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Drug-eluting stenting better than medical therapy in stable CAD

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Fractional flow reserve (FFR)-guided drug-eluting stenting reduces death, myocardial infarction or urgent revascularisation, as compared to medical therapy in patients with stable coronary artery disease (CAD), according to the results of the FAME 2 trial presented for the first time today at ESC Congress by principal investigator Dr Bernard De Bruyne (Belgium).

Dr De Bruyne said: "Percutaneous coronary intervention (PCI) has been performed for more than 30 years. Nevertheless, its benefits in terms of 'hard endpoints' as compared to medical therapy (MT) have never been demonstrated in patients with stable CAD. Therefore, MT remains the preferred initial management strategy."

The Fractional flow reserve versus Angiography for Multivessel Evaluation 2 trial (FAME 2) compared contemporary PCI plus MT to MT alone in patients with stable CAD. 'Contemporary' refers to PCI guided by FFR and using second generation drug-eluting stents (DES). The predefined primary endpoint was a composite of death from any cause, nonfatal myocardial infarction (MI), or unplanned hospitalisation leading to urgent revascularisation during the first two years.

Between 15 May 2010 and 15 January 2012, FAME 2 enrolled 1 220 patients from 28 sites in Europe and North America in whom PCI with DES was planned. In contrast to most previous trials in patients with stable CAD, only those with a stenosis able to induce myocardial ischaemia as assessed by an FFR value ≤0.80 were included. These

patients were randomised to either PCI + MT (n=447) or to MT alone (n=441). The remaining 332 patients were not randomised but followed-up in a registry and treated with MT.

Recruitment to the trial was interrupted prematurely because of a highly statistically significant between-group difference favouring PCI + MT. Today Dr De Bruyne reports on the primary endpoint after two years. The rate of death, MI, or urgent revascularisation at two years was lower with PCI than MT (8.1% vs 19.5%, hazard ratio [HR] 0.39, 95% confidence interval [CI] 0.26-0.57, p