Analysis Shows Better Health Outcomes And Cost Effectiveness For Coronary Intervention Using Abbott's Fractional Flow Reserve (FFR) Diagnostic In Patients With Stable Coronary Artery Disease

- After three years, patients who underwent FFR-guided percutaneous coronary intervention (PCI) in combination with medical therapy had significantly fewer major adverse cardiac events compared to patients who received medical therapy alone

- FFR-guided PCI was well below the commonly accepted threshold for cost efficacy and was comparable in cost to medical therapy alone after three years

DENVER, Nov. 2, 2017 – Abbott today announced that patients with coronary artery disease who underwent a percutaneous coronary intervention (PCI) guided by Abbott's PressureWire™ fractional flow reserve (FFR) diagnostic tool in combination with medical therapy had better health outcomes – including significantly fewer major adverse cardiac events (MACE) after three years – at comparable costs than patients who received medical therapy alone.

The data, from the FAME 2 study, were presented during a late-breaking session at the 29th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

FFR measures the pressure of blood as it flows through a blockage in the coronary artery to help cardiologists determine which vessels to treat, thereby potentially avoiding unnecessary stenting.

"In clinical practice, FFR is a useful tool to help doctors determine their strategy for a PCI, but FFR's long-term clinical benefits and cost-effectiveness have not been known until now," said co-principal investigator William F. Fearon, M.D., professor of cardiovascular medicine, Stanford University School of Medicine. "This analysis showed that FFR-guided PCI in combination with medical therapy worked better than medical therapy alone after three years and saved money."

Analysis showed that 90 percent of patients in the FFR-PCI group were free from experiencing MACE, while twice as many patients in the medical therapy group experienced MACE (10.1 percent vs. 22 percent, $p<0.001$). The lower rate of MACE in the PCI group was largely driven by reduced urgent revascularization -- the need to reestablish blood flow to the heart -- a component of MACE (4.3 percent vs. 17.2 percent, $p<0.001$). There were no significant differences in rates of death or myocardial infarction between the FFR-PCI and medical therapy only groups (8.3 percent vs. 10.4 percent, $p=0.28$).

After three years, patients who received FFR-guided PCI had significantly improved quality of life as measured by quality-adjusted life years (QALY), compared to patients who received medical therapy alone (0.105 QALY vs. 0.004 QALY; $p<0.0001$). While initial costs were higher for FFR-guided PCI, the treatment was associated with substantially less follow-up costs than medical therapy alone, resulting in comparable total costs between the two groups over three years ($16,792 vs. $16,737, $p=0.94$). The resulting incremental cost-effectiveness ratio (ICER), which is calculated to determine economic value between two therapies, showed that FFR-guided PCI had an ICER of $1,600/QALY, well below the commonly accepted threshold of $50,000/QALY for cost-effectiveness.

"Since heart disease is a major driver of health care costs, treatments that improve clinical outcomes for patients, while also being cost effective, are increasingly important to health care systems and payors," said Chuck Brynelsen, senior vice president of Abbott's vascular business. "These data demonstrate that FFR-guided stenting in combination with medical therapy can have greater long-term benefits for patients, as well as health systems, over medical therapy alone."

About the study:
The study, called Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 (FAME 2), investigated whether contemporary FFR-guided PCI plus medical therapy would be superior to medical therapy alone in 888 patients with stable coronary artery disease and functionally significant stenoses (blockage or narrowing of the arteries), as determined by FFR. Data were collected from 28 sites in the U.S. and Europe. Costs were calculated based on resource utilization using Medicare reimbursement rates, and QALY were calculated using the EuroQuol 5D health survey with U.S. weights. The difference in QALY of a patient was calculated by multiplying years and change in health utility from baseline.

Important U.S. Safety Information is available at www.PressureWire.com/ISI.

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