

Study finds FFR-guided PCI non-inferior to IVUS in intermediate coronary stenosis

April 4 2022



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In the first large, randomized head-to-head comparison of two methods of evaluating patients' need for a stent in their coronary artery, patients who were evaluated using a technique that measures blood flow through

the artery did just as well, despite receiving fewer stents, as similar patients who were evaluated using a technique that visualizes the extent of the fatty buildup inside the artery. The study was presented at the American College of Cardiology's 71st Annual Scientific Session.

"Our study shows that in patients with intermediate levels of coronary arterial blockage, determining the need for a stent by measuring blood flow to the heart, rather than by the extent of arterial blockage, resulted in similar clinical outcomes, similar patient quality of life and reduced use of medical resources," said Bon-Kwon Koo, MD, of Seoul National University Hospital in South Korea and principal investigator for the study.

Patients enrolled in the study, known as FLAVOUR, had intermediate [coronary artery](#) stenosis, which means that their coronary artery—the major artery supplying blood to the heart—was 40–70% blocked by fatty deposits called plaques. This group of patients is most likely to need evaluation of their need for stenting, Koo said. In this procedure, which is also known as [percutaneous coronary intervention](#) (PCI), a catheter (a flexible tube) is used to insert the stent (a tiny mesh tube) into the coronary artery to prevent it from becoming completely blocked.

Several techniques may be used to evaluate whether patients should receive a stent and what type of stent would be best or whether the patients' coronary artery disease can continue to be managed with medication. Coronary angiography (an X-ray of the heart) and a technique known as fractional flow reserve (FFR) both measure [blood flow](#) to the heart through the partially blocked artery. By contrast, intravascular ultrasound (IVUS) uses sound waves to see the interior of the artery and the buildup of plaques on the artery's walls. Previous studies, including some conducted in patients with intermediate coronary stenosis, had shown that both FFR-guided and IVUS-guided PCI produced better patient outcomes than angiography-guided PCI, said

Koo. However, FFR-guided and IVUS-guided PCI had not been compared head-to-head.

The study enrolled 1,682 patients with intermediate coronary stenosis. The average age of patients was 65 and 71% were men. Just over half had blockages in multiple arteries supplying blood to the heart and about one-third had diabetes in addition to heart disease. Six percent of the patients had previously had a [heart attack](#) and 30% were at high risk for one.

All patients were randomly assigned to undergo evaluation for PCI using either FFR or IVUS. The decision to proceed with PCI was based on each technique's standard criteria for doing so. In accordance with standard care after PCI, patients who received PCI took two antiplatelet medications for six to 12 months after their procedure to reduce their risk of adverse events. Patients who did not receive PCI continued to manage their heart disease with medication.

The study met its primary endpoint—a composite of death from any cause, heart attack or the need for a repeat stenting procedure after two years of follow-up. Compared with patients who were evaluated by IVUS, significantly fewer patients evaluated by FFR underwent PCI (65.3% vs. 44.4%, respectively). After two years, 8.1% of the patients evaluated by FFR had died, had a heart attack or needed a repeat stenting procedure, compared with 8.5% of those evaluated by IVUS, a non-statistically significant difference. In addition, when the investigators compared patients who received PCI with those who remained on [medical therapy](#), they found no statistically significant differences in the rates of death, heart attacks or repeat procedures in either the FFR or IVUS group.

"Despite the fact that FFR-evaluated patients received significantly fewer stents than IVUS-evaluated patients, they were no more likely to

experience adverse events," Koo said. "The rates of adverse outcomes and patients' quality of life were similar in both groups. These results support considering FFR-guided PCI first for patients with intermediate coronary stenosis, as it is associated with a reduced use of medical resources."

The study has some limitations, Koo said. Its findings apply only to patients with intermediate coronary stenosis and not those with more severe blockages of the coronary artery. Also, the study examined only FFR guidance compared with IVUS guidance. Additional studies are needed to comparatively evaluate other technologies for evaluating patients' need for PCI.

More information: Koo will present the study, "Comparison of Fractional Flow Reserve-guided and Intravascular Ultrasound-guided Percutaneous Coronary Intervention in Intermediate Coronary Artery Stenosis: The FLAVOUR Randomized Clinical Trial," on Monday, April 4.

Provided by American College of Cardiology

Citation: Study finds FFR-guided PCI non-inferior to IVUS in intermediate coronary stenosis (2022, April 4) retrieved 7 May 2024 from <https://medicalxpress.com/news/2022-04-ffr-guided-pci-non-inferior-ivus-intermediate.html>

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