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Title:

PCI versus a placebo procedure for stable coronary artery disease

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Rasha Al-Lamee and colleagues (2 November, 2017)¹ report that in patients with medically treated angina and a severe single-vessel coronary stenosis, PCI did not increase exercise time by more than the effect of a placebo procedure. The authors should be commended for performing the first blinded trial to address this issue. However, we have concerns that some features of the trial design may limit the applicability of the findings to routine clinical practice.

Current ESC/EACTS guidelines recommend that revascularisation should be performed for any coronary stenosis >50% in the presence of limiting angina unresponsive to medical therapy, but require documented ischaemia or an FFR ≤ 0.80 for those with a stenosis <90%².

In the ORBITA trial, patients were not required to have documented ischaemia and FFR was not used to guide revascularisation. Indeed, 29% of patients had an a FFR >0.80 and would therefore not meet current recommendations for revascularisation. Furthermore, following a 6-week period of intensive medical therapy optimisation, 9% of PCI patients had no symptoms (CCS Class 0), mean angina frequency was monthly (SAQ angina frequency score 79) and mean exercise time was normal (smoothed Bruce treadmill protocol duration 8:48). For these reasons, it is not surprising that PCI failed to show a significant improvement in exercise time, when compared with a placebo procedure.

In our opinion, caution should be exercised before changing practice on the basis of this trial.

Keywords: Percutaneous Transluminal Coronary Angioplasty; Coronary Artery Disease; Fractional Flow Reserve, Myocardial; Angina, Stable

1. Al-Lamee R, Thompson D, Dehbi HM, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. *Lancet (London, England)* 2017.
2. Kolh P, Windecker S, Alfonso F, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *European journal of cardio-thoracic surgery : official journal of the European Association for Cardio-thoracic Surgery* 2014; **46**(4): 517-92.