INTERVENTIONAL CARDIOLOGY
Thierry Gillebert, Ghent University, Belgium

Lecture set kindly provided by Marco Roffi, Geneva, Switzerland
CONTENT

- **Antithrombotic treatment**
  - Prolonged DAPT, bivalirudin

- **BVS/DES**
  - BVS vs. EES
  - Long-term results of EES vs. BMS in STEMI
  - First vs. second generation DES

- **PCI**
  - Long-term results of FFR-based strategy
  - Radial approach

- **Heart failure / cardiac arrest**
  - Prevention of LV remodeling post MI
  - Outcomes of out of hospital cardiac arrest
Randomization of patients free of MACCE or bleeding

DES insertion

0

12 ± 3 months

ASPIRIN + CLOPIDOGREL

ASPIRIN ALONE

12 months

ASPIRIN + CLOPIDOGREL

48 months

End of the study

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 OUTCOME: COMPOSITE OF DEATH, MI, STROKE, MAJOR BLEEDING

**Major Bleeding**

- **Extended-DAPT group**
- **Aspirin group**

**Event probability (any death)**

- **R 0.75, 95% CI 0.50-1.28**
- **P=0.17**

- **HR 0.98, CI 0.47-2.05**
- **P=0.95**

G. HELFT (Paris, FR), FP 3159
NSTEACS or STEMI with invasive management
Aspirin+P2Y12 blocker

Trans-Radial Access

Trans-Femoral Access

Bivalirudin Mono-Tx

Heparin ±GPI

Stop Infusion

Prolong ≥ 4 hs infusion

Lancet. 2015; 385(9986):2465-76

ACC 2015, oral presentation

NCT01433627

New England Journal of Medicine online

M. Valgimigli (Bern, CH) Hot Line 6004
Trans-radial versus trans-femoral access

All-cause mortality (left)

Major bleeding (right)

Lancet. 2015; 385(9986):2465-76
### Radial vs femoral meta-analysis

<table>
<thead>
<tr>
<th>Event</th>
<th>RR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-CABG major bleeds</td>
<td>0.58 (0.46–0.72)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Death, MI, or stroke</td>
<td>0.86 (0.77–0.95)</td>
<td>0.0051</td>
</tr>
<tr>
<td>Death</td>
<td>0.72 (0.60–0.88)</td>
<td>0.0011</td>
</tr>
<tr>
<td>MI</td>
<td>0.91 (0.79–1.04)</td>
<td>0.16</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.05 (0.69–1.60)</td>
<td>0.80</td>
</tr>
</tbody>
</table>

N>19 000

ESCAPR CONGRESS LONDON 2015
 MATRIX
Co-primary composite outcomes at 30 days

- N=8404
- NSTE-ACS + STEMI
- Radial vs. femoral

Valgimigli M et al.
Lancet. 2015;385:2465-76

All-cause mortality, MI, stroke

Rate ratio 0.85; 95% CI 0.74–0.99, p=0.0307

All-cause mortality, MI, stroke, or BARC 3 or 5 bleeding

Rate ratio 0.83; 95% CI 0.73–0.96, p=0.0092
PRIMARY EP: death, MI or stroke, urgent TVR, stent thrombosis and major bleeding (BARC 3 or 5)

Rate Ratio, 0.91 (95% CI, 0.74-1.11)

Cumulative Incidence (%) vs Day since Randomisation

- **No post-PCI bivalirudin**
- **Post-PCI bivalirudin**

11.9%
11.0%

New England Journal of Medicine online

M. Valgimigli (Bern, CH) Hot Line 6004
ABSORB STEMI TROFI II

N = 191
DAPT ≥ 1 y

ABSORB arm
N = 95 P

Scaffolding (ABSORB)

6M Angio + OFDI
N = 86 P/86 L

Thrombectomy
+/- predilatation

Sizing Dmax

+/- postdilatation/thrombectomy

Xience Expedition arm
N = 96 P

Stenting (Xience)

6M Angio + OFDI
N = 87 P/89 L

Primary endpoint (non-inferiority):
**Healing score at 6 months according to OFDI**

P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998
**Healing score**

\[ \text{Healing score} = [\% \text{ ILD} \times 4] + [\% \text{ MU} \times 3] + [\% \text{ U} \times 2] + [\% \text{ M}] \]

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

_P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998_
ABSORB STEMI TROFI II
CUMULATIVE CURVE OF HEALING SCORE

- Absorb $1.74 \pm 2.39$ (N = 84)
- EES $2.80 \pm 4.44$ (N = 87)

$P_{\text{non-inferiority}} < 0.001$
$P_{\text{superiority}} = 0.053$

In-device LL, mm

ABS 0.20 ± 0.31  EES 0.08 ± 0.28  P = 0.01

P.W.J.C. Serruys (Rotterdam, NL) Hot Line 5998
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, D_max ≥ 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

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

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

Sample size calculation:
- Assumed event rate of 12-month TLF in the CoCr-EES arm: 9%
- Non-inferiority margin: 8.6%, power: 90%

N=400

European Heart Journal online

T. Kimura (Kyoto, JP) Hot Line 6001
Primary Endpoint:
12-Months TLF (target lesion failure)

Major Secondary Angiographic Endpoint:
13-Month In-Segment LLL (late lumen loss)

Non-inferiority P < 0.0001

12-Month TLF

BVS: 4.2%
CoCr-EES: 3.8%
P = 0.85

13-Month In-segment LLL

BVS: 0.13 mm
CoCr-EES: 0.12 mm
P = 0.74

European Heart Journal online

T. Kimura (Kyoto, JP) Hot Line 6001
NEW-GENERATION VS. EARLY-GENERATION DES: POOLED DATA OF 4 RCT, 2-YEAR FOLLOW-UP

**Cdeaths, MI, TLR**

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

**Target-Lesion Revasc**

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

**Definite Stent Thrombosis**

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

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

Adjusted for age, diabetes, renal failure, previous myocardial infarction

R. PICCOLO (Bern, CH), FP 362
<table>
<thead>
<tr>
<th>Primary Endpoint</th>
<th>New-DES</th>
<th>Early-DES</th>
<th>Adj HR (95% CI)</th>
<th>p</th>
<th>p_interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac death</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>
<td></td>
</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>0.001</td>
<td></td>
</tr>
<tr>
<td>Any MI</td>
<td></td>
<td></td>
<td></td>
<td></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>ID-TLR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>
<td></td>
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<tr>
<td>ID-TVR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>
<td></td>
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</tbody>
</table>

**Definite ST**

| SYNTAX score ≤11 | 20 (0.9%) | 10 (1.3%) | 0.94 (0.40-2.23) | 0.89  |               |
| SYNTAX score >11 | 22 (1.0%) | 28 (3.9%) | 0.24 (0.13-0.44) | <0.001 |               |

**Favours New-DES**

R. PICCOLO (Bern, CH), FP 362
PATIENT-ORIENTED ENDPOINT
(5 years ALL-CAUSE DEATH, ANY MYOCARDIAL INFARCTION OR ANY REVASCULARIZATION)

Log-rank p=0.03

26.0%

21.4%

N=1498
Definite/probable ST 2.0% EES vs. 3.1% BMS p = 0.17

M. SABATE (Barcelona, ES), FP 5773
**Transradial Access for PCI in British Columbia, Canada: 1999 to 2013**

**Unadjusted mortality and 10 day transfusion**

- % Non-Radial 30d mortality
- % Radial 30d mortality
- % Non-Radial 30d transfusion
- % Radial 30d transfusion

June 1999-May 2013
N= 83,659

**Adjusted odds ratio of radial vs. non-radial**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>OR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<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>
</tbody>
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W.T. ROBERTS (Vancouver, CA), FP P3117
5 YEAR FOLLOW-UP

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

N=1005
N.H.J. PIJLS (Eindhoven, NL), FP 1949
FAME STUDY: CUMULATIVE EVENTS DURING 5-YEAR FOLLOW-UP

The Lancet online
N.H.J. PIJLS (Eindhoven, NL), FP 1949
Trial hypothesis

Can the intracoronary deployment of an inert bioabsorbable cardiac matrix replace the damaged extracellular matrix and provide a temporary physical support during infarct healing and repair and prevent remodeling?

Deployment procedure

Intracoronary injection of 4 mL BCM or saline control (sham procedure) in a second procedure 2–5 days after primary PCI.
PRIMARY ENDPOINT: CHANGE IN LV END DIASTOLIC VOLUME INDEX (LVEDVI) FROM BASELINE TO 6 MONTHS

6-mo point estimate 3.8 (95% CI -0.5–8.0)

Secondary endpoints (NYHA class, functional capacity): no difference

U. Zeymer (Ludwigshafen, DE) Hot Line 6007
1-MONTH SURVIVAL AND NEUROLOGIC OUTCOMES AFTER OHCA

N = 17,238

ROSC = Return to spontaneous circulation
CPC 1-2 = favourable neurological outcomes

After 35 min of CPR no more gain

Y.GOTO (Kanazawa, JP), FP 1321
TAKE HOME MESSAGE

INTERVENTIONAL CARDIOLOGY

- **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-tarm safety of FFR-based approach (FAME)
  - Radial approach reduces bleeding and transfusions (BC registry)

- **Heart Failure / Cardiac arrest**
  - No benefit of bioabsorbable cardiac matrix injection (PRESERVATION)
  - In OHCA perform CPR for at least 35 min (Japanese registry)
INTERVENTIONAL CARDIOLOGY

M. Roffi (Geneva, CH)

Research funding (departmental or institutional):
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