Comparison of renal MRA and Angiography Data in the CORAL study

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Introduction: The Cardiovascular Outcomes in Renal Atherosclerotic Lesions (CORAL) study randomizes patients with atherosclerotic renal artery stenosis to either medical therapy or balloon angioplasty/stent and follows these patients to determine which therapy has a better outcome. Recently, renal MRA has become an accepted pathway for identifying patients with hemodynamically significant renal artery stenosis for the purposes of CORAL study randomization. This paper compares the MRA and DSA results in the 50% of patients randomized to angioplasty and stent therapy.

Materials and Methods: CORAL is a prospective, multi-center, unblinded, two-arm, study that will randomize 1080 patients at up to 100 sites in the US and 100 sites outside the US. Patients with a history of systolic hypertension, who have documented renal artery stenosis, are enrolled into this study and randomized after renal artery diagnostic evaluation to either medical therapy or medical therapy with renal artery stenting and closely monitored for blood pressure control and management of other risk factors from ~ 5 years. Stenosis $\geq 60\%$ (positive) must be observed by the core labs prior to randomization which can be done using either duplex ultrasound, renal artery magnetic resonance angiography (MRA), or catheter angiography. For randomization by MRA, stenosis > 90% on high quality MRA or stenosis >75% on MRA with spin dephasing on 3D phase contrast or stenosis > 75% on MRA and two of the following: 1. Ischemic kidney > 1 cm smaller than contralateral kidney; 2. Ischemic kidney enhances less on arterial phase; 3. Ischemic kidney has delayed Gd excretion; 4. Ischemic kidney hyper-concentrates urine; 5. 2-D phase contrast flow waveform shows delayed systolic peak; or 6. post stenotic dilatation. After image and data review indicates that the patient has met all inclusion criteria and none of the exclusion criteria, all such patients who have signed informed consent are randomized to renal artery stenting with medical therapy versus medical therapy alone.

Results: 326 patients have entered the CORAL study. A total of 55 renal MRA studies from 15 sites (14 in the US and 1 outside the US) have been reviewed by MRA core lab for randomization, of which 26 (47%) were diagnosed as having $\geq 60\%$ stenosis. Fifteen patients were enrolled via the MRA pathway. For the seven randomized to balloon angioplasty and stent therapy, angiography at the time of stent placement confirmed that MRA correctly identified 8 lesions as hemodynamically significant which are shown in Table 1. Although the accuracy was 100%, at this point the numbers are too small to assess the predictive power of each of the individual signs of functional significance. Among these 55 patients, 35 had MRA reports from the local radiologist. MRA readings by coral lab were consistent with the readings by local radiologist in 19 patients (54%). These included 15 positive studies and 4 negative studies. In the remaining 16 patients, local radiologists overestimated the severity of renal artery stenoses. Other local radiologist errors included failure to identify accessory renal arteries, failure to identify a renal infarct

Patient	MRA					DSA percent stenosis
	percent stenosis	Post-stenotic dilatation	Smaller kidney	Less arterial phase enhancement	Delayed Gd excretion	
1L	90%	yes	no	yes	-	70.61%
2R	90%	no	yes	no	-	71.67%
3R	90%	yes	yes	no	-	64.66%
4R	90%	yes	no	no	-	76.37%
4L	60%	yes	no	no	-	66.54%
5R	80%	yes	yes	no	yes	86.02%
6L	75%	yes	yes	no	-	70.69%
7R	> 90%	no	no	no	-	100%

Conclusion: CORAL is an important study for assessing how to treat renal artery stenoses and thus far, MRA has proven to be an accurate method of identifying patients for study randomization. High number of local radiologist reporting errors suggests there is opportunity for improving MRA through continuing medical education.

References
1: Kramer U. 2006;41:125-32. 2: Leung DA. Radiol Clin North Am. 2002 ;40:847-65. 3: Schoenberg SO. J Am Soc Nephrol. 2002;13:158-69. 4: Marchand B. J Mal Vasc. 2000;25:312-320. 5: Matos C. Rev Med Brux. 1999;20:A348-51. 6: Schoenberg SO. 1999;10:347-56. 7: Grist TM. Coron Artery Dis. 1999;10:151-6. 8: Miller S. 1999;170:163-7. 8: Miller S.Magn Reson Imaging. 1998;16:1005-12.9: Westenberg JJ, Magn Reson Imaging. 1998;16:249-60. 10: Schoenberg SO. Magn Reson Imaging Clin N Am. 1998;6:351-70. 10: Dawson DL. Semin Vasc Surg. 1996;9:172-81.
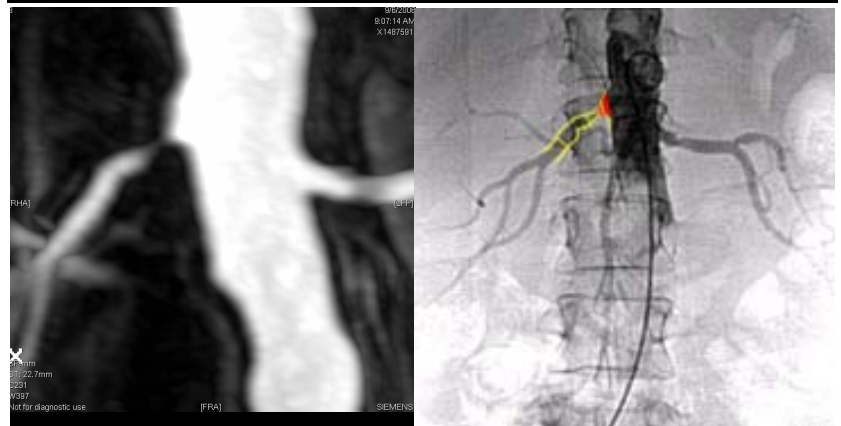
Figure1. CORAL patient with a 90% right renal artery stenosis on MRA confirmed by angiography (72%).