

Meeting abstract

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## 1048 Randomized controlled trial of the effect of rosiglitazone on carotid atherosclerosis in diabetic patients

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### Introduction

There has been much interest in carotid artery wall thickening as a marker of atherosclerosis, both by ultrasound and more recently by magnetic resonance (MR). Ultrasound measurements are limited by the presumption that the vessel is uniform. MR does not have this limitation. Rosiglitazone (RSG) is a nuclear PPAR-gamma agonist and has important effects in diabetes control which has led to its widespread use as a complement to existing diabetes drugs. It is known to lead to minor fluid retention in some patients, and recent reports suggest that it may be associated with an increased risk of ischemic cardiovascular events. However, this effect is controversial and may not be seen with all glitazones.

### Purpose

We conducted a CMR study of the use of rosiglitazone in diabetic patients to determine its effect on atherosclerotic burden.

### Methods

We enrolled 48 patients with type 2 diabetes mellitus. There were 41 male and 7 female subjects, 80% were taking statins/fibrates. Subjects were eligible if they had documented carotid atheroma on screening carotid ultrasonography and then underwent carotid CMR at baseline, six months, and after 1 year. Patients were randomised to RSG 4 mg od (up-titrated to RSG 4 mg bd at 12 wks) or placebo in addition to their background anti-diabetic therapy in a double-blind manner. Carotid CMR study was performed using a 1.5 T Siemens Sonata scanner and phased-array surface carotid coils. We acquired a

3D stack of high-resolution fast spin echo images centred on the carotid bifurcation. Maximal coverage was 56 mm (28 mm either side of the bifurcation) with a slice thickness of 2 mm. Where possible, bilateral carotid evaluation was undertaken. Using dedicated semi-automated software (Atheroma Tools, Cardiovascular Imaging Solutions, London) we traced the internal and external carotid artery surfaces for each slice and hence measured the luminal area and the wall area. Using the 3D model of the carotid artery generated by this analysis, we measured the lumen volume and total vessel volume to generate a total wall volume, a measure of atherosclerotic burden. Data was analysed using analysis of covariance.

### Results

There was no significant difference in carotid atheroma between subjects treated with Rosiglitazone or placebo after 1 year. (Table 1).

### Conclusion

Rosiglitazone has no effect on the development of carotid atheroma in patients with type 2 diabetes over one year.

Table 1:

Carotid Plaque	Treatment Group	
	RSG	Placebo
Total Wall Volume (mm <sup>3</sup> )	(N = 25)	(N = 29)
N	21	26
Baseline (mean ± SD)	1354 ± 532	1146 ± 550
End of Treatment (mean ± SD)	1348 ± 531	1134 ± 523
Change from Baseline (mean ± SD)	-5.7 ± 79.4	-12.1 ± 105
Model Adjusted Change from Baseline (mean ± SE)	12.7 ± 22.8	-2.9 ± 20.9
Difference from Placebo: mean (95% CI <sup>2</sup> )	15.7 (-39.5, 70.9)	-
P-value	0.57	-

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