets in terms of sensitivity, specificity, accuracy, positive predictive value (PPV), and negative predictive value (NPV) for detection of significant (≥51%) renal artery stenosis compared to DSA. Findings were compared using McNemar and Wald tests; assessments of FP diagnostic preference were evaluated using the Wilcoxon Signed Rank test; and reader agreement (kappa [k]) was determined. In addition, a full safety evaluation was performed.
Results: Blinded experts consistently found CE-MRA after gadobenate dimeglumine to be superior to CE-MRA after gadofosveset in terms of sensitivity (76-87% vs 68-76%), specificity (92-99% vs 91-94%), accuracy (89-96% vs 86-90%), PPV (70-94% vs 65-76%), and NPV (94-97% vs 92-94%; see Table 1). Moreover, this difference was statistically significant for the gadobenate dimeglumine-enhanced MRA exam as evaluated by 2 readers for specificity (P=0.02), accuracy (P=0.005), and PPV (P=0.018). SS images obtained following gadofosveset administration provided no additional diagnostic benefit. Three-reader agreement was excellent (k=0.78-0.86). Readers 1, 2, and 3 preferred gadobenate dimeglumine in 11, 17, and 13 patients and gadofosveset in 5, 4, and 5 patients; no preference was expressed for the remaining subjects. Adverse events were reported for 2/38 (5.3%) of patients given gadofosveset and 0/39 patients given gadobenate dimeglumine.

Table 1: Diagnostic Performance Results of First Pass CE-MRA vs DSA

	Reader 1		Reader 2		Reader 3	
	Gadobenate dimeglumine	Gadofosveset	Gadobenate dimeglumine	Gadofosveset	Gadobenate dimeglumine	Gadofosveset
Patients (n)	34	34	34	34	33	34
Segments (n)	189	187	183	185	183	186
Sensitivity	75.7%	68.4%	78.4%	68.4%	86.5%	76.3%
Specificity	92.1%	91.3%	96.6%*	90.5%	98.6%*	93.9%
Accuracy	88.9%	86.6%	92.9%*	85.9%	96.2%*	90.3%
PPV	70.0%	66.7%	85.3%*	65.0%	94.1%*	76.3%
NPV	94.0%	91.9%	94.6%	91.7%	96.6%	93.9%

*Statistically significant difference (P<0.05) from gadofosveset.

Conclusions: A significant preference was noted for CE-MRA of the renal arteries performed after administration of 0.1 mmol/kg gadobenate dimeglumine vs that performed after 0.03 mmol/kg of the intravascular blood pool agent gadofosveset. Using DSA as a reference standard, gadobenate dimeglumine-enhanced images provided higher sensitivity, specificity, PPV, NPV, and accuracy compared to those performed using gadofosveset.



CE-MRA images obtained with (A) gadobenate dimeglumine and (B) gadofosveset, and (C) corresponding DSA image.