

Table 1

MRA in the Diagnosis of Hemodynamically Significant Artery Stenosis

I. Renal Arteries

Author /Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
Bongers V 2000	<p>P, B, Consecutive</p> <p>Inclusion criteria: Pts with clinical suspicion of RAS</p> <p>Exclusion criteria: MRI contraindications</p> <p>All pts had captopril renography (CR) & MRA within 6 weeks before DSA</p> <p>Renogram read by 2 nuclear medicine MDs in consensus who were not aware of MRA or DSA results</p> <p>DSA read by 2 additional radiologists who did not perform the DSA, nor were they aware of CR or MRA results</p> <p>MRA read by 2 radiologists in consensus, prior to performing DSA. Neither were aware of renogram result</p>	<p>43 pts, 121 arts 57yrs(21-40) 23♀, 20 ♂</p>	<p>3D CE-MRA vs. DSA</p>	<p>100 %</p>	<p>94%</p>	<p>The sens/spec in this table reflects comparative results of MRA vs. DSA only</p> <p>Out of 19 accessory arteries found by DSA, MRA missed 2</p>

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Chan et al, 2001	P A single radiologist independently compared all patients to DSA within 5 wks of the CE-MRA	17 pts 17 arts 41yrs (34-64) 6♀, 11 ♂ Out of a pool of 196 f/u renal transplant recipients, 17 were recruited for systolic bruit in the transplant region 18.8 mo (2-86.3 mo) after transplant	3D CE-MRA vs. DSA	100%- iliac artery 100%- Anastomosis 100%- graft renal artery	100%- iliac artery 83%- Anastomosis 100%- graft renal artery	Uncertain whether the assessors were masked The sensitivity and specificity varied depending on the area of assessment 2 FP of >50% stenosis by MRA. 1 pt due to marked turbulence from sharp kinking of transplant artery.
De Cobelli et al, 1996	P, B, consecutive Pts screened for hypertension and other factors using criteria described 28/50 pts had confirmatory exam using DSA as reference standard. DSA performed within 1 week of MRA. MRA analyzed by 2 radiologists in consensus, who were masked DSA findings	50 pts, 101 arts 53 yrs (16-83) 27♀, 23 ♂ All pts were suspected to have renocardiovascular disease	3D CE-MRA vs. DSA	90%	99%	MRA detected 101 of the 103 arteries detected by DSA. The missed arteries were 1 accessory artery outside the imaging volume, and 1 artery with a stent Not all 50 pts received a DSA, and no explanation was given 1 FP, 2 FN (1 severe proximal stenosis was depicted as mild and 1 distal stenosis not seen on MRA was due to fibromuscular dysplasia.)

Author/ Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
De Cobelli et al, 2000	<p>P, B</p> <p>DSA was conducted within 2 wks of the MRA and US and read by 1 vascular radiologist masked to results of MRA and US.</p> <p>2 radiologists assessed results of MRA by consensus and were masked to results of DSA</p> <p>1 vascular radiologist assessed results of US</p>	<p>45 pts, 103 arts</p> <p>58yrs (23-75) 22♀, 23 ♂</p> <p>Pts referred for suspected RAS.</p> <p>Selected on basis of clinical criteria for moderate to high possibility of renovascular disease</p>	<p>Protocol evaluated combined 2D & 3D unenhanced MRA vs. Doppler ultrasonography vs. DSA</p>	<p>MRA: 100% US: 79%</p> <p>Both MRA & US had 100% sensitivity for totally occluded vessels</p>	<p>MRA: 93% US: 93%</p> <p>Both MRA and US had 100% specificity for totally occluded vessels</p>	<p>17 of 45 pts were enrolled in another study whose findings were published in DeCobelli et al, 1997</p> <p>Depiction of 89 of 103 (86%) arteries possible through US</p> <p>Depiction of 102 of 103 (99%) arteries possible through MRA</p> <p>The MRA results reported were combined for both enhanced and unenhanced MRA</p> <p>MRA classified 2 normal arteries as severe stenoses and 3 mild stenoses as severe stenosis</p> <p>Because the assessors had to reach consensus the inter-rater reliability cannot be assessed</p>

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De Haan et al, 1996	<p>P, B</p> <p>One inclusion criteria was ability to conduct MRA 48 hours before DSA. or CA</p> <p>DSA was performed in cases where arteries were not clearly depicted</p> <p>1 radiologist without knowledge of pts clinical background or MRA results, assessed results of CA or DSA</p> <p>1 vascular radiologist and 1 MR radiologist who had no knowledge of the clinical background of pts evaluated results of all 3 MRA techniques individually</p>	<p>38 pts, 89 arts</p> <p>60 yrs (37-78) - men</p> <p>55 yrs (24-74) - women</p> <p>24 ♀, 14 ♂</p> <p>All pts had therapy-resistant hypertension and were referred for testing</p> <p>Most of the pts had undergone routine evaluation for renovascular hypertension</p>	<p>3D MRA with and without cardiac synchronization vs. CA or DSA</p> <p>(no contrast used)</p>	<p>100% with no gating</p> <p>100% with diastolic gating</p> <p>100% with systolic gating</p>	<p>96% with no gating</p> <p>96% with diastolic gating</p> <p>82% with systolic gating</p>	<p>Reference of CA or DSA was not consistent</p> <p>3 pts were excluded (2 for claustrophobia and 1 for metal fragments in the back)</p> <p>Of 87 arteries, 82 were seen by MRA without gating, 83 by MRA with systolic gating, and 84 by one observer and 83 by the other for MRA with diastolic gating</p> <p>No significant difference between the 3 MRA techniques in the diagnosis of >50% stenosis</p>

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Fain et al, 2001	<p>P, B</p> <p>180 pts with suspected RAS received MRA. Of these, the 25 pts in the study population then also underwent DSA.</p> <p>All 25 pts received DSA, and <u>small</u>-FOV MRA.</p> <p>Only 23/25 pts received DSA and <u>large</u>-FOV MRA.</p> <p>Assessors were masked to the results of the second MRA, but there was no mention of whether they knew the results of the previous MRA</p> <p>2 MR angiographers reached consensus for each observation</p>	<p>25 pts, 55 arts</p> <p>65yrs (8-83) 17♀, 8♂</p>	<p>Small-FOV 3D CE-MRA and large-FOV 3D CE-MRA vs. DSA</p>	<p>97%- high-spatial-resolution small-FOV 3D MRA</p> <p>79%-large-FOV 3D MRA</p>	<p>92%-small-FOV 3D MRA</p> <p>91%-large-FOV 3D MRA</p>	<p>Small-FOV depicted 9/10 accessory renal arteries and 45/45 main arteries</p> <p>Large-FOV depicted 8/10 accessory renal arteries and 41/41 main arteries</p> <p>Using small-FOV MRA, 2 cases of significant RAS were missed and 1 overestimated</p> <p>Using large-FOV MRA, 2 cases of significant RAS were missed and 6 overestimated.</p> <p>There was no explanation of why only 25 pts out of 180 were included in the study. Two pts did not receive large-FOV. One was technically unsuccessful. The other was not performed. No reason given.</p> <p>Because the assessors had to reach consensus the inter-rater reliability cannot be assessed</p>

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Hahn et al, 1999	<p>P, B</p> <p>MRA was conducted between 0-69 days (mean 6.6 days) after CA</p> <p>MRA assessed by 2 independent radiologists with no knowledge of CA results</p> <p>Results of CA and MRAs were graded by consensus observations</p>	<p>22 pts</p> <p>67yrs (25-83) 7♀, 15 ♂</p> <p>All patients had at least 1 RAS previously confirmed by CA</p>	<p>3D phase-contrast unenhanced MRA</p> <p>3D phase-contrast CE-MRA</p> <p>3D single breath-hold CE-MRA</p> <p>vs. catheter angiography</p>	<p>95% Unenhanced phase-contrast 3D MRA</p> <p>85% phase-contrast 3D CE-MRA</p> <p>91% single breath-hold 3D CE-MRA</p> <p>100% for occluded vessels in all 3 MRA</p>	<p>38% Unenhanced phase-contrast 3D MRA</p> <p>52% phase-contrast 3D CE-MRA</p> <p>79% single breath-hold 3D CE- MRA</p> <p>100% for occluded vessels in all 3 MRA</p>	<p>2 pts were excluded from analysis because of an incomplete MR examination due to claustrophobia</p> <p>Inter-rater reliability (0.62) was best for 3D single breath-hold CE-MRA for detection of significant stenosis</p> <p>Unenhanced phase-contrast 3D MRA failed to detect 8 accessory renal arteries</p> <p>Phase-contrast 3D CE-MRA failed to detect 8 accessory renal arteries</p> <p>Single breath-hold 3D CE-MRA failed to detect 3 accessory renal arteries</p>

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Huber et al, 2001	<p>P, B</p> <p>Indication for DSA after examination by MRA was allograft failure of the kidney or hypertension</p> <p>DSA assessed by 2 vascular radiologists reaching consensus and unaware of the MRA results</p> <p>MRA assessed by 2 MR radiologists separately then together who were unaware of the DSA results</p>	<p>41 pts</p> <p>42yrs (+/-17.4yrs)</p> <p>All pts post-kidney transplantation with goal of assessing postoperative complications</p>	3D CE-MRA vs. DSA	<p>Radiologist #1 100%</p> <p>Radiologist #2 100%</p> <p>100% - consensus</p>	<p>Radiologist #1 97%</p> <p>Radiologist #1 93%</p> <p>100% - consensus</p>	<p>Inter-rater reliability was 0.92 for patient-based and 0.96 for segment-based analysis</p> <p>Radiologist #1 – 1 false positive overestimation of a mild stenosis in external iliac artery</p> <p>Radiologist #2 – 2 false positive overestimations of a mild stenosis in the renal artery and segment artery</p>

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Korst et al, 2000	<p>P, B</p> <p>DSA assessed by 2 radiologists who were unaware of the results of MRA</p> <p>MRA assessed by 2 radiologists who were unaware of DSA results</p> <p>Consensus was obtained for both DSA and MRA results</p>	<p>38 pts, 93 arts</p> <p>54yrs (18-75) 25♀, 13 ♂</p> <p>Pts suspected of having RAS</p>	Enhanced 3D CE- MRA vs. DSA	<p>100%</p> <p>100% for totally occluded vessels</p>	<p>85%</p> <p>100% for totally occluded vessels</p>	<p>MRA depicted 75 of 75 (100%) main arteries and 13 of 17 (76%) accessory arteries</p> <p>Inter-rater reliability was 0.90 for DSA and 0.91 for MRA</p> <p>No adverse reactions or complications occurred during DSA nor MRA</p> <p>4 arteries were overestimated as having significant stenosis by MRA</p>
Mittal TK 2001	<p>P,B</p> <p>MRA performed prior to DSA in all but 1 pt. Both tests performed within 1 week of each other</p> <p>MRA performed and evaluated by a separate radiologist masked to results of DSA.</p>	<p>41 pts, 52 arts 30-85yr 24♀, 18♂</p> <p>26 pts w/ clinical suspicion of RAS</p> <p>16 pts who were potential kidney donors (1 excluded for claustrophobia)</p>	3D CE-MRA vs. DSA	95%	93%	<p>MRA identified all 52 main arts and 7 accessory arts shown on DSA in patients with suspected RAS</p> <p>In kidney donors, MRA identified all 25 main renal arts without early branching seen on DSA, and 4 of 5 renal arts with early branching. The unidentified early branch on MRA led to the art being classified as the main renal artery. Breathing artifact was blamed for this error.</p> <p>MRA also correctly identified 4 accessory arts seen on DSA.</p>

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Qanadli SD 2001	<p>P,B</p> <p>79 kidneys analyzed (2 inconclusive)</p> <p>MRA read by 2 radiologists, masked to results of other exams</p> <p>If there was >1 renal art, the most stenotic was considered. If there was >1 stenotic area, the most stenotic was considered</p> <p>Inclusion criteria: Pts with suspected RAS due to one or more of the following: Severe HTN, Refractory HTN despite optimal medical management, acceleration of HTN, abdominal or flank bruit</p> <p>The exclusion criteria were extensive, but were defined <i>a priori</i></p>	<p>41 pts, 52 arts 64yrs(41-78) 15♀, 26♂</p> <p>During study period, 107 patients initially approved, but 30 excluded for various reasons. Also, 36 refused to undergo all 4 examinations.</p>	<p>All 41 pts received Captopril Doppler, Captopril Scintigraphy, DSA & CE-MRA within 3 months</p>	95%	82%	<p>Vessels evaluated at 50% and 70% stenotic threshold</p> <p>Indeterminate Cap Dopp or Cap Scint results considered + as per usual clinical practice</p> <p>Compared to DSA, CE-MRA tended to overestimate degree of stenosis. Among 41 kidneys with >50% stenosis on DSA, the % stenosis on MRA was 78%±22. vs 69%±14 on DSA.</p> <p>MRA identified 96 of 99 arts seen on DSA (97%)</p> <p>Inter-rater reliability:</p> <p>DSA @ 50% stenotic threshold = 0.73</p> <p>MRA @ 50% stenotic threshold = 0.83</p>

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Thornton, J 1999	<p>P,B, Consecutive</p> <p>Patients suspected of having secondary hypertension.</p> <p>Patients first had DSA followed by MRA within 1 month.</p> <p>All CE-MRA and DSA images reviewed by 3 masked observers. Consensus reached in each case.</p> <p>All pts had both studies</p>	62 pts, 138 arts (age and sex unknown)	3D CE-MRA vs. DSA	88%	98%	<p>MRA identified 129 of 138 arteries seen DSA (93%)</p> <p>MRA missed 9 accessory arteries seen on DSA</p> <p>Because the assessors had to reach consensus the inter-rater reliability cannot be assessed</p> <p>21 stenoses detected by MRA, with 19 seen on DSA (2 false positives)</p> <p>3 false negatives also reported</p>

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Voiculescu 2001	<p>P,B, Consecutive</p> <p>Pts with clinical suspicion of RAS were included</p> <p>DSA interpreted by 2 radiologists masked to each other</p> <p>Where radiologists disagreed on % of stenosis for DSA, a mean value was determined for final stenotic grade</p> <p>MRA interpreted by 2 other readers, masked to each other and to DSA results</p>	<p>36 pts, 77 arts</p> <p>54yrs(24-79) 18♀, 28♂</p>	CE-MRA and color Doppler vs. DSA	<p>89% for all renal arts</p> <p>96% in main renal arts</p>	<p>88% for all renal arts</p> <p>86% for main renal arts</p>	<p>>60% stenosis is considered clinically significant</p> <p>CE-MRA was able to detect 90.9% of all renal arts, but only 55.5% of accessory arts</p> <p>No mention of how reader discordance was managed for CE-MRA</p> <p>Inter-rater reliability was not reported</p> <p>Compared to DSA, CE-MRA tended to overestimate degree of stenosis. With MRA, 6 main renal arteries showed stenosis, while DSA showed them as nonstenosed. In 2 of these 6 arteries, MRA showed >60% stenosis, while DSA indicated 45-50% stenosis</p>

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Völk, M 2000	<p>P,B, Consecutive</p> <p>Inclusion: Pts with clinical suspicion of RAS</p> <p>In 33 pts, DSA & MRA were performed within 24 hrs. In 7 pts, the studies were performed within 1 day to 4 months of each other</p> <p>4 radiologists independently read MRA and DSA. Readers were unaware of DSA findings when reviewing MRA and vice versa. Nor were readers aware of pt. clinical history</p>	<p>40 pts, 99 arts 63yrs(25-81) 11♀, 29♂</p>	<p>3D CE-MRA Vs. DSA</p>	93%*	83%*	<p>In one pt, MRA was not diagnostic due to injector failure</p> <p>MRA vs. DSA for accessory arteries excluded from overall sens/spec calculations</p> <p>MRA detected 17 of 19 accessory arts confirmed by DSA</p> <p>Inter-rater reliability higher in MRA than DSA. 0.641 for DSA 0.494 for MRA</p>

*Average value of all four radiologists for main renal artery findings

II. Aorto-Iliac Arteries

Author/ Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
Dorenbeck, 2002	<p>P, B</p> <p>Inclusion: All pts underwent bypass surgery for arterial occlusive disease</p> <p>Exclusion: Pts with general MRI contraindications</p> <p>DSA done within 3 days following bypass surgery, and MRA done within 5 days after DSA</p> <p>4 radiologists reviewed MRAs independently and in a masked fashion</p> <p>Method for reviewing DSA not stated</p>	15 pts Age/sex not stated	3D CE-MRA vs. DSA	100%	100%	<p>No occlusions detected on either DSA or MRA</p> <p>MRA overestimated 5 stenoses. MRA called 4 of 5 vessels grade 2, while they were grade 1 on DSA</p> <p>In 1 MRA a vessel was labeled >75% stenosed, while on DSA it was 50-74% stenosed</p> <p>No overestimation was by more than 1 grade, and, in no case did it affect the diagnosis of significance</p> <p>Inter-rater reliability was 0.77</p>

Author/Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
Haney, TF 1997	<p>P,B, Consecutive</p> <p>Inclusion criteria: 1) Pts referred for symptomatic aortoiliac disease; 2) Informed consent; 3) Could undergo MRA within 48 hrs of DSA</p> <p>Exclusion criteria: General MRI contraindications</p> <p>DSA read by 1 radiologist who was masked to MRA results</p> <p>MRA read by another radiologist who was masked to DSA results</p>	<p>39 pts, 323 arts 62yrs(34-81) 11♀, 28♂</p>	<p>3D CE-MRA vs. DSA</p>	<p>93% renal</p> <p>96% common iliac</p> <p>93% external iliac</p> <p>96% internal iliac</p>	<p>98% renal</p> <p>100% common iliac</p> <p>93% external iliac</p> <p>94% internal iliac</p>	<p>No inter-rater reliability reported</p>

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Meaney, 1999	<p>P, B, consecutive</p> <p>Pts underwent elective DSA for lower extremity claudication</p> <p>MRAs reviewed by 2 independent radiologists in masked fashion</p> <p>If MRA readers disagreed on whether a vessel was patent or occluded, the 2 radiologists reached consensus</p> <p>DSAs reviewed by pairs of radiologists in consensus (masking to MRA results not stated)</p> <p>Time between MRA and DSA not stated</p> <p>Unclear if radiologists reading DSA were masked to MRA results</p>	<p>20 pts 65 yrs (47-83) 12 ♂ 8♀</p> <p>(26 pts invited, 5 refused, 1 had pacemaker)</p>	3D CE-MRA vs DSA	<p>The following sens info is based on comparison of CE-MRA to DSA for all segments reviewed. This included aorto-iliac and lower extremity vessels. (Sens data on only aorto-iliac vessels was not provided):</p> <p>sensitivity for diagnosing <50% from >50% stenosis = 81%</p> <p>sensitivity for diagnosing 100% stenosis (i.e. occlusion) = 94%</p>	<p>The following spec info is based on comparison of CE-MRA to DSA for all segments reviewed. This included aorto-iliac and lower extremity vessels. (Spec data on only aorto-iliac vessels was not provided):</p> <p>specificity for diagnosing <50% from >50% stenosis = 89%</p> <p>specificity for diagnosing 100% stenosis (i.e. occlusion) = 97%</p>	

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Ruehm, 2000	<p>P, B</p> <p>Inclusion: Pts referred for DSA to assess PVD (50) or graft patency (11), lack of contraindication to MRI, ability to do MRA within 72 hrs of DSA</p> <p>DSA and MRA interpreted by separate radiologists in a masked and independent fashion</p> <p>For evaluation purposes, arterial system divided into: distal aorta (DA), common iliac (CA), internal iliac (II), external iliac (EI), and leg arteries</p>	<p>61 pts 64yrs(41-83) 41 ♂ 20 ♀</p> <p>1769 arterial segments</p>	3D CE-MRA vs. DSA	<p><u>@ 50% stenosis</u> DA = not reported CI = 93% EI = 94% II = 96%</p> <p><u>@ 100% stenosis</u> DA = not reported CI = 100% EI = 100% II = 67%</p>	<p><u>@ 50% stenosis</u> DA = not reported CI = 99% EI = 96% II = 93%</p> <p><u>@ 100% stenosis</u> DA = not reported CI = 100% EI = 100% II = 99%</p>	<p>Poor quality MRA in 3% of arterial segments (58/1769)</p> <p>39 arterial segments noted as >50% stenotic on MRA were graded as not significantly stenotic on DSA</p> <p>15 arterial segments noted as >50% stenotic on DSA were graded as not significantly stenotic on DSA</p> <p>All aneurysms noted on DSA were also noted on MRA (n=9)</p>

Schoenberg 2002	P, B Inclusion criterion: All pts had DSA within 2 months before MRA MRA & DSA reviewed by 3 radiologists, each unaware of initial results of MRA or DSA	41 pts, 165 arts 56yrs(48-79) 12♀, 29♂ 76 renal 58 common iliac 31 external iliac	3D CE-MRA vs. DSA	Reader 1: 94% renal 80% common iliac 100% external iliac Reader 2: 97% renal 78% common iliac 78% external iliac Reader 3: 85% renal 85% common iliac 88% external iliac	Reader 1: 86% renal 90% common iliac 83% external iliac Reader 2: 85% renal 83% common iliac 92% external iliac Reader 3: 75% renal 89% common iliac 96% external iliac	Mean CE-MRA inter- rater reliability: Renal: 0.77 Common iliac: 0.77 External iliac: 0.49
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Torreggiani, 2002	P,B Inclusion criteria: 1) Pts with symptoms of aortoiliac occlusion, and 2) Pts unable to have perferomral angiogram performed 28 pts presented. Of those, 9 were excluded (5 <u>could</u> have perferomral angiogram, 1 had a pacemaker, and MRA not available for 3 pts) All pts had MRA within 48 hrs of DSA MRA reviewed independently by 2 radiologists masked to DSA results. If MRA reviewers disagreed, then MRA reviewed in consensus	19 pts 62yrs(45-77) 14 ♂ 5♀	3D CE-MRA vs DSA 5 pts received trans-lumbar DSA 14 pts received brachial DSA	aortic occlusions 88% iliac occlusions 100%	aortic occlusions 100% iliac occlusions 97%	Sens/spec information on aortic or iliac stenosis not given MRA image quality reported as excellent in 13 pts and good in 6 pts. Trans-lumbar and brachial DSA results combined results for sens/spec calculation

(See legend on next page)

Legend

#Arts = number of arteries
#Pts = number of patients
B = blinded
CA = catheter angiography
CE-MRA = contrast enhanced MRA
CI = common iliac
DSA = digital subtraction angiography
EI = external iliac
F-C = femorocrural
F-F = femorofemoral
FOV = field of view
F-P = femoralpopliteal
GD = gastroduodenal artery
HTN = hypertension
I-F = iliacofemoral
II – internal
I-P = iliacprofundal
MIP = maximum intensity projection
MRA = magnetic resonance angiography
N/A = not applicable
NB = not blinded
NR =not reported
P= prospective
PVD = peripheral vascular disease
R= retrospective
RAS = renal artery stenosis
RI = renal insufficiency
RVH = renovascular hypertension
Sens = sensitivity
SMA= superior mesenteric artery
Spec = specificity
Sten = stenosis