GLOBAL EXPERTS, LOCAL LEARNING

MEXICO CITY
JUNE 22 - 24, 2017
June 23rd, 1:15 p.m. - 2:00 p.m.

Unanswered Questions in Coronary Artery Disease

Spencer B. King III MD MACC

Emeritus Professor of Medicine
Emory University School of Medicine
The Andreas Gruentzig Cardiovascular Center
Editor-in-Chief: JACC Cardiovascular Interventions
Unanswered Questions in Coronary Artery Disease

Does PCI Improve Survival in SIHD?
Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O’Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

Survival Free of Death from Any Cause and Myocardial Infarction

Hazard ratio, 1.05; 95% CI (0.87–1.27); P=0.62

OMT=18.5%

PCI+OMT=19.0%
Conclusion:
A strategy of routine PCI did not reduce Death or MI in SIHD patients
Fractional Flow Reserve–Guided PCI for Stable Coronary Artery Disease

Bernard De Bruyne, M.D., Ph.D., William F. Fearon, M.D., Nico H.J. Pijls, M.D., Ph.D., Emanuele Barbato, M.D., Ph.D., Pim Tonino, M.D., Ph.D., Zsolt Piroth, M.D., Nikola Jagic, M.D., Sven Mobius-Winkler, M.D., Gilles Rioufol, M.D., Ph.D., Nils Witt, M.D., Ph.D., Petr Kala, M.D., Philip MacCarthy, M.D., Thomas Engström, M.D., Keith Oldroyd, M.D., Kreton Mavromatis, M.D., Ganesh Manoharan, M.D., Peter Verlee, M.D., Ole Frobert, M.D., Nick Curzen, B.M., Ph.D., Jane B. Johnson, R.N., B.S.N., Andreas Limacher, Ph.D., Eveline Nüesch, Ph.D., and Peter Jüni, M.D., for the FAME 2 Trial Investigators*

Stable CAD patients scheduled for 1-, 2- or 3-vessel DES-PCI (N = 1220)

FFR in all target lesions

At least 1 stenosis with FFR ≤ 0.80 (n=888)

Randomization 1:1

PCI + MT

MT

When all FFR > 0.80 (n=332)

MT

Follow-up after 1 mo, 6 mo, 1, 2, 3, 4, and 5 years
Primary Outcome: 2 Year Death, MI or Urgent Revascularization

Cumulative incidence (of total revascularization) over months:
- PCI+MT vs. MT: HR 0.16 (95% CI 0.11-0.22) P<0.001
- PCI+MT vs. Registry: HR 0.66 (95% CI 0.38-1.14) P=0.13
- MT vs. Registry: HR 4.26 (95% CI 2.66-6.81) P<0.001

No. at risk:
- MT: 441, 389, 360, 337, 315, 302, 290, 277, 272, 268, 260, 254, 218
- PCI+MT: 447, 440, 434, 429, 427, 422, 417, 410, 407, 406, 402, 399, 343
- Registry: 166, 165, 162, 160, 157, 156, 153, 149, 144, 142, 141, 141, 116
**Conclusion:**

In patients with stable CAD and functionally significant stenoses, FFR-guided PCI plus the best OMT as compared to OMT alone, decreased the need for urgent revascularization.

The trial was underpowered for mortality which was <1%

<table>
<thead>
<tr>
<th>No. at risk</th>
<th>MT</th>
<th>PCI+MT</th>
<th>Registry</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>441</td>
<td>447</td>
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<tr>
<td></td>
<td>218</td>
<td>343</td>
<td>116</td>
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</tbody>
</table>
Strategies for Multivessel Revascularization in Patients with Diabetes

1900 patients with DM and MVD underwent either PCI with DES or CABG. The patients were followed for a minimum of 2 years (median among survivors, 3.8 years).

**Primary Outcome**

- P=0.005 by log-rank test
- 5-Yr event rate: 26.6% vs. 18.7%

![Graph showing survival rates over 5 years with PCI and CABG](image)
1900 patients with DM and MVD underwent either PCI with DES or CABG. The patients were followed for a minimum of 2 years (median among survivors, 3.8 years).

P = 0.049 by log-rank test
5-Yr event rate: 16.3% vs. 10.9%
1900 patients with DM and MVD underwent either PCI with DES or CABG. The patients were followed for a minimum of 2 years (median among survivors, 3.8 years).

**Conclusion:**

For patients with diabetes and advanced CAD, CABG was superior to PCI in that it significantly reduced rates of Death and MI with a higher rate of stroke.
Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

1905 patients with LM disease and SX Score < 32 underwent PCI or CABG.
1905 patients with LM disease and SX Score < 32 underwent PCI or CABG

Death from Any Cause

Hazard ratio, 1.34 (95% CI, 0.94–1.91)
P=0.11
1905 patients with LM disease and SX Score < 32 underwent PCI or CABG

Conclusion:

In patients with LM CAD and low or intermediate SX Scores PCI with EES was non-inferior to CABG with respect to the rate of the composite end point of Death, Stroke, or MI at 3 years.
Does PCI improve survival over medical therapy in SIHD?

- Average RCT outcomes will not help very much.
- Trials, large enough to drill down to many subsets are needed.
- New trials of low ischemic risk should compare PCI with OMT.
- The ongoing ISCHEMIA Trial is looking at higher risk patients with selection based on physiology (large ischemic burden on nuclear scan).
- Trials with selection based on anatomy (invasive angiography or CTA) are also needed.
Unanswered Questions in Coronary Artery Disease

-2-

Is Completeness of Revascularization Needed in SIHD?
Unanswered Questions in Coronary Artery Disease

-3-

Is Completeness of Revascularization Needed in the Clinical Setting of STEMI & MVD?
Objectives: We conducted a systematic pairwise and network meta-analysis to assess optimal treatment strategies in patients with **ST-segment elevation myocardial infarction (STEMI) and multivessel coronary artery disease (MV-CAD)** undergoing primary PCI.

Background: Patients with STEMI and MV-CAD have a worse prognosis than those with single-vessel CAD. The optimal revascularization strategy for these patients is uncertain.

32 Studies
Total N= 54,148 patients
N= 42,112 Infract Related Artery-only PCI
N= 8,138 single procedure MV-PCI
N= 3,898 staged MV-PCI
Survival After Varying Revascularization Strategies in Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Coronary Artery Disease

Giuseppe Tarantini, MD, PhD, Gianpiero D’Amico, MD, Sorin J. Brener, MD, Paola Tellaroli, MSc, PhD, Marco Basile, MD, Alessandro Schiavo, MD, Marco Mojoli, MD, Chiara Fraccaro, MD, PhD, Alfredo Marchese, MD, Giuseppe Musumeci, MD, Gregg W. Stone, MD
Infract Related Artery only PCI vs. Multivessel Single Procedure PCI

**Long-term mortality**

<table>
<thead>
<tr>
<th>Study</th>
<th>IRA–only PCI</th>
<th>Single procedure MV–PCI</th>
<th>Odds ratio (95% CI)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
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<tr>
<td>Retrospective</td>
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<td></td>
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<tr>
<td>Abe (2013)</td>
<td>24</td>
<td>220</td>
<td>17</td>
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<td>Corpus (2004)</td>
<td>42</td>
<td>354</td>
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<td>Hannan (2010)</td>
<td>14</td>
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<td>36</td>
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<tr>
<td>Iqbal (2014)</td>
<td>255</td>
<td>3429</td>
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<tr>
<td>Mohamad (2011)</td>
<td>3</td>
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<tr>
<td>Qarawani (2008)</td>
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<td>Roe (2001)</td>
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<td>Random effects model</td>
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**Prospective**

<table>
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<tr>
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<th>Single procedure MV–PCI</th>
<th>Odds ratio (95% CI)</th>
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<td>Gershlick (2015)</td>
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<td>Jeger (2014)</td>
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<td>Politi (2010)</td>
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<td>Wald (2013)</td>
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**Favors IRA-only PCI**

**Favors MV-PCI**
### Infract Related Artery only PCI vs. Staged Multivessel PCI Long-term Mortality

#### Odds ratio (95% CI)

<table>
<thead>
<tr>
<th>Study</th>
<th>IRA–only PCI</th>
<th>Staged MV–PCI</th>
<th>OR</th>
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<td>Li–Xiang (2015)</td>
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<td>Meliga (2011)</td>
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<td>Mohamad (2011)</td>
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<td>12</td>
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<td>Rigattieri (2008)</td>
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<td>Russo (2015)</td>
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<tr>
<td>Dambrink (2010)</td>
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<td>Engstrom (2015)</td>
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<td>Hlinomaz (2015)</td>
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<td>Fixed effect model</td>
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</table>

Heterogeneity: I²-squared=43.6%, tau-squared=0.16, p=0.07

Favors IRA–only PCI

Favors Staged MV–PCI
MV-PCI Single procedure vs. Staged MV-PCI

Long-term Mortality

<table>
<thead>
<tr>
<th>Study</th>
<th>Single procedure MV-PCI</th>
<th>Staged MV-PCI</th>
<th>Odds ratio (95% CI)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
</tr>
<tr>
<td>Retrospective</td>
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</tr>
<tr>
<td>Corpus (2004)</td>
<td>5</td>
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<td>Hannan (2010)</td>
<td>36</td>
<td>503</td>
<td>10</td>
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<td>Jensen (2012)</td>
<td>36</td>
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<td>Mohamad (2011)</td>
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<td>7</td>
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<tr>
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<td>Random effects model</td>
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<tr>
<td>heterogeneity: I-squared=49.5%, tau-squared=0.22, p=0.11</td>
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</tbody>
</table>

| Prospective          |        |       |        |       |       |             |
| Kornowski (2011)     | 25     | 275   | 9      | 393   | 4.27  | [1.96; 9.29] |
| Maamoun (2011)       | 2      | 42    | 1      | 36    | 1.75  | [0.15; 20.14]|
| Ochala (2004)        | 0      | 48    | 0      | 44    | 0.92  | [0.02; 47.22]|
| Politi (2010)        | 6      | 65    | 4      | 65    | 1.55  | [0.42; 5.78] |
| Fixed effect model   | 430    |       | 538    |       | 3.08  | [1.64; 5.76] |
| Random effects model |         |       |        |       | 3.04  | [1.61; 5.75] |
| heterogeneity: I-squared=0%, tau-squared=0, p=0.51 |

<table>
<thead>
<tr>
<th>Favors MV-PCI Single procedure</th>
<th>Favors Staged MV-PCI</th>
</tr>
</thead>
</table>

Interventional Cardiovascular Medicine

JACC Cardiovascular Interventions

ACC Latin America Conference 2017

Spencer B. King III
Conclusion:
In patients with MV-CAD presenting with STEMI undergoing primary PCI, a staged multivessel revascularization strategy may improve survival.
Culprit Vessel Versus Multivessel Versus In-Hospital Staged Intervention for Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Disease

Stratified Analyses in High-Risk Patient Groups and Anatomic Subsets of Nonculprit Disease

M. Bilal Iqbal, MD, PhD a,b Imad J. Nadra, MD, PhD a,b Lillian Ding, MSc c Anthony Fung, MD d Eve Aymong, MD e Albert W. Chan, MD f Steven Hodge, MD g Anthony Della Siega, MD a,b Simon D. Robinson, MD a,b on behalf of the British Columbia Cardiac Registry Investigators

METHODS We compared revascularization strategies (MVI, CVI-O, and CVI-S) in 6,503 patients with STEMI and multivessel disease enrolled in the British Columbia Cardiac Registry (2008 to 2014). We evaluated all-cause mortality and repeat revascularization at 2 years.
Culprit Vessel Versus Multivessel Versus In-Hospital Staged Intervention for Patients With ST-Segment Elevation Myocardial Infarction and Multivessel Disease

Stratified Analyses in High-Risk Patient Groups and Anatomic Subsets of Nonculprit Disease
Conclusion:
In patients with STEMI undergoing primary PCI, a strategy of CVI-S seems to be associated with lower mortality and repeat revascularization rates.
Fractional Flow Reserve–Guided Multivessel Angioplasty in Myocardial Infarction

Pieter C. Smits, M.D., Ph.D., Mohamed Abdel-Wahab, M.D., Franz-Josef Neumann, M.D., Bianca M. Boxma-de Klerk, Ph.D., Ketil Lunde, M.D., Carl E. Schotborgh, M.D., Zsolt Piroth, M.D., David Horak, M.D., Adrian Wlodarczak, M.D., Paul J. Ong, M.D., Rainer Hambrecht, M.D., Oskar Angerås, M.D., Gert Richardt, M.D., Ph.D., and Elmir Omerovic, M.D., for the Compare-Acute Investigators*
885 patients with STEMI and MVD who had undergone primary PCI of an infarct-related coronary artery were randomized to 1:2 ratio to undergo complete revascularization of a non–infarct-related coronary artery guided by FFR (295 patients) or to undergo no revascularization of non–infarct-related coronary artery (590 patients).
MACCE denotes the composite of all-cause mortality, nonfatal myocardial infarction, any revascularization, and cerebrovascular events.
Trials that randomized 2285 STEMI patients with MVD to any combination of the 4 different revascularization strategies (i.e., complete revascularization at the index procedure, staged procedure during the hospitalization, staged procedure after discharge or culprit-only revascularization) were included.
Complete or Culprit-Only Revascularization for Patients With Multivessel Coronary Artery Disease Undergoing Percutaneous Coronary Intervention

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
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<td>MACE</td>
<td>2016</td>
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<td>Hamza et al</td>
<td>2016</td>
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<tr>
<td>PRAGUE 13</td>
<td>2015</td>
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<td>DANAMI-3-PRIMULTI</td>
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<td>CvLPRIT</td>
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<td>Ghani et al</td>
<td>2012</td>
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<td>Politi et al</td>
<td>2010</td>
</tr>
<tr>
<td>HELP-AMI</td>
<td>2004</td>
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<tr>
<td>Subtotal (I-squared = 56.6%, p = 0.024)</td>
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</tbody>
</table>

Better outcome with complete revascularization
Comparison of timing of revascularization strategies

<table>
<thead>
<tr>
<th>Outcome</th>
<th>RR (95% CI)</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>MACE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete-index vs. culprit</td>
<td>0.37 (0.24, 0.59)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Staged-hospital vs. culprit</td>
<td>0.49 (0.27, 0.91)</td>
<td>0.02</td>
</tr>
<tr>
<td>Staged-after vs culprit</td>
<td>0.58 (0.35, 0.97)</td>
<td>0.04</td>
</tr>
<tr>
<td>Complete-index vs Staged-hospital</td>
<td>0.76 (0.36, 1.59)</td>
<td>0.46</td>
</tr>
<tr>
<td>Complete-index vs. Staged-after</td>
<td>0.64 (0.36, 1.15)</td>
<td>0.13</td>
</tr>
<tr>
<td>Staged-hospital vs. Staged-after</td>
<td>0.85 (0.38, 1.87)</td>
<td>0.68</td>
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<tr>
<td>Mortality</td>
<td></td>
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<tr>
<td>Complete-index vs. culprit</td>
<td>0.68 (0.39, 1.19)</td>
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<td>Staged-hospital vs. culprit</td>
<td>1.23 (0.57, 2.64)</td>
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<tr>
<td>Staged-after vs culprit</td>
<td>0.71 (0.34, 1.49)</td>
<td>0.37</td>
</tr>
<tr>
<td>Complete-index vs Staged-hospital</td>
<td>0.55 (0.22, 1.42)</td>
<td>0.22</td>
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<tr>
<td>Complete-index vs. Staged-after</td>
<td>0.96 (0.41, 2.24)</td>
<td>0.92</td>
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<tr>
<td>Staged-hospital vs. Staged-after</td>
<td>1.73 (0.59, 5.03)</td>
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<td>Revascularization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete-index vs. culprit</td>
<td>0.32 (0.19, 0.54)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Staged-hospital vs. culprit</td>
<td>0.31 (0.15, 0.65)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Staged-after vs culprit</td>
<td>0.46 (0.25, 0.85)</td>
<td>0.01</td>
</tr>
<tr>
<td>Complete-index vs Staged-hospital</td>
<td>1.01 (0.42, 2.46)</td>
<td>0.98</td>
</tr>
<tr>
<td>Complete-index vs. Staged-after</td>
<td>0.69 (0.36, 1.34)</td>
<td>0.27</td>
</tr>
<tr>
<td>Staged-hospital vs. Staged-after</td>
<td>0.68 (0.26, 1.79)</td>
<td>0.44</td>
</tr>
</tbody>
</table>
Comparison of timing of revascularization strategies

Conclusion:
None of the strategies have been shown to reduce the overall mortality. In the absence of other evidence decisions must be highly individualized.
Comparison of timing of revascularization strategies

Factors influencing decisions in approaching STEMI patients:

1. Severity and importance of the non-culprit lesion
2. Time of presentation, regular vs. off hours
3. Expertise of operator and team
Is culprit vessel primary PCI inferior to MVD primary PCI?

- Future trials should have the vessels stratified by the non culprit vessel. (Is the vessel left unrevascularized the LAD?)
- Current studies are inconclusive.
- Future studies should aim at establishing which scenarios are unsafe for leaving non culprit vessels unrevascularized.
Unanswered Questions in Coronary Artery Disease -4- CTO: Who needs Revascularization?
834 patients randomized from 2010.3.22 to 2016.10.10

19 withdrew consents

398 allocated to OMT
- 310 treated with OMT
- 72 treated with PCI: 72
- 5 treated with OMT after failed PCI
- 11 had incomplete data

1-year FU
- 348/357 (97.5%)

3-year FU
- 215/231 (93.1%)

5-year FU
- 87/99 (87.9%)

417 allocated to PCI
- 346 treated with PCI
- 29 treated with OMT
- 36 treated with OMT after failed PCI
- 6 had incomplete data

1-year FU
- 344/354 (97.2%)

3-year FU
- 218/238 (91.6%)

5-year FU
- 85/102 (83.3%)
DECISION-CTO
Primary Endpoint: Death, MI, Stroke, Any Revasc

Crude HR 0.95 (95% CI, 0.74-1.22), P=0.67
Adjusted HR 0.91 (95% CI, 0.68-1.23), P=0.54

ACC 2017,
Seung-Jung Park
DECISION-CTO: Death

Crude HR 1.50 (95% CI, 0.75-3.03), P=0.25

ACC 2017, Seung-Jung Park
DECISION-CTO
Primary Endpoint: Any Revasc

OMT as an initial strategy was non-inferior to PCI with respect to the primary endpoint of the composite of Death, MI, Stroke, or any Revascularization at 3 years.

Crude HR 0.81 (95% CI, 0.52-1.28), P=0.38

ACC 2017, Seung-Jung Park
A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions

EURO-CTO
A Randomized Multicentre Trial to Evaluate the Utilization of Revascularization or Optimal Medical Therapy for the Treatment of Chronic Total Coronary Occlusions

Multivessel CAD including CTO

Treat non-occlusive disease by PCI before CTO with DES

Angina or angina-equivalent symptoms

Single-vessel disease CTO only

Randomisation 2:1

PCI with DES + OMT
n=300

OMT
n=150

Success

Failure

Decision as per usual clinical care

Medical Rx

Clinically indicated interim PCI

CABG

Ongoing angina despite OMT*

Repeat Exercise Tolerance Test (ETT) for objective assessment of ischemia @ 12m and 36months

OMT to include:
- Aspirin,
- Statin,
- ACE-inhibitor where tolerated
- + up to 2 anti-anginal agents at max tolerated dose including rate-limiting agent where appropriate. Ischaemic symptoms should be confirmed with non-invasive test.
MACCE at 12 months was similar between the PCI and OMT arms (5.2% vs 6.7%; \( P = 0.52 \)) and included two non-CTO-related deaths, five MIs, and one stent thrombosis event in the PCI cohort.

The study showed significant improvement in angina frequency with CTO PCI over OMT \( (P = 0.009) \) as well as greater improvements in Canadian Cardiovascular Society angina scores with PCI over OMT \( (P < 0.001) \).
Long-Term Follow-Up of Elective Chronic Total Coronary Occlusion Angioplasty

Analysis From the U.K. Central Cardiac Audit Database

Sudhakar George, MD,* James Cockburn, MD,* Tim C. Clayton, MSc† Peter Ludman, MD,‡ James Cotton, MD,§
James Spratt, MA,‖ Simon Redwood, MD,# Mark de Belder, MD,¶ Adam de Belder, MD,* Jonathan Hill, MA,**
Angela Hoye, MBCnB, PhD,†† Nick Palmer, MD,†† Sudhir Rathore, MD,§§ Anthony Gershlick, MB BS,|||
Carlo Di Mario, MD, PhD,## David Hildick-Smith, MD,* on behalf of the British Cardiovascular Intervention Society
and the National Institute for Cardiovascular Outcomes Research

Adjusted hazard ratio: 0.72; 95% confidence interval: 0.62 to 0.83; p < 0.001.)
Successful Recanalization of Native Coronary Chronic Total Occlusion Is Not Associated With Improved Long-Term Survival

Pil Hyung Lee, MD, Seung-Whan Lee, MD, PhD, Hee-Soon Park, MD, Se Hun Kang, MD, Byeong Joo Bae, MD, Mineok Chang, MD, Jae-Hyung Roh, MD, Sung-Han Yoon, MD, Jung-Min Ahn, MD, Duk-Woo Park, MD, PhD, Soo-Jin Kang, MD, PhD, Young-Hak Kim, MD, PhD, Cheol Whan Lee, MD, PhD, Seong-Wook Park, MD, PhD, Seung-Jung Park, MD, PhD
Do CTO interventions save lives?

- Requires randomized controlled trials
- Observational studies can not avoid bias
- Trials should be large enough to allow subset analysis of:
  1. Isolated CTO
  2. CTO as part of multivessel revascularization
  3. CTO of LAD or other vessels
Unanswered Questions in Coronary Artery Disease

-5-

BRS: Where are we?
Five-Year Optical Coherence Tomography Follow-Up of an Everolimus-Eluting Bioresorbable Vascular Scaffold Changing the Paradigm of Coronary Stenting?

Antonios Karanasos, MD; Cihan Simsek, MD; Patrick Serruys, MD, PhD; Jurgen Ligthart, BSc; Karen Witberg, CCRN; Robert-Jan van Geuns, MD, PhD; George Sianos, MD, PhD; Felix Zijlstra, MD, PhD; Evelyn Regar, MD, PhD

(Circulation. 2012;126:e89-e91.)
Bioresorbable Scaffolds versus Metallic Stents in Routine PCI

Joanna J. Wykrzykowska, M.D., Ph.D., Robin P. Kraak, M.D., Sjoerd H. Hofma, M.D., Ph.D., Rene J. van der Schaaf, M.D., Ph.D., E. Karin Arkenbout, M.D., Ph.D., Alexander J. Ijsselmuiden, M.D., Ph.D., Joëlle Elias, M.D., Ivo M. van Dongen, M.D., Ruben Y.G. Tijssen, M.D., Karel T. Koch, M.D., Ph.D., Jan Baan, Jr., M.D., Ph.D., M. Marije Vis, M.D., Ph.D., Robbert J. de Winter, M.D., Ph.D., Jan J. Piek, M.D., Ph.D., Jan G.P. Tijssen, Ph.D., and Jose P.S. Henriques, M.D., Ph.D., for the AIDA Investigators*
Bioresorbable Scaffolds versus Metallic Stents in Routine PCI

1845 patients undergoing PCI: BVS (n=924) or a metallic Xience stent (n=921)
The primary end point was TVF (a composite of cardiac death, MI, or TVL).
All comers: ACS (STEMI-NSTEMI), SAP

2Y: 11.7% vs 10.7%,
Hazard ratio, 1.12 (95% CI, 0.85–1.48)
P=0.43
1845 patients undergoing PCI: BVS (n=924) or a metallic Xience stent (n=921)
The primary end point was TVF (a composite of cardiac death, MI, or TVL).
All comers: ACS (STEMI-NSTEMI), SAP

2Y: 3.5% (31) vs. 0.9% (8)
Hazard ratio, 5.39 (95% CI, 2.08–14.00)
P<0.001

2008 patients with stable or unstable angina were randomly assigned in a 2:1 ratio to receive an Absorb BVS (1322 patients) or an XV stent (686 patients).

The primary end point, which was tested for both non-inferiority and superiority, was **TLF at 1 year**.
Target Lesion Failure @ 1Y:
7.8% of patients in the Absorb group and in 6.1% of patients in the Xience group

Hazard ratio, 1.30 (95% CI, 0.91–1.87)
P = 0.15

No. at Risk
Absorb 1322 1254 1230 1218 1205
Xience 686 661 651 643 638
Device thrombosis within 1y occurred in 1.5% of patients in the Absorb group and in 0.7% of patients in the Xience group (p=0.13)

All RVD ≥2.25 mm
(N=1623)

ST: 1.5 vs. 0.7%, p=0.13
Device thrombosis within 1y occurred in 1.5% of patients in the Absorb group and in 0.7% of patients in the Xience group (p=0.13).
Device thrombosis within 1y occurred in 1.5% of patients in the Absorb group and in 0.7% of patients in the Xience group (P=0.13).

In this large-scale, randomized trial, treatment of noncomplex obstructive coronary artery disease with an everolimus-eluting bioresorbable vascular scaffold, as compared with an everolimus-eluting cobalt–chromium stent, was within the prespecified margin for non-inferiority with respect to TLF @ 1 year.

FAD IFU: If RVD < 2.5-mm - DO NOT IMPLANT ABSORB
**ABSORB III: TLF by 2 Years**

**QCA RVD > 2.25 mm**

- HR [95%CI] = 1.35 [0.93, 1.96]
- p = 0.12

- Absorb BVS (N=1074)
- Xience CoCr-EES (N=541)

**Overall**

- HR [95%CI] = 1.42 [1.04, 1.94]
- p = 0.03

- Absorb BVS (N=1322)
- Xience CoCr-EES (N=686)

TCT 2016: Stephen G. Ellis, MD, Dean J. Kereiakes, MD, & Gregg W. Stone, MD for the ABSORB III Investigators

Spencer B. King III
## ABSORB III: Clinical Endpoints by 2 Years

<table>
<thead>
<tr>
<th>Event</th>
<th>Overall</th>
<th>QCA RVD ≥ 2.25mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absorb (N=1322)</td>
<td>XIENCE (N=686)</td>
</tr>
<tr>
<td>TLF</td>
<td>11.0% (143)*</td>
<td>7.9% (53)*</td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>1.1% (14)</td>
<td>0.6% (4)</td>
</tr>
<tr>
<td>TV-MI</td>
<td>7.3% (95)**</td>
<td>4.9% (33)**</td>
</tr>
<tr>
<td>ID-TLR</td>
<td>5.3% (69)</td>
<td>4.3% (29)</td>
</tr>
<tr>
<td>ST (Def/Prob)</td>
<td>1.9% (24)</td>
<td>0.8% (5)</td>
</tr>
</tbody>
</table>
**Letter to Healthcare providers:**

FDA Investigating Increased Rate of Major Adverse Cardiac Events Observed in Patients Receiving Abbott Vascular’s Absorb GT1 Bioresorbable Vascular Scaffold (BVS)

<table>
<thead>
<tr>
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<th>Overall</th>
<th>QCA RVD ≥ 2.25mm</th>
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<td>1.9% (24)</td>
<td>0.8% (5)</td>
</tr>
</tbody>
</table>
The rates of clinical events, including TLF, cardiac death, TV-MI, ID-TLR, and device thrombosis were generally low and comparable between Absorb BVS and XIENCE V through 2 years.
Scaffold Thrombosis @ 1, 2 & 3 Years
based on PSP Implementation in the ABSORB Trials

- AB II
- AB III
- AB Extend
- AB Japan
- AB China

Non-PSP: 3.4%

PSP: 0.7%

Time Post Index Procedure (Days)

Log-rank p = 0.13
(PSP vs Non-PSP)

n=2973


Spencer B. King III
The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months.
The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months.
The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months.
The ISAR Absorb Registry enrolled 419 consecutive patients undergoing BRS implantation in routine clinical practice. Angiographic follow-up was scheduled after 6-8 months and clinical follow-up to 24 months.

**Conclusion:**
Long-term follow-up of patients treated with BRS in routine practice showed higher event rates than expected.
What needs to be done to establish the value of Bioresorbable scaffolds?

Preclinical technological improvements to achieve

- improved strut profile
- low thrombogenicity
- good biocompatibility

need to precede any further large clinical trials
Unanswered Questions in Coronary Artery Disease

What is the role of Percutaneous Assist Devices in Cardiogenic Shock?
Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*

600 patients with cardiogenic shock complicating acute myocardial infarction to IABP (n=301 patients) or no intraaortic balloon counterpulsation (control group, n=299 patients).
Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

- Days since Randomization
- Mortality (%)
- Control
- IABP

P = 0.92 by log-rank test
Conclusion:

The use of IABP did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned.
A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

Tamara M. Atkinson, MD, E. Magnus Ohman, MD, William W. O’Neill, MD, Tanveer Rab, MD, Joaquin E. Cigarroa, MD, on behalf of the Interventional Scientific Council of the American College of Cardiology

<table>
<thead>
<tr>
<th></th>
<th>IABP</th>
<th>IMPELLA</th>
<th>TANDEMHEART</th>
<th>VA-ECMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Flow</td>
<td>0.3-0.5 L/ min</td>
<td>1-5 L/ min (Impella 2.5, Impella CP, Impella 5)</td>
<td>2.5-5 L/ min</td>
<td>3-7 L/min</td>
</tr>
<tr>
<td>Mechanism</td>
<td>Aorta</td>
<td>LV → AO</td>
<td>LA → AO</td>
<td>RA → AO</td>
</tr>
<tr>
<td>Maximum implant days</td>
<td>Weeks</td>
<td>7 days</td>
<td>14 days</td>
<td>Weeks</td>
</tr>
<tr>
<td>Sheath size</td>
<td>7-8 Fr</td>
<td>13-14 Fr Impella 5.0 - 21 Fr</td>
<td>15-17 Fr Arterial 21 Fr Venous</td>
<td>14-16 Fr Arterial 18-21 Fr Venous</td>
</tr>
<tr>
<td>Femoral Artery Size</td>
<td>&gt;4 mm</td>
<td>Impella 2.5 &amp; CP - 5-5.5 mm Impella 5 - 8 mm</td>
<td>8 mm</td>
<td>8 mm</td>
</tr>
</tbody>
</table>
A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

Tamara M. Atkinson, MD, E. Magnus Ohman, MD, William W. O’Neill, MD, Tanveer Rab, MD, Joaquin E. Cigarroa, MD, on behalf of the Interventional Scientific Council of the American College of Cardiology

Cardiogenic Shock

<table>
<thead>
<tr>
<th>Pre/Early</th>
<th>Shock</th>
<th>Severe Shock</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP &lt;100mmHg</td>
<td>HR &gt;100 bpm</td>
<td>SBP &lt;90mmHg</td>
</tr>
<tr>
<td>HR 70-100</td>
<td>Lactate &gt;2</td>
<td>HR &gt;120</td>
</tr>
<tr>
<td>Normal Lactate</td>
<td>Altered mental status</td>
<td>Lactate &gt;4</td>
</tr>
<tr>
<td>Normal Mentation</td>
<td>Cool Extremities</td>
<td>Obtunded</td>
</tr>
<tr>
<td>Cool Extremities</td>
<td>CI 1.5-2.0</td>
<td>Cool Extremities</td>
</tr>
<tr>
<td>CI 2-2.2</td>
<td>PCWP &gt;20</td>
<td>CI &lt;1.5</td>
</tr>
<tr>
<td>PCWP &lt;20</td>
<td>LVEDP &gt;20</td>
<td>PCWP &gt;30</td>
</tr>
<tr>
<td>LVEDP &gt;20</td>
<td>CPO &lt;1W</td>
<td>LVEDP &gt;30</td>
</tr>
<tr>
<td>CPO &gt;1W</td>
<td>Vasoactive Medications</td>
<td>CPO &lt;.6 W</td>
</tr>
<tr>
<td>Vasoactive Medications 0 or 1 low dose</td>
<td>1 moderate-high dose</td>
<td>Vasoactive Medications 2 or more</td>
</tr>
</tbody>
</table>

Cardiac Arrest

- ROSC
- NO - ROSC

High Risk PCI

- UPLMN
- Last patent vessel
- EF <35%
- Complex 3VD
- Comorbidities - severe AS/MR

Multidisciplinary Heart Team Consultation - Interventional Cardiology, Cardiothoracic Surgery, Advanced Heart Failure, Intensive Care

Interventional Cardiovascular Medicine

What hemodynamic support should be used in cardiogenic shock?

- Balloon pumping was not effective in the SHOCK Trial however it is the most commonly used device.
- Trials of hemodynamically effective devices such as the 3.5 L Impella or Tandem Heart device are needed to document survival advantage.
- However these are unlikely to be done therefore single arm registries should be compared to historic controls.
Unanswered Questions in Coronary Artery Disease

How long should antiplatelet therapy be used following PCI?
Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

Laura Mauri, M.D., Dean J. Kereiakes, M.D., Robert W. Yeh, M.D., Priscilla Driscoll-Shempp, M.B.A., Donald E. Cutlip, M.D., P. Gabriel Steg, M.D., Sharon-Lise T. Normand, Ph.D., Eugene Braunwald, M.D., Stephen D. Wiviott, M.D., David J. Cohen, M.D., David R. Holmes, Jr., M.D., Mitchell W. Krucoff, M.D., James Hermiller, M.D., Harold L. Dauerman, M.D., Daniel I. Simon, M.D., David E. Kandzari, M.D., Kirk N. Garratt, M.D., David P. Lee, M.D., Thomas K. Pow, M.D., Peter Ver Lee, M.D., Michael J. Rinaldi, M.D., and Joseph M. Massaro, Ph.D., for the DAPT Study Investigators*
Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

**Major Adverse Cardiovascular and Cerebrovascular Events**

- **12–30 mo**  
  Thienopyridine vs. placebo, 4.3% vs. 5.9%; hazard ratio, 0.71; P<0.001

- **12–33 mo**  
  Thienopyridine vs. placebo, 5.6% vs. 6.5%; hazard ratio, 0.82; P=0.02
Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

**Conclusion:**
DAPT beyond 1 year after placement of a DES, as compared with aspirin therapy alone, significantly reduced the risks of stent thrombosis and major adverse cardiovascular and cerebrovascular events but was associated with an increased risk of bleeding.
Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

Philip Urban, M.D., Ian T. Meredith, M.B., B.S., Ph.D., Alexandre Abizaid, M.D., Ph.D., Stuart J. Pocock, Ph.D., Didier Carrié, M.D., Ph.D., Christoph Naber, M.D., Ph.D., Janusz Lipiecki, M.D., Ph.D., Gert Richardt, M.D., Andres Iñíguez, M.D., Ph.D., Philippe Brunel, M.D., Mariano Valdes-Chavarri, M.D., Ph.D., Philippe Garot, M.D., Suneel Talwar, M.B., B.S., M.D., Jacques Berland, M.D., Mohamed Abdellaoui, M.D., Franz Eberli, M.D., Keith Oldroyd, M.B., Ch.B., M.D., Robaayah Zambahari, M.B., B.S., M.D., John Gregson, Ph.D., Samantha Greene, B.A., Hans-Peter Stoll, M.D., and Marie-Claude Morice, M.D., for the LEADERS FREE Investigators*
Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

Primary Safety Endpoint: Death, MI, Stent Thrombosis

A Primary Safety End Point

- Bare-metal stent
- Drug-coated stent

P<0.001 for noninferiority
P=0.005 for superiority
Primary Safety Endpoint: Death, MI, Stent Thrombosis

Conclusion:

A polymer-free umirolimus-coated stent was superior to a BMS with respect to the primary safety and efficacy endpoints when used with a 1-month course of DAPT.
Out of 2,031 patients 926 were randomized to 6 months and 924 to 24 months DAPT

![Graph showing cumulative death, MI, TVR, stroke, major bleeding rate over time](graph.png)

Logrank p = 0.799
Composite endpoint at 2 years in patients with previous myocardial infarction

Two-year outcomes in the ITALIC trial confirmed the 1-year results and showed that patients receiving 6 months DAPT after PCI with second-generation DES have similar outcomes with those receiving 24 months.
3773 patients with SIHD or ACS undergoing Nobori stent implantation were randomized 1:1 to receive DAPT for 6 or 18 months.

**Graph:**
- **Long-term DAPT**
- **Short-term DAPT**
- HR: 2.25 (95% CI: 0.93, 5.43)
- logrank p=0.05

**Mortality**

**Cumulative Incidence (%)**
- 0.0
- 1.0
- 2.0
- 3.0
- 4.0
- 5.0

**Months since Enrollment**
- 0
- 6
- 9
- 12
- 18
3773 patients with SIHD or ACS undergoing Nobori stent implantation were randomized 1:1 to receive DAPT for 6 or 18 months.

Six months of DAPT was not inferior to 18 months of DAPT following implantation of a DES with a biodegradable abluminal coating.
How long is DAPT (dual antiplatelet therapy) needed?

- Longer and shorter duration is now advocated.
- Studies are needed for specific indications such as high bleeding risk as well as high thrombotic risk patients.
- New agents with and without ASA need further evaluation.
- Study new combinations when oral anticoagulant therapy is required (atrial fibrillation).
Thank you