Final Five-Year Follow-up of the SYNTAX Trial:

Optimal Revascularization Strategy in Patients With

3-Vessel and/or Left Main Disease

On behalf of the SYNTAX investigators
SYNTAX Trial Design

Heart Team (surgeon & interventional cardiologist)

Amenable for both treatment options

Amenable for only one treatment approach

Stratification: LM and Diabetes

Randomized Arms
N=1800

CABG n=897
vs
TAXUS* n=903

3VD n=549 (66.3%)
LM n=348 (33.7%)

Two Registry Arms
N=1275

CABG n=1077
PCI n=198

*TAXUS Express

62 EU Sites + 23 US Sites

23 US Sites

62 EU Sites

SYNTAX 5-year Outcomes • ESC 2012 • Mohr • August 2012 • Slide 2
### Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>CABG RCT N=897</th>
<th>PCI RCT N=903</th>
<th>P value</th>
<th>CABG Registry N=644</th>
<th>PCI Registry N=192</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age* (y)</td>
<td>65.0±9.8</td>
<td>65.2±9.7</td>
<td>0.55</td>
<td>65.7±9.4</td>
<td>71.2±10.4</td>
</tr>
<tr>
<td>Male, %</td>
<td>78.9</td>
<td>76.4</td>
<td>0.20</td>
<td>80.7</td>
<td>70.3</td>
</tr>
<tr>
<td>Diabetes*†, %</td>
<td>24.6</td>
<td>25.6</td>
<td>0.64</td>
<td>26.4</td>
<td>30.2</td>
</tr>
<tr>
<td>Additive euroSCORE*</td>
<td>3.8±2.7</td>
<td>3.8±2.6</td>
<td>0.78</td>
<td>3.9±2.7</td>
<td>5.8±3.1</td>
</tr>
<tr>
<td>Total Parsonnet score*</td>
<td>8.4±6.8</td>
<td>8.5±7.0</td>
<td>0.76</td>
<td>9.0±7.1</td>
<td>14.4±9.5</td>
</tr>
<tr>
<td>Total SYNTAX Score</td>
<td><strong>29.1±11.4</strong></td>
<td><strong>28.4±11.5</strong></td>
<td>0.19</td>
<td><strong>37.8±13.3</strong></td>
<td><strong>31.6±12.3</strong></td>
</tr>
<tr>
<td>Mean # of lesions</td>
<td><strong>4.4±1.8</strong></td>
<td><strong>4.3±1.8</strong></td>
<td>0.44</td>
<td><strong>4.6±1.7</strong></td>
<td><strong>4.5±1.8</strong></td>
</tr>
<tr>
<td>3VD only, %</td>
<td>66.3</td>
<td>65.4</td>
<td>0.70</td>
<td>59.7</td>
<td>66.7</td>
</tr>
<tr>
<td>Left main, any, %</td>
<td>33.7</td>
<td>34.6</td>
<td>0.70</td>
<td>40.3</td>
<td>33.3</td>
</tr>
<tr>
<td>Total occlusion, %</td>
<td>22.2</td>
<td>24.2</td>
<td>0.33</td>
<td>56.4</td>
<td>36.5</td>
</tr>
<tr>
<td>Complete revasc, %</td>
<td>63.2</td>
<td>56.7</td>
<td><strong>0.005</strong></td>
<td>74.7</td>
<td>36.5</td>
</tr>
</tbody>
</table>

Values are mean±SD or %. Core laboratory reported unless *Site-reported †Medically treated
The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

Final Five-year Follow-up of the SYNTAX Trial: Optimal Revascularization Strategy in Patients with Three-vessel Disease
Patient Disposition to 5 Years
3VD Subset Intent-to-Treat

**RCT: Enrolled**
- CABG: 549
- PCI*: 546

**1 Year Follow-up**
- CABG: 513
- PCI*: 536
- CABG: 93.4%
- PCI: 98.2%

**2 Year Follow-up**
- CABG: 505
- PCI*: 533
- CABG: 92.0%
- PCI: 97.6%

**3 Year Follow-up**
- CABG: 502
- PCI*: 536
- CABG: 91.4%
- PCI: 98.2%

**4 Year Follow-up**
- CABG: 495
- PCI*: 530
- CABG: 90.2%
- PCI: 97.1%

**5 Year Final Follow-up**
- CABG: 483
- PCI*: 525
- CABG: 88.0%
- PCI: 96.2%
Summary of 1-Year Results

3VD Subset

- Death/Stroke/MI rates were similar between CABG and PCI
- Stroke was not significantly increased in CABG
- Repeat revascularization and MACCE increased in PCI vs CABG
All-Cause Death/CVA/MI to 5 Years
3VD Subset

ITT population

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>CABG (N=549)</th>
<th>TAXUS (N=546)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1 year*</td>
<td>6.6% vs 8.0%</td>
<td>P=0.39</td>
<td></td>
</tr>
<tr>
<td>1–2 years*</td>
<td>1.8% vs 3.7%</td>
<td>P=0.07</td>
<td></td>
</tr>
<tr>
<td>2–3 years*</td>
<td>2.5% vs 4.4%</td>
<td>P=0.10</td>
<td></td>
</tr>
<tr>
<td>3–4 years*</td>
<td>2.1% vs 4.4%</td>
<td>P=0.053</td>
<td></td>
</tr>
<tr>
<td>4–5 years*</td>
<td>2.4% vs 3.7%</td>
<td>P=0.29</td>
<td></td>
</tr>
</tbody>
</table>

Cumulative KM Event Rate ± 1.5 SE; log-rank P-value; *Binary rates

ITT population
Repeat Revascularization to 5 Years
3VD Subset

Cumulative KM Event Rate ± 1.5 SE; log-rank $P$ value; *Binary rates

Before 1 year*
5.5% vs 14.6%
P < 0.001

1–2 years*
2.8% vs 3.9%
P = 0.35

2–3 years*
2.5% vs 3.0%
P = 0.63

3–4 years*
0.6% vs 4.4%
P < 0.001

4–5 years*
2.0% vs 4.5%
P = 0.03
MACCE to 5 Years
3VD Subset

Before 1 year*
11.5% vs 19.2%
\(P<0.001\)

1–2 years*
4.4% vs 7.0%
\(P=0.08\)

2–3 years*
4.6% vs 7.4%
\(P=0.06\)

3–4 years*
2.8% vs 7.7%
\(P<0.001\)

4–5 years*
4.5% vs 6.9%
\(P=0.11\)

\(P<0.001\)

Cumulative KM Event Rate ± 1.5 SE; log–rank \(P\) value;*Binary rates

ITT population
MACCE to 5 Years by SYNTAX Score Tercile
3VD Subset Low Scores 0–22

CABG (N=171)
TAXUS (N=181)

3-Vessel Disease

<table>
<thead>
<tr>
<th>Event</th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>9.3%</td>
<td>10.2%</td>
<td>0.81</td>
</tr>
<tr>
<td>CVA</td>
<td>3.9%</td>
<td>1.8%</td>
<td>0.24</td>
</tr>
<tr>
<td>MI</td>
<td>4.9%</td>
<td>8.8%</td>
<td>0.20</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>14.8%</td>
<td>17.5%</td>
<td>0.56</td>
</tr>
<tr>
<td>Revasc.</td>
<td>14.6%</td>
<td>23.1%</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population
## MACCE to 5 Years by SYNTAX Score Tercile

### 3VD Subset Intermediate Scores 23–32

<table>
<thead>
<tr>
<th></th>
<th>CABG (N=208)</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>9.6%</td>
<td>16.3%</td>
<td>0.047</td>
</tr>
<tr>
<td>CVA</td>
<td>3.6%</td>
<td>2.5%</td>
<td>0.53</td>
</tr>
<tr>
<td>MI</td>
<td>3.1%</td>
<td>13.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>14.7%</td>
<td>23.2%</td>
<td>0.04</td>
</tr>
<tr>
<td>Revasc.</td>
<td>11.0%</td>
<td>25.1%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

![Graph showing MACCE event rates by SYNTAX Score tercile for 3-vessel disease subset.](image)

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population

---

P<0.001
MACCE to 5 Years by SYNTAX Score Tercile
3VD Subset High Scores ≥33

<table>
<thead>
<tr>
<th>Event</th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>8.8%</td>
<td>17.8%</td>
<td>0.02</td>
</tr>
<tr>
<td>CVA</td>
<td>2.6%</td>
<td>5.1%</td>
<td>0.31</td>
</tr>
<tr>
<td>MI</td>
<td>1.9%</td>
<td>8.7%</td>
<td>0.008</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>12.5%</td>
<td>26.2%</td>
<td>0.002</td>
</tr>
<tr>
<td>Revasc.</td>
<td>12.6%</td>
<td>28.2%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Site-reported Data; ITT population

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

SYNTAX 5-year Outcomes · ESC 2012 · Mohr · August 2012 · Slide 12
The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

Final Five-year Follow-up of the SYNTAX Trial

Left Main Disease

Conflicts of Interest: None
### Patient Disposition to 5 Years

**LM Subset Intent-to-Treat**

<table>
<thead>
<tr>
<th>Event</th>
<th>CABG n</th>
<th>PCI* n</th>
<th>CABG Rate</th>
<th>PCI Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RCT: Enrolled</strong></td>
<td>348</td>
<td>357</td>
<td>96.6%</td>
<td>99.4%</td>
</tr>
<tr>
<td><strong>RCT: 1 Year Follow-up</strong></td>
<td>336</td>
<td>355</td>
<td>92.0%</td>
<td>97.1%</td>
</tr>
<tr>
<td><strong>RCT: 2 Year Follow-up</strong></td>
<td>331</td>
<td>533</td>
<td>95.1%</td>
<td>98.6%</td>
</tr>
<tr>
<td><strong>RCT: 3 Year Follow-up</strong></td>
<td>502</td>
<td>352</td>
<td>93.4%</td>
<td>97.8%</td>
</tr>
<tr>
<td><strong>RCT: 5 Year Final Follow-up</strong></td>
<td>325</td>
<td>349</td>
<td>92.5%</td>
<td>96.9%</td>
</tr>
</tbody>
</table>

*Taxus Express*
Death/Stroke/MI and MACCE rates were similar between groups.

Stroke was significantly increased in CABG and revascularization in PCI.
CVA to 5 Years
**Left Main Subset**

- **ITT population**
  - **P=0.03**
  - 4.3%

### Months Since Allocation

- **Before 1 year**
  - 2.7% vs 0.3%
  - **P=0.009**
- **1-2 years**
  - 0.9% vs 0.6%
  - **P=0.68**
- **2-3 years**
  - 0.3% vs 0.3%
  - **P=1.00**
- **3-4 years**
  - 0.3% vs 0.3%
  - **P=1.00**
- **4-5 years**
  - 0% vs 0%
  - **P=Undefined**

### Cumulative KM Event Rate

- **CABG (N=348)**
- **TAXUS (N=357)**

Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates

**ITT population**
All-Cause Death/CVA/MI to 5 Years
Left Main Subset

**ITT population**

<table>
<thead>
<tr>
<th>Time Period</th>
<th>CABG Event Rate (%)</th>
<th>TAXUS Event Rate (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1 year</td>
<td>9.2%</td>
<td>7.0%</td>
<td>0.29</td>
</tr>
<tr>
<td>1–2 years*</td>
<td>2.8% vs 3.2%</td>
<td>2.8% vs 3.2%</td>
<td>0.76</td>
</tr>
<tr>
<td>2–3 years*</td>
<td>2.6% vs 3.0%</td>
<td>2.6% vs 3.0%</td>
<td>0.76</td>
</tr>
<tr>
<td>3–4 years*</td>
<td>3.7% vs 4.9%</td>
<td>3.7% vs 4.9%</td>
<td>0.45</td>
</tr>
<tr>
<td>4–5 years*</td>
<td>4.2% vs 2.3%</td>
<td>4.2% vs 2.3%</td>
<td>0.18</td>
</tr>
</tbody>
</table>

Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates

ITT population
Repeat Revascularization to 5 Years

Left Main Subset

**ITT population**

- **P<0.001**

- **15.5%**

- **Cumulative Event Rate (%)**

- **25**

- **Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates**

- **Before 1 year**
  - **6.5% vs 11.8%**
  - **P=0.02**

- **1–2 years**
  - **5.0% vs 8.2%**
  - **P=0.10**

- **2–3 years**
  - **2.6% vs 3.9%**
  - **P=0.36**

- **3–4 years**
  - **3.0% vs 4.0%**
  - **P=0.50**

- **4–5 years**
  - **1.7% vs 3.9%**
  - **P=0.12**

**TAXUS (N=357) CABG (N=348)**
MACCE to 5 Years
Left Main Subset

CABG (N=348) vs TAXUS (N=357)

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>CABG Rate (%)</th>
<th>TAXUS Rate (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1 year*</td>
<td>13.7% vs 15.8%</td>
<td>P=0.44</td>
<td></td>
</tr>
<tr>
<td>1–2 years*</td>
<td>7.5% vs 10.3%</td>
<td>P=0.22</td>
<td></td>
</tr>
<tr>
<td>2–3 years*</td>
<td>5.2% vs 5.7%</td>
<td>P=0.78</td>
<td></td>
</tr>
<tr>
<td>3–4 years*</td>
<td>6.4% vs 8.3%</td>
<td>P=0.35</td>
<td></td>
</tr>
<tr>
<td>4–5 years*</td>
<td>5.9% vs 5.5%</td>
<td>P=0.82</td>
<td></td>
</tr>
</tbody>
</table>

Cumulative KM Event Rate ± 1.5 SE; log-rank P-value;*Binary rates

ITT population
MACCE to 5 Years by SYNTAX Score Tercile

**LM Subset Low Scores 0–22**

<table>
<thead>
<tr>
<th></th>
<th>CABG (N=104)</th>
<th>PCI (N=118)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>11.3%</td>
<td>7.0%</td>
<td>0.28</td>
</tr>
<tr>
<td>CVA</td>
<td>4.1%</td>
<td>1.8%</td>
<td>0.28</td>
</tr>
<tr>
<td>MI</td>
<td>3.1%</td>
<td>6.2%</td>
<td>0.32</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>15.2%</td>
<td>13.9%</td>
<td>0.71</td>
</tr>
<tr>
<td>Revasc.</td>
<td>20.3%</td>
<td>23.0%</td>
<td>0.65</td>
</tr>
</tbody>
</table>

**LM Disease**

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population
MACCE to 5 Years by SYNTAX Score Tercile

**LM Subset Intermediate Scores 23-32**

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>19.3%</td>
<td>8.9%</td>
<td>0.04</td>
</tr>
<tr>
<td>CVA</td>
<td>3.6%</td>
<td>1.0%</td>
<td>0.23</td>
</tr>
<tr>
<td>MI</td>
<td>4.6%</td>
<td>6.0%</td>
<td>0.71</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>24.9%</td>
<td>15.7%</td>
<td>0.11</td>
</tr>
<tr>
<td>Revasc.</td>
<td>16.6%</td>
<td>22.2%</td>
<td>0.40</td>
</tr>
</tbody>
</table>

**LM Disease**

P=0.88

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population
MACCE to 5 Years by SYNTAX Score Tercile

**LM Subset Hi... Scores ≥33**

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>14.1%</td>
<td>20.9%</td>
<td>0.11</td>
</tr>
<tr>
<td>CVA</td>
<td>4.9%</td>
<td>1.6%</td>
<td>0.13</td>
</tr>
<tr>
<td>MI</td>
<td>6.1%</td>
<td>11.7%</td>
<td>0.13</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>22.1%</td>
<td>26.1%</td>
<td>0.40</td>
</tr>
<tr>
<td>Revasc.</td>
<td>11.6%</td>
<td>34.1%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

LM Disease

Cumulative KM Event Rate ± 1.5 SE; log-rank P value

Site-reported Data; ITT population
Heterogeneity in the Left Main Group

Site-reported data

- Left Main + 3VD: n=258 (37%)
- Left Main Isolated: n=91 (13%)
- Left Main + 2VD: n=218 (31%)
- Left Main + 1VD: n=138 (20%)
Five-year results of the SYNTAX trial suggest that 71% of all patients are still best treated with CABG; however, for the remaining patients PCI is an alternative to surgery.
One-Year MACCE Rates per Site
CABG vs TAXUS Express Stent

CABG MACCE (%) vs TAXUS stent MACCE (%)

SYNTAX 5-year Outcomes • ESC 2012 • Mohr • August 2012 • Slide 25
Welcome to the SYNTAX Score website. The SYNTAX Score is a unique tool to score complexity of coronary artery disease. However, it is very important to use this new scoring tool correctly, hence, it is strongly recommended to complete the tutorial first.

Calculator updated to version 2.11: four-year outcomes

Version 2.11 of the SYNTAX Score calculator contains the latest four-year SYNTAX trial results. The SYNTAX Score website now uses this version.

Unlike the online calculator, the standalone calculator is not automatically updated. Be sure to check our website regularly to ensure you are using the latest calculator version. The current version can be downloaded here:

SYNTAX Score Calculator 2.11

For a detailed changelog select read more below.