PCI guided by fractional flow reserve versus medical therapy alone in stable coronary disease

August 28 2012

Patients with stable coronary artery disease (CAD) had a lower need for urgent revascularisation when receiving fractional flow reserve (FFR)-guided PCI plus the best available medical therapy (MT) than when receiving MT alone. The results, from a final analysis of the FAME 2 trial, were presented today during a Hot Line session of ESC Congress 2012 in Munich. Treatment guided by fractional flow reserve assessment helped reduce the risk of urgent revascularisation by a factor of eight.

The FAME 2 (FFR-Guided Percutaneous Coronary Intervention (PCI) Plus Optimal Medical Therapy vs. Optimal Medical Therapy Alone in Patients with Stable Coronary Artery Disease) trial was conducted at 28 centres in Europe and North America to assess the role of FFR in the percutaneous treatment of stable coronary artery disease in one or more vessels.(1) Results were presented by the trial's co-ordinator Dr Bernard De Bruyne from the OLV Clinic in Aalst, Belgium. The study, which began in May 2010, enrolled 1220 patients with stable coronary artery disease, and compared clinical outcomes, safety and cost effectiveness of percutaneous coronary intervention (PCI) guided by FFR plus best available medical therapy (MT) with MT alone.

"These statistically significant results validate the important role that FFR-guided therapy has in improving outcomes for patients with coronary artery disease.

"The FAME 2 trial provides new evidence of the role that FFR and second-generation drug eluding stents can have in improving patient care. We now know that, if a lesion is significant as determined by FFR guidance, the stenting procedure will provide a better outcome. With this new knowledge, I believe that FFR should become the standard of care for treating most patients with stable coronary artery disease and significant coronary narrowings."

Results showed that:

- By 15 January 2012, when the trial's enrollment ended, 75 of the randomised trial patients had experienced at least one primary endpoint event (including death, heart attack, or urgent revascularisation). Event occurrence was lower in the PCI plus MT group than in the MT alone group (4.3 versus 12.7%).
- There was a large difference in rates of urgent revascularisation between the two groups, with patients in the PCI plus MT arm less likely to receive revascularisation. However, there was no significant difference in mortality or AMI rates between patients with PCI plus MT and patients with MT alone.
- Patients in whom FFR found no evidence of ischemia-producing lesions were treated with medications alone and were followed up in a registry. Primary endpoint events including death, AMI or urgent revascularisation were low (3%).

The FAME 2 trial was stopped early (January 2012) after its independent data safety monitoring board (DSMB) deemed it unjustified to continue with the MT-alone arm. The DSMB found a statistically significant reduction in the need for unplanned hospital readmission and urgent revascularisation when FFR-guided assessment was used to direct treatment. As a result, patients already enrolled in the trial continued to be followed, but no new patients were added.

"The trial provides new information on the benefits of coronary intervention and answers questions raised by the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial, which found no difference in outcomes between PCI plus MT and MT alone," said Dr De Bruyne.

"The data show that in patients with stable CAD and functionally significant stenoses as assessed by FFR, FFR-guided PCI plus MT decreases the need for urgent revascularisation when compared with MT alone. In contrast, in patients without ischaemia-producing lesions, outcome is favourable with MT alone."

More information: 1. Fractional flow reserve specifically identifies which coronary narrowings are responsible for obstructing the blood flow (ischaemia) to a patient's heart muscle.

Provided by European Society of Cardiology