SJM PressureWire™ Fractional Flow Reserve-Guided PCI for Stable Coronary Artery Disease (FAME 2 Study - 2 Year Follow-up)\textsuperscript{1}
Background:

- FAME 2 represents patient two-year follow-up from the original clinical study published in 2012 using SJM PressureWire™ FFR².

- The authors hypothesized that percutaneous coronary intervention (PCI) is superior to medical therapy (MT) alone in patients with stable coronary artery disease (CAD) and functionally significant stenoses, as determined by FFR.

Note: The FAME 2 study enrollment was halted based on the DSMB recommendation due to a significantly increased risk of MACE events among patients randomized to MT compared to patients randomized to FFR-guided PCI + MT. This represents 2-year follow up in those subjects enrolled in FAME 2.²
Objective:
- To determine whether PCI plus medical therapy as determined by FFR, is superior to medical therapy alone in stable CAD patents.
- This report describes the 2 year primary outcome results in 1220 patients.
FAME 2 Study Endpoints

**Primary Endpoint**
Composite of:
- all-cause death
- myocardial infarction
- unplanned hospitalization with urgent revascularization

*as adjudicated by an independent CEC*

**Secondary Endpoints**
- Individual components of MACE
- Nonurgent revascularization procedures
- Functional class
- Number of antianginal medications
- Cerebrovascular event

Urgent revascularization was defined as a patient admitted to the hospital with persisting or increasing chest pain (with or without ST-T changes or elevated biomarkers) and the revascularization procedure was performed during the same hospitalization.
FAME 2 Methods

Stable patients scheduled for 1, 2 or 3 vessel DES stenting

FFR in all target lesions

**RANDOMIZED TRIAL**
- At least 1 stenosis with FFR ≤0.80
- Randomization 1:1
  - PCI + medical therapy
  - medical therapy

**REGISTRY**
- When all FFR > 0.80
  - medical therapy

Follow-up after 1, 6 months, 1, 2, 3, 4 and 5 years
FAME 2 Methods

- Patients
  - Patients enrolled = 1220
  - Patients having at least one stenosis with an FFR≤0.80 were randomized to FFR-guided PCI plus MT (n=447) or to MT alone (n=441).
  - 332 registry patients with angiographically visible stenosis had an FFR>0.80.
  - Due to DSMB recommendation, patient recruitment was halted on January 15, 2012 after recruitment of 54% of the initially planned randomized patients.
# FAME 2 Primary Endpoint - Clinical Events at 2-year Follow-up

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>PCI + MT N (%)</th>
<th>MT Alone N (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 447</td>
<td>N=441</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Endpoint</td>
<td>36 (8.1)</td>
<td>86 (19.5%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Components of Primary Endpoint**

<table>
<thead>
<tr>
<th>Component</th>
<th>PCI + MT</th>
<th>MT Alone</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>6 (1.3)</td>
<td>8 (1.8)</td>
<td>0.58</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>26 (5.8)</td>
<td>30 (6.8)</td>
<td>0.56</td>
</tr>
<tr>
<td>Urgent Revascularisation</td>
<td>18 (4.0)</td>
<td>72 (16.3)</td>
<td>&lt;0.001</td>
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<tr>
<td>Death or myocardial infarction</td>
<td>29 (6.5)</td>
<td>36 (8.2)</td>
<td>0.35</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>3 (0.7)</td>
<td>3 (0.7)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

**Revascularisation**

<table>
<thead>
<tr>
<th>Component</th>
<th>PCI + MT</th>
<th>MT Alone</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Revascularisation</td>
<td>36 (8.1)</td>
<td>179 (40.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Non-urgent revascularisation</td>
<td>18 (4.0)</td>
<td>117 (26.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

FFR-guided PCI + OMT subjects had a 77% reduction in the risk of urgent revascularizations than patients receiving MT alone (4.0% vs. 16.3%, p <0.001)
The rate of death, MI, or urgent revascularization at 2 years was significantly lower with FFR-guided PCI than MT alone (8.1% vs 19.5%) \( p < 0.001 \)
Cumulative Incidence of Death or Myocardial Infarction

FFR-guided PCI plus MT reduced the rate of death or MI beyond 7 days from randomization by 44% when compared to MT alone (4.6% vs 8.0%) \( p < 0.04 \)
Cumulative Incidence of Urgent Revascularization

FFR-guided PCI + MT patients experienced a **77% reduction in the risk of urgent revascularization** than patients receiving MT alone at 2 years (4.0% vs 16.3%) p<0.001
Study Conclusions

- In patients with stable CAD and ischemia as proven by the presence of at least one stenosis with an FFR value ≤0.80, 2 year clinical outcome is improved by SJM PressureWire FFR-guided PCI with second generation drug-eluting stenting plus the best available MT as compared to the best MT alone.

- In patients without hemodynamically significant stenosis, the best available MT alone is associated with an excellent 2-year clinical outcome regardless of the angiographic appearance of the stenoses.
References


Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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