

# Results from the DEFINE-FLOW study reported

October 17 2020

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A new observational study of deferred lesions following combined fractional flow reserve (FFR) and coronary flow reserve (CFR) assessments found that untreated vessels with abnormal FFR but intact CFR do not have non-inferior outcomes compared to those with an FFR greater than 0.8 and a CFR greater than or equal to two when treated medically.

Findings were reported today at TCT Connect, the 32nd annual scientific symposium of the Cardiovascular Research Foundation (CRF).

The role for invasive CFR assessment in the current era remains unclear since FFR has become a reference standard guiding decisions for revascularization. While [observational data](#) from invasive and noninvasive tools has indicated that [lesions](#) with intact CFR do well, few of these studies simultaneously assessed FFR. To address the limitations of the current literature, researchers designed and carried out the DEFINE-FLOW study.

A total of 455 patients were enrolled from 12 sites in six countries. Of those enrolled, 430 patients (533 lesions) were protocol-treated and followed for two years. Stable coronary lesions underwent simultaneous FFR and CFR measurement in at least duplicate with central core lab review of the tracings. Treatment followed the local measurements according to a uniform protocol whereby only lesions with both  $FFR \leq 0.8$  and  $CFR \geq 2.0$ , received initial [medical therapy](#).

The primary endpoint was the composite of all-cause death, myocardial infarction, and revascularization at two years. The study findings for MACE were 5.8% for FFR-/CFR-, 10.8% for FFR+/CFR-, 12.4% for FFR-/CFR+, and 14.4% for FFR+/CFR+ (after PCI). The difference of FFR+/CFR- compared to FFR-/CFR- was 5.0% (95%CI -1.5% to +11.5%, p-value 0.065 for non-inferiority). Therefore, the study found that vessels with abnormal  $\text{FFR} \leq 0.8$  but intact  $\text{CFR} \geq 2.0$  did not have non-inferior outcomes compared to  $\text{FFR} > 0.8$  and  $\text{CFR} \geq 2.0$  when treated medically.

"Because the study was observational, it is not clear what the outcomes among FFR+/CFR- lesions would have been had they undergone PCI instead of medical therapy," said Nils Johnson, MD, MS, Associate Professor of Medicine and Weatherhead Distinguished Chair of Heart Disease, Division of Cardiology, Department of Medicine and the Weatherhead PET Imaging Center at McGovern Medical School at UT Health (Houston) and Memorial Hermann Hospital—Texas Medical Center. "There were a number of limitations to this study such as few lesions with severe FFR/CFR as well as unblinded subjects and physicians. The limitations coupled with the results makes this a hypothesis-generating study that can help to further understand the role of invasive CFR and how to treat CFR/FFR discordance."

Provided by Cardiovascular Research Foundation

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