

## FAME II trial: Better patient outcomes with FFR-guided stenting

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**Mumbai:** Results of the FAME II trial, which was conducted by St Jude Medical, demonstrated that patients with FFR-guided stenting plus the best available medical therapy had superior outcomes as compared to those treated with medical therapy alone.

The results, published online in the *New England Journal of Medicine* (NEJM), revealed that use of the PressureWire (a technology used to measure blood flow restriction in the coronary arteries) yielded 86 percent relative risk reduction for unplanned re-admission to the hospital with urgent re-vascularization in patients with stable coronary artery disease.

FAME II stands for FFR-guided percutaneous coronary intervention plus optimal medical treatment vs optimal medical treatment alone in patients with stable coronary artery disease. The trial examined the role of fractional flow reserve (FFR) in the treatment of stable coronary artery disease in one or more vessels.

The FAME II trial began enrolling patients in May 2010. At the time enrollment was stopped in January, 1,220 patients with stable coronary artery disease were enrolled at 28 centers across Europe, the US and Canada. FFR was measured using the PressureWire Aeris or PressureWire Certus from St Jude Medical.

FFR specifically identifies which coronary narrowings are responsible for obstructing blood flow to a patient's heart muscle, and is measured using PressureWire FFR measurement technology from St Jude Medical. The randomized trial compared percutaneous coronary intervention (PCI) guided by FFR plus the best available medical therapy (MT) to MT alone.

"The FAME II trial provides new evidence-based guidance demonstrating the profound role that FFR and second generation drug eluting 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 knowledge, I believe that FFR should become the standard of care for treating patients with stable coronary artery disease and significant coronary narrowings," said Dr Ashwin B Mehta, head, cardiology department, Jaslok Hospital.

"As the sponsor of the FAME family of studies, St Jude Medical is proud to provide the medical community with additional

evidence supporting the critically important role that the PressureWire FFR measurement technologies play in improving patient outcomes," said Dr Frank Callaghan, president, cardiovascular division, St Jude Medical."Publication of this groundbreaking research in the New England Journal of Medicine coinciding with a Hot Line session during ESC demonstrates that the role of FFR in guiding medical care has moved to broader and more mainstream acceptance within the cardiology community."