The SYNTAX II strategy - Importance of imaging and physiological assessment in a multivessel disease case

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Hospital Clínico San Carlos, Madrid
• Speaker at educational events: Abbott and Boston Scientific
Myocardial revascularisation in stable triple vessel disease: ESC Guidelines

<table>
<thead>
<tr>
<th>Extent of CAD</th>
<th>CABG</th>
<th>PCI</th>
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<tbody>
<tr>
<td>3VD with a SYNTAX Score ≤22</td>
<td>I A I B</td>
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<tr>
<td>3VD with a SYNTAX Score 23-32</td>
<td>I A III B</td>
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<tr>
<td>3VD with a SYNTAX Score &gt;32</td>
<td>I A III B</td>
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Recommendations largely influenced by the results of SYNTAX I trial.

Major changes in PCI technique since SYNTAX I.

The impact of these changes on PCI outcomes was addressed by the SYNTAX II trial.
The SYNTAX II strategy

- Higher success rates in CTO PCI
- IVUS optimisation and guidance

Heart Team discussion

State-of-art PCI

New generation DES (Synergy)

Better risk stratification (SYNTAX II score)

Physiology based revascularisation (iFR/FFR)

Study flowchart: PCI procedure

Patient included in the SYNTAX II study

iFR in all intended to treat stenoses

- iFR < 0.86
  - FFR ≤ 0.80: Stenosis treated with SYNERGY™ EES
  - IVUS optimization

- iFR 0.86 – 0.93
  - FFR

- iFR > 0.93
  - FFR > 0.80: Stenosis not treated

Optimal medical therapy with strict LDL control (≤ 1.8mmol/L)
Syntax II strategy. A case example from clinical practice

- 72 yo woman, Type 2 DM (AOD), HT, dyslipidemia.
- Progressive angina
- ECG: SR, LBBB
- Echo: LVEF 60%, no regional motion abnormalities
- AngioCT: high Calcium score
- Angiogram: 2 vessel disease.

Syntax score I: 9 points
Syntax score II: PCI 35.0, CABG 26.4 (equipoise PCI/CABG)
RCA evaluation
Findings with physiology and IVUS evaluation

- Functionally non-significant proximal RCA stenosis

- Ischemia-generating stenosis in LAD with a focal FFR pullback pattern

- Calcific LAD stenosis with a distal ring of calcium and positive vessel remodeling in the proximal region

- LAD dimensions at stent landing zones: 2.8 and 3.5 (prox) mm.
In patients with 3VD the **use of the SYNTAX-II strategy was associated with improved clinical outcomes** at one and 2 years, compared to matched patients treated percutaneously in the original SYNTAX-I trial.
Session comprising selected EuroPCR 2018 Late-Breaking Trial submissions

- **WEDNESDAY 23 MAY 2018**
- **10:30 -12:00**
- **ROOM MAILLOT / LEVEL 2**
- **FOCUS ON INNOVATION**

**SESSION FORMAT:** HOT LINE / LATE-BREAKING TRIALS

11:49

**SYNTAX II:** Two-year clinical outcomes of the study using state-of-the-art percutaneous coronary revascularisation in patients with de novo three-vessel disease

*P.W. Serruys*
Components of the SYNTAX II strategy

- Syntax II score: **clinical and anatomical** variables to guide revascularization decision
- **Physiology**-based revascularization
- Second generation DES (**Synergy™** stent)
- **IVUS-guided optimization** of stent deployment

Impact of intracoronary physiology on PCI

Lesion treatment after iFR/FFR interrogation (n=1177)
- PCI deferred: 31%
- PCI performed: 69%

Lesions treated per patient (n) in SYNTAX II and SYNTAX I
- SYNTAX II: 2.64
- SYNTAX I: 4.02
  - P < 0.001

Cases of three-vessel PCI (%) in SYNTAX II and SYNTAX I
- SYNTAX II: 37.2%
- SYNTAX I: 83.3%
  - P < 0.001
Components of the SYNTAX II strategy

Syntax II score: **clinical and anatomical** variables to guide revascularization decision

**Physiology**-based revascularization

Second generation DES (**Synergy™ stent**)

**IVUS-guided optimization** of stent deployment

Thin strut platinum chromium platform
- 74μm (0.0029in) strut thickness
Visibility
Strength
Flexibility
Conformability
Recoil

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

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

SYNERGY Stent Technology Design
Components of the SYNTAX II strategy

Syntax II score: **clinical and anatomical** variables to guide revascularization decision

**Physiology**-based revascularization

Second generation DES (thin strut, biodegradable polymer, everolimus-eluting **Synergy™ stent**)  

**IVUS-guided optimization** of stent deployment
Post-implantation IVUS led to further optimisation of the stented lesion in 30.2%.

Use of intravascular ultrasound (IVUS)

**SYNTAX II**

**Patient level**
- IVUS: 84.1%
- No IVUS: 15.9%

**Lesion level**
- IVUS: 76.4%
- No IVUS: 23.6%

**IVUS use in SYNTAX II and SYNTAX I (patient level, % of cases)**

- **SYNTAX II**: 84.1%
- **SYNTAX I**: 4.8%

*p* < 0.0001
• The Syntax II strategy incorporates technical and procedural developments in PCI with the objective of improving outcomes in patients with multivessel disease

• Physiological evaluation in multivessel disease can identify lesions that do not have functional impact reducing the number of lesions that need to be treated

• Treating only lesions with functional impact using a last generation DES (Synergy) implanted with IVUS optimization has demonstrated improved outcomes in patients with multivessel disease
Thank you!
All-cause death

HR 0.69 (95% CI 0.27-1.73), p=0.43
Myocardial infarction

HR 0.27 (95% CI 0.11-0.70), p=0.007
Stroke

HR 0.69 (95% CI 0.10-4.89), p=0.71
Any repeat revascularisation

HR 0.57 (95% CI 0.37-0.90), p=0.015

SYNTAX I PCI: 315 305 299 295 288 284 279 274 272 266 263 262 261

SYNTAX II: 450 442 438 435 433 430 427 423 419 415 414 411 409
Definite stent thrombosis

HR 0.26 (95% CI 0.0.7-0.97), p=0.045

Patients (%)
Any repeat revascularization

HR 0.62 (95% CI 0.41-0.94), p=0.022

HR 0.57 (95% CI 0.37-0.89), p=0.014
All-cause death

HR 0.48 (95% CI 0.23-1.02), p=0.055

HR 0.69 (95% CI 0.27-1.73), p=0.42

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<th>Number at risk</th>
<th>SYNTAX I PCI</th>
<th>SYNTAX II PCI</th>
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<td>315</td>
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Myocardial infarction

According to SYNTAX I definition

HR 0.34 (95% CI 0.15-0.76), p=0.008

HR 0.32 (95% CI 0.13-0.78), p=0.012

Number at risk
SYNTAX I PCI
315 299 296 292 291 291 285 281
SYNTAX II PCI
454 448 444 440 432 431 427 383
Definite stent thrombosis

HR 0.30 (95% CI 0.09-0.99), p=0.048

HR 0.26 (95% CI 0.07-0.97), p=0.045

Number at risk
SYNTAX I PCI
315 304 300 296 295 294 289 285
SYNTAX II PCI
454 448 444 441 435 434 430 386
In patients with 3VD the use of the SYNTAX-II strategy was associated with improved clinical outcomes at one and 2 years, compared to matched patients treated percutaneously in the original SYNTAX-I trial.