Predictive factors for in-stent late loss and coronary lesion progression in patients with type 2 diabetes mellitus randomized to rosiglitazone or placebo.

BACKGROUND: Type 2 diabetics (DM2) are at increased risk for restenosis as well as nonculprit coronary artery lesion (NCCL) progression. Rosiglitazone (RSG) favorably modifies many of the altered biologic processes in DM2, although recent reports have questioned its safety. We conducted a double-blind randomized trial to assess the effects of RSG versus placebo on in-stent late lumen loss (LL) and angiographic progression of NCCL. METHODS: A total of 65 DM2 were randomized to RSG (4 mg/d) (n = 32) or placebo (n = 33) at the time of stenting and underwent clinical and laboratory analysis at 1 and 4 months and 8-month angiography (n = 46 patients). Rapid angiographic progression (RAP) was defined as > or =20% diameter reduction of preexisting NCCL by quantitative coronary angiography, or a new narrowing > or =30%. RESULTS: Mean LL in RSG (n = 33 lesions) was not different from that of placebo (0.62 +/- 0.59 vs 0.70 +/- 0.67, P = NS). Seven (13.5%) of 52 NCCLs have RAP in RSG versus 9 (16.1%) of 56 in placebo (P = NS). High-sensitivity C-reactive protein (hs-CRP) was the only predictor of RAP. Patients with a 120-day hs-CRP > or =75th percentile had an OR of 7.35 (95% CI 2.35-23) for RAP versus those below. Although
RSG treatment also lowered log (hs-CRP) at 4 months (RSG 0.10 +/- 0.37 vs placebo 0.26 +/- 0.49, P = .06), it did not decrease the likelihood of plaque progression while also raising LDL and N-terminal brain naturetic peptide. CONCLUSIONS: Rosiglitazone appears not to lower LL or reduce angiographic progression of NCCL in DM2 and had complex effects on markers of cardiac risk.