ESC CONGRESS HIGHLIGHTS

INTERVENTIONAL CARDIOLOGY

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Conflicts of Interest
None to declare regarding the contents of this presentation
Antithrombotic treatment

- Prolonged DAPT (OPTIDUAL)
- Bivalirudin (MATRIX)
Follow-up (every 6 months between 12 and 48 months)

OPTIDUAL

Randomization of patients free of MACCE or bleeding

End of the study

0

12 months

48 months

DES insertion

ASPIRIN + CLOPIDOGREL

ASPIRIN ALONE

PCI w/ ≥1 DES for Stable CAD or ACS

1,385 Pts, 58 French sites

Early termination (resources/enrolment) → 1385 patients in ITT analysis instead of 1966 patients for 80% power to detect an ARR of 3% in the primary outcome

G. HELFT (Paris, FR), FP 3159
Primary MACCE Endpoint
Death, MI, stroke, and major bleeding

Extended-DAPT group
Aspirin group

HR 0.75, 95% CI 0.50-1.28 P=0.17

Mortality was 2.3% w/ extended-DAPT and 3.5% w/ aspirin (P=0.18)
Post-hoc outcome composite rate of death, MI or stroke was 4.2% w/ extended-DAPT and 6.4% w/ aspirin (HR 0.64, 95%CI 0.40–1.02, P=0.06)

Major Bleeding

HR 0.98, CI 0.47-2.05 P=0.95

G. HELFT (Paris, FR), FP 3159
MATRIX PROGRAM

What’s the most effective antithrombotic regimen for preventing ischemic complications while limiting bleeding risk in invasively managed ACS Pts?

NSTEACS or STEMI with planned PCI (n=8,404)
Aspirin+P2Y12 blocker

- Trans-Radial Access
  - Bivalirudin Mono-Tx
    - Stop Infusion
    - Prolong ≥4 hs infusion
  - Heparin ±discretional GPI
    - ACC 2015, oral presentation
    - Treatment Duration N=3610

- Trans-Femoral Access
  - Lancet. 2015; 385(9986):2465-76
  - MATRIX Antithrombin N=7,213
  - Stop Infusion
  - Prolong ≥4 hs infusion

New England Journal of Medicine online
Primary MACE Endpoint
All-cause death, MI, stroke

- Biv was associated with a less death from any cause (1.7% vs. 2.3%; \( P = 0.04 \)) (50% explained by less fatal bleeding) as well as less death from cardiac causes (1.5% vs. 2.2%; \( P = 0.03 \))
- Definite ST rate was higher w/ Biv (1.0% vs. 0.6%; \( P = 0.048 \)), but definite or probable ST rates did not differ significantly
- Major bleeding rate was lower w/ Biv (1.4% vs. 2.5%; \( P < 0.001 \))

• Similar rates for definite ST, but higher rate of subacute definite ST with post-PCI Biv
CONTENT

- **Antithrombotic treatment**
  - Prolonged DAPT (OPTIDUAL)
  - Bivalirudin (MATRIX)

- **BVS/DES**
  - BVS vs. EES (ABSORB TROFI II, ABSORB JAPAN)
  - Long-term results of EES vs. BMS in STEMI (EXAMINATION)
  - First vs. second generation DES (Meta-analysis)
Comparison of the ABSORB™ Everolimus Eluting Bioresorbable Vascular Scaffold System With a Everolimus-Eluting Metal Stent (Xience™) in STEMI <24hrs

N= 191
DAPT ≥ 1 y

Thrombectomy +/- predilatation

Sizing Dmax

+/- postdilatation/thrombectomy

Primary endpoint (non-inferiority):
Healing score at 6 months according to OFDI
ABSORB STEMI TROFI II

Arterial healing response of the two technologies was assessed by optical frequency domain imaging (OFDI)

Healing score = [% ILD x 4] + [% MU x 3] + [% U x 2] + [% M]

**ILD**: intraluminal defect  
**MU**: malapposed and uncovered  
**U**: uncovered  
**M**: malapposed

and their weighting points in the formula

<table>
<thead>
<tr>
<th>Xience metallic stent</th>
<th>Absorb bioresorbable scaffold</th>
<th>Xience metallic stent</th>
<th>Absorb bioresorbable scaffold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraluminal defect: 4 points</td>
<td>Malapposed (covered): 1 points</td>
<td>Uncovered (apposed): 2 points</td>
<td>Malapposed and uncovered: 3 points</td>
</tr>
</tbody>
</table>

*P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998*
ABSORB STEMI TROFI II

Absorb: Healing Score 0

Pre  Post  6M

Xience: Healing Score 12.2

Pre  Post  6M

P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998
ABSORB STEMI TROFI II

Cumulative curve of arterial healing score

- **Absorb** 1.74±2.39  \( (N = 84) \)
- **EES** 2.80±4.44  \( (N = 87) \)

- **P** non-inferiority < 0.001
- **P** superiority = 0.053

• Scaffolding culprit lesions w/ Absorb in STEMI resulted in nearly complete arterial healing (comparable to that of metallic EES at 6 months)
• Malapposed, and both malapposed and uncovered struts were less often in the Absorb arm

P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998
• BVS provide antiproliferative drug-eluting capability without the chronic limitations of permanent metallic implants
• This may translate into long-term benefits, by mitigating the risk of very late (>1 year) adverse events reported after metallic drug-eluting stent (DES) implantation, namely, very late stent thrombosis and restenosis

• Even if so, it is important to ensure at least comparable short- and mid-term (i.e. 1-year) safety and efficacy profiles
• Two moderate-sized randomized controlled trials compared Absorb BVSs with newer generation metallic DESs and have suggested comparable 9-month angiographic and 1-year clinical results
• ABSORB JAPAN was designed to support regulatory approval of the ABSORB BVS in Japan
Primary Clinical Endpoint:
Target Lesion Failure (TLF):
Cardiac death, TV-MI, ID-TLR at 12 months

Major Secondary Angiographic Endpoint:
In-segment Late Lumen Loss at 13 months

Inclusion:
- Patients with up to 2 de novo target lesions in separate native coronary arteries
- Lesion length ≤ 24 mm, Dmax ≥ 2.5 mm to ≤ 3.75 mm, %DS ≥50% to <100%

Exclusion:
- AMI, EF <30%, eGFR <30 mL/min/1.73m², LMCA, Ostial lesion, Excessive vessel tortuosity, Heavy calcification, Myocardial bridge, Bifurcation with side branch ≥2 mm

N=400

BVS
Tx. with single study device
Diameter: 2.5, 3.0, 3.5 mm
Length: 8, 12, 18, 28 mm

CoCr-EES
Tx. with single study device
Diameter: 2.5, 3.0, 3.5 mm
Length: 8, 12, 18, 28 mm
Primary Endpoint

12-Month TLF

- BVS: 4.2%
- CoCr-EES: 3.8%

Non-inferiority P < 0.0001

P = 0.85

Major Secondary Angiographic Endpoint:

13-Month In-segment LLL

- BVS: 0.13 mm
- CoCr-EES: 0.12 mm

Non-inferiority P < 0.0001

P = 0.74

• Safety measures with BVS, including the rates of death, MI (all and peri-procedural), and ST, occurred with similar frequency as with CoCr-EES
Randomised controlled trial comparing the performance of EES versus BMS in an all-comer STEMI population (n=1498)

**Composite primary endpoint** (patient-oriented):
- all-cause death, any recurrent MI and any revascularization

Definite/probable ST 2.0% EES vs. 3.1% BMS p = 0.17
NEW-GENERATION VS. EARLY-GENERATION DES: POOLED DATA OF 4 RCT, 2-YEAR FOLLOW-UP

**Cdeath, MI, TLR**

Adjusted HR 0.75 (0.63-0.89), P=0.001

New-DES 10.4%, Early-DES 13.2%

**Target-Lesion Revasc**

Adjusted HR 0.56 (0.44-0.70), P<0.001

New-DES 5.0%, Early-DES 8.6%

**Definite ST**

Adjusted HR 0.40 (0.25-0.65), P<0.001

New-DES 0.9%, Early-DES 2.5%

New-DES (n =4,554), Early-DES (n =1,527).
Follow-up available in 97.2% of patients at 2-year

HR Adjusted for age, diabetes, renal failure, previous myocardial infarction
No significant interaction between the type of DES and the SYNTAX score

R. PICCOLO (Bern, CH), FP 362
### STRATIFIED ANALYSIS OF CLINICAL ENDPOINTS

<table>
<thead>
<tr>
<th></th>
<th>New-DES</th>
<th>Early-DES</th>
<th>Adj HR (95% CI)</th>
<th>p</th>
<th>Pinteraction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Endpoint</strong></td>
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<tr>
<td>SYNTAX score ≤11</td>
<td>175 (8.0%)</td>
<td>71 (8.9%)</td>
<td>0.86 (0.64-1.16)</td>
<td>0.32</td>
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</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>287 (12.7%)</td>
<td>129 (17.8%)</td>
<td>0.68 (0.54-0.85)</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Cardiac death</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.042</td>
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</tr>
<tr>
<td>SYNTAX score ≤11</td>
<td>39 (1.8%)</td>
<td>10 (1.3%)</td>
<td>1.03 (0.51-2.09)</td>
<td>0.93</td>
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</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>67 (3.0%)</td>
<td>40 (5.5%)</td>
<td>0.46 (0.31-0.70)</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Any MI</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.87</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score ≤11</td>
<td>87 (4.0%)</td>
<td>28 (3.5%)</td>
<td>1.16 (0.73-1.84)</td>
<td>0.54</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>141 (6.2%)</td>
<td>41 (5.7%)</td>
<td>1.18 (0.80-1.73)</td>
<td>0.41</td>
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<tr>
<td><strong>ID-TLR</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.059</td>
<td></td>
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<tr>
<td>SYNTAX score ≤11</td>
<td>88 (4.1%)</td>
<td>45 (5.7%)</td>
<td>0.74 (0.50-1.08)</td>
<td>0.12</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>129 (5.9%)</td>
<td>84 (11.9%)</td>
<td>0.46 (0.34-0.61)</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>ID-TVR</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.039</td>
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<tr>
<td>SYNTAX score ≤11</td>
<td>110 (5.1%)</td>
<td>52 (6.6%)</td>
<td>0.81 (0.57-1.15)</td>
<td>0.23</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>167 (7.6%)</td>
<td>100 (14.1%)</td>
<td>0.51 (0.39-0.66)</td>
<td>&lt;0.001</td>
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<tr>
<td><strong>Definite ST</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.013</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score ≤11</td>
<td>20 (0.9%)</td>
<td>10 (1.3%)</td>
<td>0.94 (0.40-2.23)</td>
<td>0.89</td>
<td></td>
</tr>
<tr>
<td>SYNTAX score &gt;11</td>
<td>22 (1.0%)</td>
<td>28 (3.9%)</td>
<td>0.24 (0.13-0.44)</td>
<td>&lt;0.001</td>
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*Favours New-DES* 0.25 0.5 1 2  *Favours Early-DES*

R. PICCOLO (Bern, CH), FP 362
CONTENT

○ **Antithrombotic treatment**
  ➔ Prolonged DAPT (OPTIDUAL)
  ➔ Bivalirudin (MATRIX)

○ **BVS/DES**
  ➔ BVS vs. EES (ABSORB TROFI II, ABSORB JAPAN)
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  ➔ First vs. second generation DES (Meta-analysis)

○ **PCI**
  ➔ Long-term results of FFR-based strategy (FAME)
  ➔ Radial approach (Canada)
FAME hypothesis: FFR-guided PCI in multivessel disease is superior to angiography-guided PCI

1005 Pts undergoing (1st generation) DES-stenting for multivessel CAD (20 US + European centers)

- **Angiography-guided PCI**
  - N=496
  - Complete 5-y fu in 86.5%
  - 429 patients

- **FFR-guided PCI**
  - N=509
  - Complete 5-y fu in 85.7%
  - 436 patients

Stenting only stenoses w/ FFR ≤ 0.80

*The Lancet online*  
*N.H.J. PIJLS (Eindhoven, NL), FP 1949*
FAME – 5 Year Outcomes

Primary endpoint: composite of death, MI or repeat revascularization

Cumulative No. Of Events per 100 Patient-Yr

Follow-Up (years)

N.H.J. PIJLS (Eindhoven, NL), FP 1949
Transradial Access for PCI in British Columbia, Canada: 1999 to 2013

Cross-linkage with central transfusion registry

Unadjusted mortality and 10 day transfusion

Adjusted odds ratio of radial vs. non-radial

<table>
<thead>
<tr>
<th>Outcome</th>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>30-Day mortality</td>
<td>0.80 (0.70, 0.90)</td>
<td>0.004</td>
</tr>
<tr>
<td>10-Day RBC transfusion</td>
<td>0.49 (0.44, 0.55)</td>
<td>&lt; 0.0001</td>
</tr>
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W.T. ROBERTS (Vancouver, CA), FP P3117
**TAKE HOME MESSAGE**

- **Antithrombotic treatment**
  - No benefit/harm in prolonging DAPT (OPTIDUAL)
  - Bivalirudin infusion can be discontinued at the end of PCI (MATRIX)

- **BVS/DES**
  - Comparable and near complete arterial healing after BVS and EES for STEMI at 6 months (TROFI II)
  - Comparable LLL at 13 months in simple lesions treated with BVS and EES (ABSORB JAPAN)
  - Superiority of EES over BMS in STEMI at 5 years (EXAMINATION)
  - Superiority of second over first generation DES at 2 years

- **PCI**
  - Long-term safety of FFR-based approach (FAME)
  - Radial approach reduces bleeding and transfusions (BC registry)
Antithrombotic treatment

- The optimal duration of dual antiplatelet therapy after PCI with DES is PERSISTS one of the hottest topics in interventional cardiology.

- Bivalirudin might not be more harmful than UFH + discretional GPI, but it also does not seem to be better, even when prolonging the infusion after PCI.

- Reducing the rate of major bleeding events among ACS patients treated with PCI does not necessarily affect the risk of major ischemic adverse CV events.
BVS/DES

- Low healing scores for both the Absorb and EES are reassuring for an eventual need of antiplatelet treatment disruption or cessation before the 1-year prescription time.

- First time in STEMI since primary PCI demonstrated superiority over thrombolysis, that a device (EES stent) has shown clinical benefit beyond restenosis prevention, setting a new «gold-standard».

- Additional benefits conferred by new-generation DES can be expected in patients with high SYNTAX scores, which may have important implications in the comparative effectiveness of PCI versus CABG.