

Physiology-stratified analysis of ORBITA

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Invasive physiology data from 196 patients from the Objective Randomised Blinded Investigation with optimal medical Therapy of Angioplasty in stable angina (ORBITA) trial were used to assess the fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) predictors of placebo-controlled efficacy of percutaneous coronary intervention (PCI) in stable coronary artery disease. Patients enrolled had stable angina and single vessel coronary artery disease. At pre-randomisation the majority had Canadian Cardiovascular Society class II or III symptoms (150/196, 76.5 percent). Mean FFR and iFR were 0.69 ± 0.16 and 0.76 ± 0.22 , respectively. 97 percent of patients had one or more positive non-invasive or invasive tests for ischaemia.

"In particular, from this study, we've seen that the degree of ischaemia on iFR and FFR entirely predicts the degree of improvement in ischaemia that's seen on dobutamine stress echo. What this means for physicians is that we will be able to use the iFR and FFR data before an intervention to predict exactly how much improvement in ischaemia we can expect for our patients following successful stenting. This is the first placebo-controlled evidence we have had of this kind," says Rasha Al-Lamee, Interventional Cardiology Consultant and Principal Investigator, ORBITA.

FFR and iFR was performed solely for this research question, and so the Interventionalist in the catheterisation laboratory was blinded to the results. Assessment of response variables, treadmill exercise time, stress echo score, symptom frequency, and angina severity were performed at pre-randomisation and blinded follow-up. Effects were calculated by

analysis of covariance. The ability of FFR and iFR to predict placebo-controlled changes in response variables was tested using regression modelling.

The placebo-controlled effect of PCI was more clearly seen by stress echo score and freedom from angina than change in treadmill exercise time. The estimated effect of PCI on between-arm pre-randomisation-adjusted total exercise time was 20.7s (95 percent CI: -4.0 to 45.5; $p=0.100$) with no dependence on FFR ($p_{\text{interaction}}=0.318$) and iFR ($p_{\text{interaction}}=0.523$). PCI improved stress echo score more than placebo (1.07 segment units, 95 percent CI: 0.70 to 1.44, p less than than 0.00001). The placebo-controlled effect of PCI on stress echo score increased progressively with decreasing FFR ($p_{\text{interaction}}$

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