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
  - 7 were deferred with positive IVUS
  - 5 received PCI with plain balloon angioplasty or DES 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)

- Deferred vessels (Vessel N = 614)
- Revascularized vessels (Vessel N = 365)

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

- Deferred vessels (Vessel N = 565)
- Patients with deferred lesion (Patient N = 273)

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

<table>
<thead>
<tr>
<th>Proportion of Deferred Lesion</th>
<th>Vessel-Level</th>
<th>Patient-Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVUS-Guidance</td>
<td></td>
<td></td>
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<tr>
<td>41.6%</td>
<td>3.5% IVUS-Revascularized</td>
<td>10.2% IVUS-Without Def</td>
</tr>
<tr>
<td>FFR-Guidance</td>
<td>66.8%</td>
<td>3.6% FFR-Revascularized</td>
</tr>
</tbody>
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3.8% IVUS-Deferred

4.1% FFR-Deferred

5.9% FFR-With Defeer

P=0.856