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## **Impact of an Interactive CT/FFR<sub>CT</sub> Interventional Planner on Coronary Artery Disease Management Decision Making**

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A fractional flow reserve derived from computed tomography (FFR<sub>CT</sub>) interactive planner (HeartFlow, Redwood City, California) that combines coronary CT angiography data with computational fluid dynamics from which a theoretical, modeled, post-stent FFR has been derived was developed. It has previously been shown to have a good correlation with invasive FFR as measured after percutaneous coronary intervention (PCI) (1,2). The aim of the present study was to explore how the integration of this novel technology impacts decision making for performing revascularization.

A total of 101 patients with at least 1 stenosis  $\geq 40\%$  narrowing (a threshold selected given previously published potential for abnormal physiology [3]), were included with FFR<sub>CT</sub> data and invasive coronary angiography (ICA). Patients provided explicit consent to allow this analysis. This study was approved by the institutional review boards or ethics panels from the relevant studies. To enable fast recalculation of FFR<sub>CT</sub> for different stent configurations at PCI, an accelerated method for updating FFR<sub>CT</sub> was used (1).

The revascularization strategy was chosen by 3 experienced interventional cardiologists working as a panel and reaching decision by consensus. First, they provided a management strategy based on ICA. The available outcomes were: optimal medical treatment (OMT); additional invasive physiology data required to determine the appropriate strategy, PCI in 1 or more lesions; or coronary artery bypass surgery (CABG). Then, using the FFR<sub>CT</sub> interactive planning tool with computed values for alternate PCI strategies (based on different stent locations and length[s] on the 3-dimensional model), an updated, second FFR<sub>CT</sub>-based decision was agreed upon.

The primary endpoint of the study was the difference in treatment plans between the 2 consensus decisions. Continuous variables are presented as median (interquartile range) and categorical variables as percentages. Paired Student's *t*-tests were performed, and a 2-sided *p* value  $< 0.05$  was considered significant.

The total number of stenoses in the 101 patients was 327 ( $3.24 \pm 1.61$  stenoses/patient). Based on ICA, the plan was that 63 of 101 patients would undergo PCI, with 87 stents recommended to cover 78 segments (105 lesions). ICA-defined multivessel disease (at least 1 stenosis  $\geq 40\%$  narrowing in 2 different vessel territories) was present in 85% of cases. Serial stenoses ( $\geq 2$  lesions in a row in the same vessel territory) were present in 81% of patients and occurred more frequently in the left anterior descending coronary artery territory than in the left circumflex coronary artery or the right coronary artery (64%, 27%, and 26%, respectively).

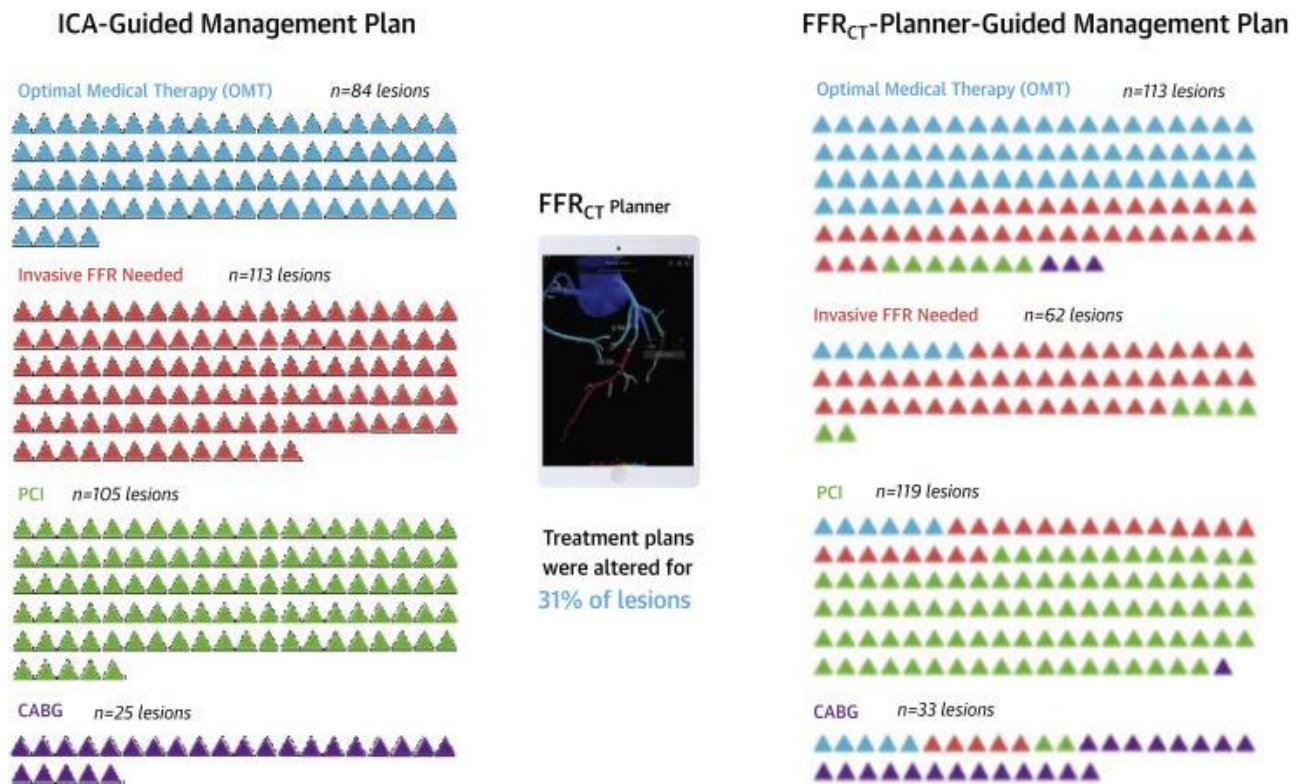


Figure 1. Treatment Decision Stratified by Lesion Based on ICA and Interactive Planner and Their Changes

Each lesion is color-coded according to the management based on ICA and then FFR<sub>CT</sub> planner. As can be seen, FFR<sub>CT</sub> planner analysis was associated with a change of management in 31% of the lesions. CABG = coronary artery bypass surgery; FFR<sub>CT</sub> = fractional flow reserve derived from computed tomography; ICA = invasive coronary angiography; PCI = percutaneous coronary intervention.

After a review of the FFR<sub>CT</sub> planner data, the PCI strategy was changed in 45% of patients and for 31% of lesions (Figure 1). These changes affected 26 of 66 PCI patients (39%); 4 of 7 CABG patients (57%); and 15 of 28 patients (54%) believed to need OMT, based on the original PCI analysis. Following reclassification by the FFR<sub>CT</sub> planner, the number of patients referred to revascularization increased from 71.9% to 78.2% (+6.3%;  $p = 0.01$ ).

Sixty-three patients were considered for PCI following ICA review. Following the data from the FFR<sub>CT</sub> planner, PCI was cancelled for 6 patients, whereas 10 new patients (originally deemed to be managed with OMT) were appropriate for PCI, giving a total of 67 patients for revascularization in 89 segments (119 lesions). Among the 78 segments (105 lesions) recommended for PCI by ICA, the strategy remained unchanged in 44 segments (56%). In 17 segments (22%), PCI was no longer recommended, and in 17 segments (22%), PCI was still the preferred option, however, with a different stent length (increased:  $n = 11$ ) or decreased ( $n = 6$ ). PCI was newly proposed in 28 segments that had not been initially considered by ICA review. Change in revascularization strategy was more common in vessel territories with serial lesions ( $\geq 2$  lesions in a row in the same vessel territory) compared with vessel territory with a single lesion (52 of 78 vessel territories [66%] vs. 40 of 112 vessel territories [36%]).

Our study showed that, in patients with predominantly multivessel disease and serial lesions, the use of an FFR<sub>CT</sub> planner may modify treatment recommendations in almost 1 in 3 lesions (Figure 1) and approaching one-half of the patients. These findings are comparable to

previously published data for the impact of invasive FFR plus ICA versus ICA alone and FFR<sub>CT</sub> versus coronary computed tomographic angiography alone (3,4).

We acknowledge that these findings are theoretical and hypothesis-generating only and that our data do not validate accuracy or correlate with post-PCI invasive FFR, as in other studies (1,2). This requires further clinical analysis. The impact of the FFR<sub>CT</sub> planning tool on revascularization decision making and clinical outcomes is being evaluated in the P3 (Precise Percutaneous Coronary Intervention Plan; NCT03782688) study, which is actively enrolling.

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