CORONARY ARTERY DISEASE

FFR-guided revascularization versus medical therapy—the debate goes on

Fractional flow reserve (FFR)-guided revascularization reduces the need for subsequent urgent revascularization in patients with stable coronary artery disease and functionally significant stenosis. This finding comes from FAME 2, which was presented at the ESC Congress in August 2012 and published in the *New England Journal of Medicine*.

FFR indicates the potential of a stenotic vessel to induce myocardial ischemia. The index is measured during coronary angiography using a pressure guidewire that is advanced through the narrowed artery. In FAME 2, patients with at least one artery with an FFR ≤ 0.80 were considered to have functionally significant stenosis. They were then randomly allocated to FFR-guided percutaneous coronary intervention (PCI) with a second-generation, drug-eluting stent plus optimal medical therapy, or to optimal medical therapy alone. Patients with no stenoses with an FFR ≤ 0.80 were entered into a registry and received optimal medical care.

The investigators planned to enroll 1,632 patients. However, the independent data and safety monitoring board halted recruitment after 1,220 patients had enrolled, because of evidence of a significant advantage in the FFR-guided PCI group. Consequently, 447, 441, and 332 patients were enrolled in the PCI study group, medical-therapy study group, and the registry, respectively. The patients who underwent PCI were significantly

less likely to experience the primary end point (a composite of death, myocardial infarction, or urgent revascularization) than those receiving only optimal medical therapy (4.3% vs 12.7%; HR 0.32, 95% CI 0.19–0.53, $P < 0.001$). This difference was primarily driven by a lower rate of urgent revascularization in the PCI group than in the medical-therapy group (1.6% vs 11.1%; HR 0.13, 95% CI 0.06–0.30, $P < 0.001$). The rate of the primary end point in the registry of patients without functionally significant stenoses was similar to that in the PCI group (3.0% vs 4.3%; HR 1.29, 95% CI 0.49–3.39, $P = 0.61$).

The data show an overwhelming short-term advantage of prompt, FFR-guided revascularization in patients with stable coronary artery disease and functionally significant stenoses. Equally, patients without functionally significant stenoses are best managed by optimal medical therapy. However, the early termination of the trial means that effects on the hard end points of death and myocardial infarction could not be fully assessed. Indeed, in an accompanying editorial in the *New England Journal of Medicine*, Dr William Boden from Albany Medical College, NY, USA comments that “the only enduring finding of the FAME 2 trial appears to be that of a reduced short-term rate of unplanned revascularization with FFR-guided PCI, with little evidence of long-term incremental benefit of prognostically important clinical outcomes”. Dr Boden is

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a coprincipal investigator of the ongoing International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), designed to evaluate long-term cardiovascular outcomes in these patients.

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