FAME follow-up confirms FFR-guided PCI benefits

MedWire News: Eighteen-month follow-up data from the FAME study confirm that using fractional flow reserve (FFR) has advantages over angiography to guide stent placement in patients undergoing percutaneous coronary intervention (PCI).

The results were presented during a clinical trial update session at the European Society of Cardiology 2009 Congress in Barcelona, Spain.

The 1-year results of FAME (FFR versus Angiography for Guiding PCI in Patients with Multivessel Coronary Artery Disease) were previously reported by MedWire News. The trial included 1005 patients with multivessel disease. Prior to randomization, lesions requiring PCI were identified based on their angiographic appearance.

In patients randomly assigned to receive angiography-guided treatment, all lesions with >50% stenosis were revascularized using a stent, whereas in the FFR arm lesions with FFR <0.80 were stented and those with FFR >0.80 were not.

Lead investigator Nico Pijls (Catharina Hospital, Eindhoven, The Netherlands) reported that the absolute rate of the primary endpoint (composite of death, myocardial infarction [MI], coronary artery bypass graft, or repeat PCI) at 18 months was a significant 5.3% lower in the FFR than the angiography arm. This indicates the rate continued to diverge between arms beyond 1 year, when it was 5.1% lower with FFR.

Subgroup analysis indicated that the benefit of FFR was consistent in patients with and without diabetes, with unstable angina, and with non-ST-elevation MI.

Pijls also noted that incremental costs were lower with FFR- than angiography-guided PCI, at US\$ 12,291 (€ 8462) versus US\$ 14,357 (€ 9882). "An FFR-guided strategy to multivessel PCI is one of those rare situations in medicine in which a new innovative treatment not only improves outcome but is also cost-saving," he commented.

The invited discussant for FAME during the session was Thomas Luescher (University of Zurich, Switzerland). He commented: "This is truly an important result showing and confirming that only hemodynamically important lesions are leading to events and we should concentrate out efforts on these lesions."

But he said he remained unsure how far the data would change clinical practice.

He indicated that they perhaps "mean we should stop to take a quick and dirty look at our lesions to assess them more appropriately – but even there we shouldn't go too far."

He continued: "Maybe we should just concentrate on the lesions between 50% and 70% [stenosed] and not those that are clear to our eye."

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