Comparison of coronary bypass surgery with drug-eluting stenting for the treatment of left main and/or three-vessel disease: 3-year follow-up of the SYNTAX trial

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Presenter Disclosure
Information

Antonio Colombo, MD

Co-founder & minor shareholder: Cappella Inc.
SYNTAX Study Objectives

- With technological advances and changes in clinical practice, the respective values of coronary artery bypass surgery and percutaneous coronary intervention needed to be reassessed.
- The SYNTAX randomized trial is an attempt to provide an evidence base to determine the most appropriate treatment option for patients in a ‘real-world’ population seen by the surgeon and the interventional cardiologist in their daily practice.
- In 2009, the ACC–AHA PCI Guidelines were updated and raised LM stenting from Class III to Class IIb (level B)\(^1\)
- In 2010, ESC–EACTS Guidelines revised and upgraded LM (isolated or in conjunction with 1 vessel disease) stenting from Class IIb C to IIa B\(^2\)

\(^1\)Kushner et al. Circulation 2009; 120:2271–2306
\(^2\)Wijns et al. EHJ 2010
Patients in SYNTAX
Randomized Controlled Trial Intent-to-Treat

RCT: Enrolled
N=1800

PCI*
n=903

PCI*
n=885

CABG
n=897

N=70
n=46 withdrawn
n=11 lost to follow-up
n=13 no/early follow-up

CABG
n=836

N=18
n=9 withdrawn
n=2 lost to follow-up
n=7 no/early follow-up

CABG
n=827

RCT: 1 Year Follow-up
N=1740 (96.7%)

RCT: 2 Year Follow-up
N=1721 (95.6%)

RCT: 3 Year Follow-up
N=1712 (95.1%)

*TAXUS Express
SYNTAX Trial

Trial Complexity

32% pts received > 100mm total stent length

Nr of Taxus Stents implanted in patients

- Taxus I: 1.0
- Taxus II: 1.03
- Taxus IV: 1.08
- Taxus V: 1.37
- SYNTAX: 4.7
Heterogeneity in the Left Main Group

- Left Main + 3VD: n=258 (37%)
- Left Main Isolated: n=91 (13%)
- Left Main + 2VD: n=138 (20%)
- Left Main + 1VD: n=218 (31%)

Site-reported data
## Patient Characteristics

**LM Subset**

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>TAXUS</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age*, mean ± SD (y)</td>
<td>65.6 ± 10.1</td>
<td>65.4 ± 9.8</td>
<td>0.78</td>
</tr>
<tr>
<td>Medically treated diabetes*, %</td>
<td>22.4</td>
<td>21.8</td>
<td>0.86</td>
</tr>
<tr>
<td>BMI, mean ± SD</td>
<td>27.7 ± 5.0</td>
<td>28.2 ± 4.9</td>
<td>0.24</td>
</tr>
<tr>
<td>Additive euroSCORE*, mean ± SD</td>
<td>3.9 ± 2.9</td>
<td>3.9 ± 2.8</td>
<td>0.91</td>
</tr>
<tr>
<td>Total Parsonnet score*, mean ± SD</td>
<td>9.1 ± 7.4</td>
<td>8.9 ± 7.8</td>
<td>0.77</td>
</tr>
<tr>
<td>Total SYNTAX Score, mean ± SD</td>
<td>26.7 ± 11.5</td>
<td>28.1 ± 12.4</td>
<td>0.13</td>
</tr>
<tr>
<td>No. lesions, mean ± SD</td>
<td>3.2 ± 1.9</td>
<td>3.3 ± 1.8</td>
<td>0.89</td>
</tr>
</tbody>
</table>

Core laboratory reported unless *Site-reported
Death/Stroke/MI and MACCE rates were similar between groups.

Stroke was significantly increased in CABG and revascularization in PCI.
Death/CVA/MI and MACCE rates were similar between groups. Stroke was significantly increased in CABG and revascularization in PCI.
All-Cause Death to 3 Years
LM Subset

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

Cumulative Event Rate (%)

Before 1 year
4.5% vs 4.2%
P=0.88

1-2 years
1.9% vs 1.5%
P=0.68

2-3 years
2.3% vs 1.8%
P=0.67

Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates
CVA to 3 Years
LM Subset

P = 0.02

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

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

Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates
Myocardial Infarction to 3 Years
LM Subset

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

0 0.14
6.9%
4.1%

0 Months Since Allocation

Before 1 year
4.2% vs 4.2%
P=0.97

1-2 years
0.0% vs 1.2%
P=0.12

2-3 years
0.0% vs 1.5%
P=0.06

ITT population

Cumulative KM Event Rate ± 1.5 SE; log-rank P value; *Binary rates
All-Cause Death/CVA/MI to 3 Years
LM Subset

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

<table>
<thead>
<tr>
<th>Period</th>
<th>CABG Rate</th>
<th>TAXUS 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%</td>
<td>3.2%</td>
<td>0.76</td>
</tr>
<tr>
<td>2-3 years</td>
<td>2.6%</td>
<td>3.0%</td>
<td>0.76</td>
</tr>
</tbody>
</table>

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

ITT population
Repeat Revascularization to 3 Years
LM Subset

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

**Cumulative Event Rate (%)**
- **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*

**Repeat Revascularization:**
- **Repeat CABG**: 1.7% vs 5.6%, *P=0.01*
- **Repeat PCI**: 10.0% vs 16.2%, *P=0.01*

Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value; *Binary rates*
MACCE to 3 Years
LM Subset

Before 1 year
13.7% vs 15.8%
$P=0.44$

1-2 years
7.5% vs 10.3%
$P=0.22$

2-3 years
5.2% vs 5.7%
$P=0.78$

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

ITT population
Symptomatic Graft Occlusion & Stent Thrombosis to 3 Years

LM Subset

CABG (n=348)  TAXUS (n=357)

3.7 4.1

P=0.80

Patients (%)

3.7  n=12  CABG

4.1  n=14  TAXUS

Post-procedure; ITT population
MACCE to 3 Years in LM Subgroups

Cumulative KM Event Rate; log-rank $P$ value; Binary rates
MACCE to 3 Years by SYNTAX Score Tercile

**Low Scores (0–22)**

<table>
<thead>
<tr>
<th>Event</th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>6.0%</td>
<td>2.6%</td>
<td>0.21</td>
</tr>
<tr>
<td>CVA</td>
<td>4.1%</td>
<td>0.9%</td>
<td>0.12</td>
</tr>
<tr>
<td>MI</td>
<td>2.0%</td>
<td>4.3%</td>
<td>0.36</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>11.0%</td>
<td>6.9%</td>
<td>0.26</td>
</tr>
<tr>
<td>Revasc.</td>
<td>13.4%</td>
<td>15.4%</td>
<td>0.69</td>
</tr>
</tbody>
</table>

Left Main

- CABG (N=104)
- TAXUS (N=118)

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

Site-reported Data; ITT population
MACCE to 3 Years by SYNTAX Score Tercile

Intermediate Scores (23–32)

<table>
<thead>
<tr>
<th></th>
<th>CABG (N=92)</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>12.4%</td>
<td>4.9%</td>
<td>0.06</td>
</tr>
<tr>
<td>CVA</td>
<td>2.3%</td>
<td>1.0%</td>
<td>0.46</td>
</tr>
<tr>
<td>MI</td>
<td>3.3%</td>
<td>5.0%</td>
<td>0.63</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>15.6%</td>
<td>10.8%</td>
<td>0.29</td>
</tr>
<tr>
<td>Revasc.</td>
<td>14.0%</td>
<td>15.9%</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Left Main

Cumulative Event Rate (%)

Months Since Allocation

P=0.90

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

Site-reported Data; ITT population
MACCE to 3 Years by SYNTAX Score Tercile

**Left Main SYNTAX Score ≥33**

<table>
<thead>
<tr>
<th></th>
<th>CABG</th>
<th>PCI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>7.6%</td>
<td>13.4%</td>
<td>0.10</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>10.9%</td>
<td>0.18</td>
</tr>
<tr>
<td>Death, CVA or MI</td>
<td>15.7%</td>
<td>20.1%</td>
<td>0.34</td>
</tr>
<tr>
<td>Revasc.</td>
<td>9.2%</td>
<td>27.7%</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

**CABG** (N=149)  
**TAXUS** (N=135)
Summary

Left Main Subset

- At 3 years, overall MACCE in the PCI group was comparable with CABG (22.3% CABG vs 26.8% PCI)
  - Similar overall safety outcomes (Death/CVA/MI) between CABG and PCI at 3 years (14.3% CABG vs 13.0% PCI)
- There was a higher rate of revascularization in the PCI group (11.7% CABG vs 20.0% PCI), and a higher rate of CVA in the CABG group (4.0% CABG vs 1.2% PCI)
- PCI outcomes are excellent relative to CABG in LM isolated and LM+1VD
Conclusions

For patients with left main disease

• Revascularization with PCI has comparable safety and efficacy outcomes to CABG

• PCI is therefore a reasonable treatment alternative in this patient population, in particular, when the SYNTAX Score is low (≤22) or intermediate (23–32)
One-year MACCE Rates per site
CABG vs. TAXUS Express Stent

Size of circle adjusted for number of patients
IVUS guidance may have even better survival in LMCA PCI

IVUS guided optimization

Absence of stent Inapposition, LM stent CSA > 9mm²
LAD or LCX stent CSA > 4mm²

Second generation stents

In the SYNTAX study only 113 pts (12.5%) had IVUS guided stent implantation and no specific criteria were used to define “Optimal IVUS guided stent implantation.”

These 3 important points will lower Stent Thrombosis and revascularization rate: the main reasons why SYNTAX did not perform as expected.

response to new antiplatelet therapeutics.