Implementing physiology and imaging to improve outcomes in the management of multivessel disease: what to expect from SYNTAX II

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Oxford
I have the following potential conflicts of interest to report:

Receipt of grants / research supports: Boston Scientific, Medtronic
Receipt of honoraria or consultation fees: Abbott
SYNTAX Trial Design

- **Randomized Arms**
  - N=1800
  - CABG n=897
    - 3VD 66.3%
    - LM 33.7%
  - vs
  - TAXUS* n=903
    - 3VD 65.4%
    - LM 34.6%

- **Two Registry Arms**
  - N=1275
  - CABG n=1077
    - 5yr f/u n=649
  - PCI n=198
  - no f/u n=428

- Heart Team (surgeon & interventionalist)
  - Amenable for both treatment options
  - Stratification: LM and Diabetes
  - Amenable for only one treatment approach

- 62 EU Sites + 23 US Sites

- SYNTAX Trial Design
  - TAXUS Express
MACCE to 5 Years

- **CABG** (N=897)
- **TAXUS** (N=903)

**Before 1 year**
- 12.4% vs 17.8%
  - *P*=0.002

**1–2 years**
- 5.7% vs 8.3%
  - *P*=0.03

**2–3 years**
- 4.8% vs 6.7%
  - *P*=0.10

**3–4 years**
- 4.2% vs 7.9%
  - *P*=0.002

**4–5 years**
- 5.0% vs 6.3%
  - *P*=0.27

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

ITT population

*P*<0.001
SYNTAX Chronology

AHA Concept Meeting
November 2003

Draft rationale
Brainstorming session
1st protocol

2004

Enrollment complete
April 2007

2005

1st patient
March 2005

2006

1 year follow-up complete

2007

2008
MACCE Components to 30 Days

CABG (n=549) | TAXUS (n=546)

| Event         | 30 Day Rate | P-Value  \\
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1.2</td>
<td>0.08*</td>
</tr>
<tr>
<td>CVA</td>
<td>1.0</td>
<td>0.03*</td>
</tr>
<tr>
<td>MI</td>
<td>2.4</td>
<td>0.20†</td>
</tr>
<tr>
<td>Revasc.</td>
<td>1.7</td>
<td>0.02*</td>
</tr>
<tr>
<td>MACCE</td>
<td>5.2</td>
<td>0.45*</td>
</tr>
</tbody>
</table>

30 day post-procedure

chi-square test; †Fisher exact test
Stent Number and Length in SYNTAX

Multi-vessel disease: 96.2%*
3-vessel disease: 90.8%
Avg. stents per patient: 4.6 ± 2.3
Avg. stented length: 86.1 mm

Total Number of Stents Implanted per Patient

*3VD+LM/3VD+LM/2VD+LM/1VD
Source: See Glossary
Why were Syntax outcomes poor for PCI

Uniquely high risk population for an RCT
Surgical cohort – MACCE rate of at 5yrs- 27% MACCE @ 5yrs

Compared exceptional (for all the wrong reasons) PCI with routine (excellent) surgery – high rates of arterial revasc

Demonstrated that experienced PCI operators can select pts for CABG
CABG registry > CABG randomised 23%MACCE @5yrs

Single sitting revascularisation
Favoured surgery – PCI excess incomplete revasc- CTOs

Angiographic assessment rather than functional (ischaemia guided)

Stent – Express – Taxus
Linear Increase in MACCE by Number of Stents in the SYNTAX Trial

- 1.5 Stents: "Typical" Real World Average
  - 1 stent: 5.6%

- 4.6 Stents: SYNTAX Average
  - 17.8%

- Avg. in pts with 5-8+ stents in SYNTAX
  - 19.6%

Graph showing 12m MACCE Probability and 12m MACCE Rate against Number of Stents Implanted.
Since 2005 what's happened in PCI?

- Better stents
- Less stent thrombosis
- Pressure wire assessment

**FAME**

- **less stents better outcomes**
- Radial PCI – standard
- Better drugs - ticagralor/prasugrel/? Less reopro
- Less stent thrombosis
- Better technique
  - more complete revasc – especially CTO

**Absolute MACCE outcomes in FAME**

FFR-guided
So how do we improve on the PCI arm of Syntax?

Better stents
Better strategy
Better results

Synergy
iFR
iVUS

May lead to a better outcome
So how do we improve on the PCI arm of Syntax?

- Better stents
- Better strategy
- Better results

Synergy
- iFR
- iVUS

May lead to a better outcome
So are our stents better - really?

@ 5yrs less

TVF
TLF
Ischaemia
Death

5-Year Results of a Randomized Comparison of XIENCE V Everolimus-Eluting and TAXUS Paclitaxel-Eluting Stents

Final Results From the SPIRIT III Trial (Clinical Evaluation of the XIENCE V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)
SYNERGY Stent

Platform
Platinum chromium
- 74 μm (0.0029 in)
- Increased Visibility

Bioabsorbable Polymer Coating
PLGA
- Abluminal
- 4 μm thick
- 85:15 ratio
- < 4 month absorption time

Drug
Everolimus
- 100 μg/cm²
- 3 month release time

SEM of coating (x5000)
Abluminal (4 μm)
Luminal

SYNERGY 74 μm
PREMIER 81 μm
Resolute Integrity 89 μm
Xience Xpedition 81 μm

Everolimus Drug
PLGA Polymer
<table>
<thead>
<tr>
<th>Better stents</th>
<th>Synergy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better strategy</td>
<td>iFR</td>
</tr>
<tr>
<td>Better results</td>
<td>iVUS</td>
</tr>
</tbody>
</table>

May lead to a better outcome
Clinical studies of FFR: FAME

- Death: ~40% decrease
  - Angio-Guided: 3%
  - FFR-Guided: 1.8%

- MI: ~35% decrease
  - Angio-Guided: 8.7%
  - FFR-Guided: 5.7%

- Repeat Revascularization: ~30% decrease
  - Angio-Guided: 9.5%
  - FFR-Guided: 6.5%

- MACE: ~35% decrease
  - Angio-Guided: 11.1%
  - FFR-Guided: 7.3%

- Death/MI: p=0.04
- MACE: p=0.02
Functional SYNTAX score

Reclassifies 1/3 patients
So how do we improve on the PCI arm of Syntax?

Better stents  Synergy
Better strategy  iFR
Better results  iVUS

May lead to a better outcome
Minimize geographic miss
Optimize expansion
modified MUSIC criteria
**SYNTAX Trial II**

Inclusion: All-Comers, angiographic, de-novo 3-vessel disease without left main involvement (visual % diameter stenosis)

- Pre-stratify Low (0-22) anatomical SYNTAX Score
- Pre-stratify Interm (23-32) anatomical SYNTAX Score
- Pre-stratify High (≥33) anatomical SYNTAX Score

**Heart Team Discussion**

- Confirm SYNTAX Score II calculation, and that recruitment of patients for PCI is based on safety (long term mortality comparisons between CABG and PCI)

**SYNTAX Score II**

- Allows PCI as an alternative to CABG
- Can 'equivalent' anatomical revascularisation be achieved*  
  > *Surgeon and interventional cardiologist in agreement

**Patient ‘Signed Off’ by Heart Team for PCI**

- SYNTAX Score II
  - **Favours CABG***
    
    > *Index revascularisation procedure type collected (CABG, PCI or medical). One year vital status collected (OPTIONAL).
SYNTAX Score II normogram

SYNTAX Score II questions and calculator outputs:

(A)
Anatomical SYNTAX (points): 48
Age (years): 74
CrCl (ml/min): 49
LVEF (%): 50
Left Main: No
Sex: Female
COPD: No
PVD: No
SSII PCI (points): 51
SSII CABG (points): 28
4-year predicted mortality PCI (%): 33
4-year predicted mortality CABG (%): 6
Treatment recommendation: CABG

(B)
Anatomical SYNTAX (points): 16
Age (years): 75
CrCl (ml/min): 62
LVEF (%): 70
Left Main: No
Sex: Male
COPD: Yes
PVD: Yes
SSII PCI (points): 48
SSII CABG (points): 60
4-year predicted mortality PCI (%): 28
4-year predicted mortality CABG (%): 57
Treatment recommendation: PCI

(C)
Anatomical SYNTAX (points): 20
Age (years): 49
CrCl (ml/min): 99
LVEF (%): 55
Left Main: No
Sex: Male
COPD: No
PVD: No
SSII PCI (points): 19
SSII CABG (points): 12
4-year predicted mortality PCI (%): 3
4-year predicted mortality CABG (%): 2
Treatment recommendation: CABG or PCI
PCI Procedure Flowchart

Patient “Signed-off” by the Heart Team for PCI

iFR in all intended to treat vessels

iFR < 0.86*

FFR ≤ 0.80

Implantation of SYNERGY™ stent(s)

Optimization by IVUS guidance (modified MUSIC Criteria)

Optimal medical therapy with strict LDL control (≤ 1.8mmol/L)

iFR 0.86 – 0.93

FFR

iFR > 0.93

FFR > 0.80

No stent implantation in lesion

* Consider FFR pullback with sequential lesions
- 2.5 x 15 mm balloon
- 3.0 x 32 mm Synergy stent
- 3.5 mm NC balloon postdilation
2.5 x 15 mm balloon

3.0 x 32 mm Synergy stent
- Failed Antegrade approach
  (Pilot 200, Fielder XT, Confianza Pro, Gaia II supported by Corsair)

- Predilation with 2.5 x 12 mm balloon
- 3.0 x 20 mm Synergy stent
- Final result to RCA
Retrograde approach

(Sion Black supported by Corsair pushed into Guideliner Exchange with RG3 300 cm wire)
Predilation with 2.0x20 mm balloon

Synergy 3.5 x 38 mm stent

Postdilation 3.5 x 20 mm NC balloon
Further postdilation with 3.5 mm NC balloon at high pressure

“It aint over till its over”
20 Participating Sites

UK, Spain, Netherlands, Poland

Belfast Health & Social Care Trust
The Royal Infirmary of Edinburgh
Liverpool Heart and Chest Hospital
Freeman Hospital, Newcastle
Manchester Royal Infirmary
Papworth Hospital, Cambridge
Imperial College London
Academic Medical Center, Amsterdam
Brighton & Sussex University Hospitals
Erasmus MC, Rotterdam
John Radcliffe Hospital, Oxford
Hospital Marqués de Valdecilla, Santander
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Brighton & Susse
Methods

Primary Endpoint

• **Primary Endpoint:** MACCE at 1 year follow-up
  – A composite of all-cause death, stroke, myocardial infarction or all-cause revascularization compared to the PCI arm of the SYNTAX I trial
  – To allow comparison, MACCE was adjudicated using SYNTAX I trial definitions.
    • Of note, periprocedural MI was defined as CK-MB ≥ 5xULN (Troponin ≥ 35ULN) *and* new pathological Q-waves in the ECG.
Methods
Design and Eligibility

• Multicenter, prospective, single-arm, open-label trial of patients with *de-novo* 3-vessel disease without left-main stem involvement

• Patients were included if the SYNTAX score II recommended either PCI or equipoise between PCI and CABG, based on the predicted mortalities at 4 years
  – The heart team can overrule the score recommendation

• Any anatomic SYNTAX score eligible for enrollment (*including* SYNTAX ≥ 33)

• The control group was created by selecting from the 3VD patients in the PCI arm of the SYNTAX I trial (n=546) those with a SYNTAX score II recommendation for PCI or Equipoise (PCI or CABG)
<table>
<thead>
<tr>
<th></th>
<th>Syntax PCI arm (n=315)</th>
<th>SYNTAX II trial (n=454)</th>
<th>Difference (95% CI)</th>
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<tbody>
<tr>
<td><strong>SYNTAX Score II PCI</strong></td>
<td>30.6±8.7</td>
<td>30.2±8.7</td>
<td>-0.4 [-1.7, 0.8]</td>
</tr>
<tr>
<td><strong>SYNTAX Score II CABG</strong></td>
<td>29.1±9.6</td>
<td>29.1±10.4</td>
<td>-0.0 [-1.5, 1.4]</td>
</tr>
<tr>
<td>4y predicted mortality PCI (%)</td>
<td>9.2±8.7</td>
<td>9.0±8.8</td>
<td>-0.3 [-1.5, 1.0]</td>
</tr>
<tr>
<td>4y predicted mortality CABG (%)</td>
<td>8.5±8.1</td>
<td>9.0±9.3</td>
<td>0.5 [-0.8, 1.8]</td>
</tr>
</tbody>
</table>
## Baseline Demographics

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<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66.7±9.1</td>
<td>66.7±9.7</td>
<td>-0.0 [-1.4, 1.4]</td>
</tr>
<tr>
<td>Male</td>
<td>93.0%</td>
<td>93.2%</td>
<td>0.1% [-3.5%, 3.8%]</td>
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<tr>
<td>Body-mass index</td>
<td>28.2±4.4</td>
<td>28.9±4.7</td>
<td>0.7 [0.0, 1.4]</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>29.2%</td>
<td>30.4%</td>
<td>1.2% [-5.4%, 7.8%]</td>
</tr>
<tr>
<td>Insulin treated</td>
<td>10.5%</td>
<td>8.5%</td>
<td>-2.0% [-6.2%, 2.3%]</td>
</tr>
<tr>
<td>Oral medication only</td>
<td>16.8%</td>
<td>19.7%</td>
<td>2.9% [-2.7%, 8.4%]</td>
</tr>
<tr>
<td>Diet only</td>
<td>1.9%</td>
<td>2.0%</td>
<td>0.1% [-1.9%, 2.1%]</td>
</tr>
<tr>
<td>Current Smoker</td>
<td>17.8%</td>
<td>14.7%</td>
<td>-3.1% [-8.5%, 2.3%]</td>
</tr>
<tr>
<td>Previous Myocardial infarction</td>
<td>28.7%</td>
<td>12.5%</td>
<td>-16.2% [-22.1%, -10.3%]</td>
</tr>
<tr>
<td>Previous Stroke</td>
<td>NA</td>
<td>5.6%</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>73.4%</td>
<td>77.0%</td>
<td>3.6% [-2.7%, 9.9%]</td>
</tr>
</tbody>
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## Baseline Demographics

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<tr>
<td>SYNTAX Score</td>
<td>22.8±8.7</td>
<td>20.3±6.4</td>
<td>-2.5 [-3.6, -1.5]</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>9.5%</td>
<td>7.7%</td>
<td>-1.8% [-5.9%, 2.3%]</td>
</tr>
<tr>
<td>COPD</td>
<td>12.7%</td>
<td>10.8%</td>
<td>-1.9% [-6.5%, 2.8%]</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>74.4%</td>
<td>77.1%</td>
<td>2.8% [-3.4%, 9.0%]</td>
</tr>
<tr>
<td>Creatinine Clearance (ml/min)</td>
<td>77.6±15.3</td>
<td>75.0±16.6</td>
<td>-2.7 [-5.0, -0.3]</td>
</tr>
<tr>
<td>Clinical Presentation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silent Ischemia</td>
<td>7.9%</td>
<td>5.3%</td>
<td>-2.6% [-6.2%, 1.0%]</td>
</tr>
<tr>
<td>Stable angina</td>
<td>61.6%</td>
<td>68.4%</td>
<td>6.9% [-0.0%, 13.7%]</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>25.1%</td>
<td>25.8%</td>
<td>0.7% [-5.6%, 7.0%]</td>
</tr>
<tr>
<td>No angina</td>
<td>5.4%</td>
<td>0.4%</td>
<td>-5.0% [-7.5%, -2.4%]</td>
</tr>
<tr>
<td>Ejection Fraction (%)</td>
<td>49.1±3.1</td>
<td>49.2±3.3</td>
<td>0.0 [-0.4, 0.5]</td>
</tr>
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## Procedural Characteristics

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<tr>
<td>N of Lesions (Anatomical Syntax score)</td>
<td>4.3±1.3</td>
<td>4.2±1.2</td>
<td>-0.2 [-0.34, 0.02]</td>
</tr>
<tr>
<td>N of Lesions intended to be treated</td>
<td>3.7±1.7</td>
<td>3.5±1.0</td>
<td>-0.2 [-0.5, 0.1]</td>
</tr>
<tr>
<td>iFR/FFR pre-procedure / per patient</td>
<td>NA</td>
<td>96.2%</td>
<td></td>
</tr>
<tr>
<td>iFR/FFR pre-procedure / per lesion</td>
<td>NA</td>
<td>75.8%</td>
<td></td>
</tr>
<tr>
<td>N of Treated Lesions</td>
<td>3.2±1.5</td>
<td>2.6±1.0</td>
<td><strong>-0.6 [-0.9, -0.4]</strong></td>
</tr>
<tr>
<td>Mean N of stents per patient</td>
<td>4.0±2.0</td>
<td>3.8±2.0</td>
<td>-0.2 [-0.5, 0.1]</td>
</tr>
<tr>
<td>Mean stent length (mm)</td>
<td>18.8±7.0</td>
<td>24.4±9.2</td>
<td><strong>5.6 [5.0, 6.2]</strong></td>
</tr>
<tr>
<td>Total stent length (mm)</td>
<td>74.9±41.9</td>
<td>92.9±53.9</td>
<td><strong>18.0 [10.8, 25.2]</strong></td>
</tr>
<tr>
<td>IVUS post performed / per patient</td>
<td>NA</td>
<td>96.6%</td>
<td></td>
</tr>
<tr>
<td>IVUS post performed / per lesion</td>
<td>NA</td>
<td>69.6%</td>
<td></td>
</tr>
</tbody>
</table>
Anatomic Target lesions (n=1556) (3.5 lesions/patient)
- SYNTAX score revised by the operator (As described in the eCRF)

- iFR performed
  - (n=1149; 74%)
    - <0.86
      - (n=602, 52%)
        - FFR performed
          - (n=16, 3%)
            - ≤0.80
              - (n=12)
                - Treated
                  - (n=599)
                    - 99.5%
            - >0.80
              - (n=4)
        - >0.86
          - (n=264, 23%)
            - FFR performed
              - (n=252, 95%)
                - ≤0.80
                  - (n=164)
                    - 65%
                  - Treated
                    - (n=178)
                      - 67%
                - >0.80
                  - (n=88)
                    - 35%
          - >0.93
            - (n=283, 25%)
              - FFR performed
                - (n=42, 15%)
                  - ≤0.80
                    - (n=20)
                      - Treated
                        - (n=178)
                          - 67%
                  - >0.80
                    - (n=22)
                      - Treated
                        - (n=25)
                          - 9%
73% (n=839) of lesions assessed without adenosine
Anatomic lesions intended to be treated before functional assessment
n=1553 lesions – 3.5 lesions/patient

Treated lesions (n=1169)
- iFR/FFR negative (n=351)
- Failed/Not attempted CTO (n=16)
- Diffuse disease/small vessel (n=8)
- Failed PCI (non-CTO) (n=4)
- Other (n=5)

75%
23%
1%
1%

Treated lesions (n=1169 lesions) – (2.6 lesions/patient)
Conclusions

• In comparison with the SYNTAX trial, in the SYNTAX II trial we observed:
  – Less lesions treated as a result of functional assessment
  – Longer stents used (availability of 38 mm SYNERGY™)
  – More stents per lesion
  – More complete revascularisation

• Staged PCI procedures were frequently used
Conclusion (2)

• iFR/FFR and IVUS guided PCI for multivessel coronary disease with SYNERGY™ stent (**SYNTAX II strategy**) results in lower MI and stent thrombosis rates at 30 days when compared to the historic control of the SYNTAX trial

• The primary endpoint of MACCE at 1 year will provide a better understanding of the benefit of the **SYNTAX II strategy**  
  – European Cardiac Society 2017