Clinical outcomes of deferred lesions by IVUS versus FFR-guided treatment decision: the FLAVOUR trial substudy


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Background: There is limited data regarding the safety of deferral of percutaneous coronary intervention (PCI) based on intravascular ultrasound (IVUS) findings. Current study sought to compare the prognosis between deferred lesions based on IVUS and FFR (fractional flow reserve)-guided treatment decision.

Methods: Study population was derived from FLAVOUR trial which is a multinational, open-label, randomized, and non-inferiority trial that compared 2-year clinical outcomes between IVUS and FFR-guided treatment decision using predefined criteria. In both IVUS and FFR groups, vessels were classified into deferred or revascularized vessels, and patients into those with or without deferred lesion. Vessel-oriented composite outcomes (VOCO) (cardiac death, target-vessel myocardial infarction, or target-vessel revascularization) in deferred vessels and patient-oriented composite outcomes (POCO) (death, myocardial infarction, or any revascularization) in patients with deferred lesion were compared between IVUS and FFR group.

Results: A total of 1682 patients and 1820 vessels were analyzed. At 2 years, there is no difference in cumulative incidence of VOCO in deferred vessels between IVUS and FFR groups (3.8% vs. 4.1%; hazard ratio [HR] 0.91; 95% confidence interval [CI] 0.47-1.75; P=0.771). The risk of VOCO was comparable between deferred and revascularized vessels following both IVUS (3.8% vs. 3.5%; HR 1.09; 95% CI 0.54-2.19; P=0.813) and FFR-guided treatment decision (4.1% vs. 3.8%; HR 1.14; 95% CI 0.56-2.32; P=0.715). In comparison of POCO in patients with deferred lesion, there was no significant difference between IVUS and FFR groups (6.2% vs. 5.9%; HR 1.05; 95% CI 0.61-1.80; P=0.856).

Conclusion: In patients with intermediate coronary artery stenosis, deferral of PCI based on IVUS-guided treatment decision showed comparable risk of clinical events with FFR-guided treatment decision.
Figure 1. Study Flow

1682 patients with intermediate stenosis underwent randomization

844 were assigned to the IVUS group
16 failed to get adequate IVUS results
28 protocol violations
16 were deferred with positive IVUS
7 underwent PCI with negative IVUS
5 received PCI with plain balloon angioplasty or DCB treatment
8 were lost to follow-up

844 patients and 901 vessels were analyzed as intention-to-treat population

Revascularized vessels (Vessel N = 526)

Deferred vessels (Vessel N = 375)

Patients without deferred lesion (Patient N = 487)

Patients with deferred lesion (Patient N = 357)

838 were assigned to the FFR group
3 failed to get adequate FFR results
16 protocol violations
12 were deferred with positive FFR
4 underwent PCI with negative FFR
5 were lost to follow-up

838 patients and 919 vessels were analyzed as intention-to-treat population

Deferred vessels (Vessel N = 614)

Revascularized vessels (Vessel N = 305)

Patients with deferred lesion (Patient N = 565)

Patients without deferred lesion (Patient N = 273)

Central Illustration. Clinical Outcomes of Deferred Lesions by IVUS versus FFR-Guided Treatment Decision

Proportion of Deferred Lesion

Vessel-Level

Patient-Level

IVUS-Guidance

41.6%

3.5% IVUS-Revascularized

3.8% IVUS-Deferred

4.1% FFR-Deferred

3.6% FFR-Revascularized

10.2% IVUS-Without Defer

6.2% IVUS-With Defer

5.9% FFR-With Defer

12.5% FFR-Without Defer