Study finds that PCI guided by FFR did not meet noninferiority for one-year outcomes compared to bypass surgery

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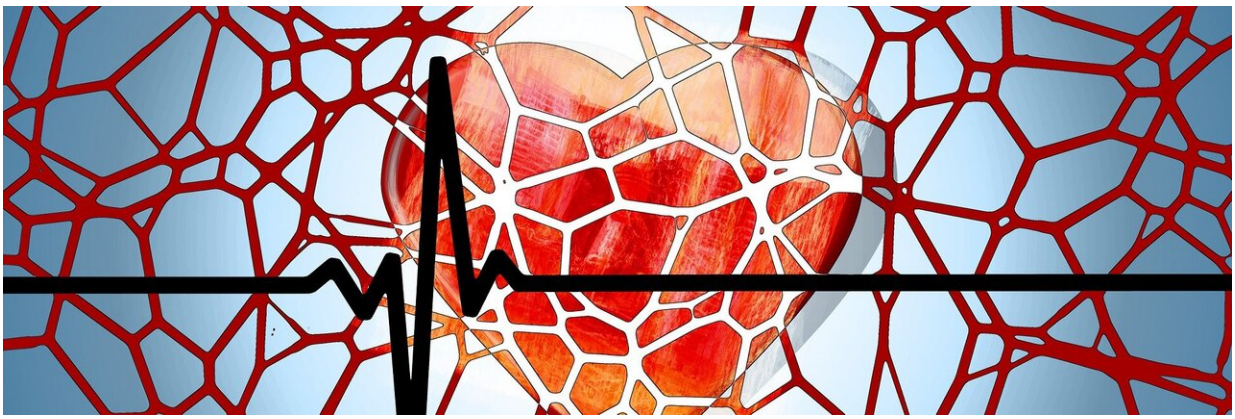

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he primary results of the Fractional Flow Reserve Versus Angiography for Multivessel Evaluation (FAME) 3 trial found that percutaneous coronary intervention (PCI) guided by fractional flow reserve (FFR) did not meet noninferiority for one-year adverse events compared to coronary artery bypass grafting (CABG) in patients with three-vessel coronary artery disease. Patients with a low SYNTAX score (which measures the complexity of coronary artery disease) had less incidence of adverse events compared to those with intermediate or high SYNTAX scores, and in this cohort of patients PCI performed more favorably.

Findings were reported today at TCT 2021, the 33rd annual scientific symposium of the Cardiovascular Research Foundation (CRF).

In patients with three vessel coronary artery disease (3V-CAD), previous studies have demonstrated improved outcomes with CABG compared with PCI. However, most of the trials used bare-metal or first-generation drug-eluting stents (DES) and none of them utilized measurement of FFR to guide PCI.

FAME 3 was a multicenter, international, randomized, controlled noninferiority trial in which patients with three-vessel CAD warranting revascularization were randomly assigned to PCI or CABG. PCI was performed with current generation zotarolimus-eluting stents guided by FFR measurement and CABG was performed with the recommendation to use multiple arterial grafts.

A total of 1,500 patients were randomized 1:1 to either CABG based on coronary angiogram or FFR-guided PCI in all lesions with an FFR ≤ 0.80 at 48 centers in Europe, North America, Australia, and Asia. For inclusion in the trial, patients had three vessel CAD, defined as ≥ 50% diameter stenosis by visual estimation in each of the three major epicardial vessels, but not involving the left main coronary artery, and amenable to revascularization by both PCI and CABG as determined by the Heart Team. A total of 757 patients underwent FFR-guided PCI and 743 received CABG.

The primary endpoint of the one-year rate of death, myocardial infarction, stroke, and repeat revascularization (MACCE) was 10.6% for PCI and 6.9% for CABG (HR 1.5, 95% CI 1.1-2.2, p=0.35 for noninferiority). The one-year rate of death (1.6% versus 0.9%), MI (5.2% versus 3.5%) and stroke (0.9% versus 1.1%) were not significantly different between the two strategies. Repeat revascularization (5.9% versus 3.9%) was higher in the PCI group.

Safety endpoints of BARC Type 3-5 bleeding, acute kidney injury, atrial fibrillation/arrhythmia and rehospitalization within 30 days were all lower with PCI compared to CABG.

When patient data was analyzed based on SYNTAX score, the one-year MACCE rate was lower for PCI compared with CABG for patients with a low SYNTAX score (5.5% vs. 8.6%) but higher with PCI compared with CABG for both intermediate (13.7% vs. 6.1%) and high SYNTAX scores (12.1% vs. 6.6%) with p for interaction by SYNTAX score=0.02.

"The one-year rate of death, MI, or stroke was not significantly different between the two strategies. However, FFR-guided PCI with a current generation drug-eluting stent performed favorably in comparison with CABG in three-vessel coronary artery disease with less complex disease according to the SYNTAX score," said William F. Fearon, MD. Dr. Fearon is Professor of Medicine (Cardiology) and Director of Interventional Cardiology at Stanford University School of Medicine and the Chief of the Cardiology Section at the VA Palo Alto Health Care System. "In patients with more complex three-vessel coronary artery disease, CABG remains the treatment of choice."

More information: Conference: www.sarnofffoundation.org/even … spx?id=283231&group=

Provided by Cardiovascular Research Foundation

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