Late Cardiac Death and Myocardial Infarction Associated With Late Stent Thrombosis in Large Vessel Stenting After 1st or 2nd Generation Drug-Eluting Compared to Bare-Metal Stents

- the BASKET PROspective Evaluation Examination -

(BASKET-PROVE)

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on behalf of the BASKET-PROVE Investigators

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⇒ no industry sponsorship/involvement

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Presenter Disclosure Information

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BASKET-PROVE

FINANCIAL DISCLOSURE:
Advisory Board: Eli Lilly Switzerland, Daiichi-Sankyo Switzerland, Astra Zeneca Switzerland
Speakers Bureau: Biotronik Switzerland, Abbott Vascular Switzerland, Eli Lilly Switzerland, Daiichi-Sankyo Switzerland

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BASKET-PROVE

FINANCIAL DISCLOSURE:
Advisory Board: Hoffmann La Roche Switzerland, Pfizer Switzerland, Eli Lilly Switzerland
Speakers Bureau: Abbott, Biotronik, Boston Scientific, Cordis, Medtronic Eli Lilly, Daiichi-Sankyo, Sanofi Aventis, Switzerland,
Background

BASKET-Trial
- 2003-2004
- single center
- n= 826
- DES vs. BMS
- unselected patients
- 3-year outcome

1° Endpoint: Cardiac death / MI
Hypothesis

⇒ In large vessels, compared to BMS, 1st generation DES
    - provide only a small reduction in TVR
    - may increase late cardiac death/MI

AIMS

⇒ First aim: to prove or refute this hypothesis in an adequately sized prospective multicenter trial

⇒ Second aim: to evaluate whether a similar risk-benefit balance would also be found for 2nd generation DES
Study Design I

Prospective randomized, 11-center, 4-country multicenter study / intention to-treat

Inclusion 2’314 consecutive patients irrespective of indication for PCI (March 2007 until May 2008)

Randomization 1:1:1 to

1\textsuperscript{st} generation SES (Cypher select ®) vs Cobalt-Chromium BMS (Vision ®) vs 2\textsuperscript{nd} generation EES (Xience V ®)
Study Design II

Exclusions
cardiogenic shock, ISR, ST, unprotected LM or SVG to be stented, planned surgery within 12 months, need for oral anticoagulation, increased bleeding risk, intolerance for long-term antiplatelet drugs, vessels >4mm

Follow-up
12 and 24 months by dedicated questionnaires ASS and Clopidogrel for 12 months in all patients clinical events (angio for clinical indication only)

Endpoints:
- 1° EP: Cardiac death / MI up to 24 months
  a) SES vs BMS  b) EES vs BMS  [c) SES vs EES]
- 2° EP: Late cardiac death / MI (7-24 months), death, cardiac death, MI, TVR, stent thrombosis, MACE
Patient Flow Chart

Included into study (n) 2'314

Randomization to stent used

- SES
  - Protocol violators: - 7
  - Withdrew consent: - 7
  - Lost < 1 year visit: - 8
  - Lost >1<2 year visit: - 9
  - Died < 2 years: -21
  - 2 year survivors with complete FU (96%): 716

- EES
  - Protocol violators: - 4
  - Withdrew consent: - 7
  - Lost < 1 year visit: - 5
  - Lost >1<2 year visit: - 7
  - Died < 2 years: - 25
  - 2 year survivors with complete FU (96%): 726

- BMS
  - Protocol violators: - 7
  - Withdrew consent: - 7
  - Lost < 1 year visit: - 5
  - Lost >1<2 year visit: - 6
  - Died < 2 years: - 34
  - 2 year survivors with complete FU (96%): 708
## Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>EES</th>
<th>EES</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>775</td>
<td>774</td>
<td>765</td>
</tr>
<tr>
<td>Male (%)</td>
<td>74</td>
<td>76</td>
<td>77</td>
</tr>
<tr>
<td>Age (years)</td>
<td>66±11</td>
<td>66±11</td>
<td>67±11</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>18</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>62</td>
<td>61</td>
<td>65</td>
</tr>
<tr>
<td>Hypercholesterol. (%)</td>
<td>61</td>
<td>64</td>
<td>75</td>
</tr>
<tr>
<td>Current Smoker (%)</td>
<td>30</td>
<td>34</td>
<td>34</td>
</tr>
<tr>
<td>Prior MI (%)</td>
<td>13</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>Prior PCI/CABG (%)</td>
<td>16</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Stable Angina (%)</td>
<td>34</td>
<td>35</td>
<td>37</td>
</tr>
<tr>
<td>UA/NSTEMI (%)</td>
<td>32</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>STEMI (%)</td>
<td>34</td>
<td>31</td>
<td>31</td>
</tr>
</tbody>
</table>

*(No significant between group differences)*
## Baseline Vessel Disease and Intervention

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>EES</th>
<th>BMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>775</td>
<td>774</td>
<td>765</td>
</tr>
<tr>
<td>MV- disease (%)</td>
<td>44</td>
<td>41</td>
<td>43</td>
</tr>
<tr>
<td>LAD treated (%)</td>
<td>52</td>
<td>53</td>
<td>52</td>
</tr>
<tr>
<td>Bifurcations treated</td>
<td>8</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>CTO treated</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>GP IIb/IIIa blockers (%)</td>
<td>26</td>
<td>28</td>
<td>25</td>
</tr>
<tr>
<td># of stented lesions/pat.</td>
<td>1,4±0,7</td>
<td>1,4±0,6</td>
<td>1,5±0,8</td>
</tr>
<tr>
<td># of stents/patient</td>
<td>1,6±0,9</td>
<td>1,7±1,1</td>
<td>1,7±1,1</td>
</tr>
<tr>
<td>total stent length/pat. (mm)</td>
<td>30±20</td>
<td>31±23</td>
<td>31±23</td>
</tr>
<tr>
<td>≥ 1 stent ≤ 2,5mm (%)</td>
<td>3</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>„Off-label“ use</td>
<td>78</td>
<td>75</td>
<td>75</td>
</tr>
<tr>
<td>Lesions with ang. success</td>
<td>98</td>
<td>98</td>
<td>98</td>
</tr>
</tbody>
</table>

(No significant between group differences)
Cumulative Clinical Events After 2 Years

P-values adjusted for multiple testing

* p=0.005  SES vs BMS
* p=0.002  EES vs BMS
* p=0.009 SES vs BMS
* p=0.005 EES vs BMS
Conclusions

In contemporary stenting of large coronary arteries

> Late safety problems of DES could no longer be confirmed

> No difference in safety nor efficacy was found between 2\textsuperscript{nd} generation EES and 1\textsuperscript{st} generation SES

> both DES showed superior efficacy compared with BMS
Findings of BASKET-PROVE imply that in patients in need of large coronary artery stenting

- *DES may be used without evidence of increased late cardiac events*

- Since BMS and DES showed similar hard event rates
  - *BMS may still be used here - however, with a higher TVR-rate*

- Since the performance of 1st and 2nd generation DES (SES and EES) was similar
  - *both DES may be used similarly in these patients*
The BASKET-PROVE Centers
(number of patients randomized)

University Hospital Basel, Switzerland (n=496)
C. Kaiser

Cardiocentro Lugano, Switzerland (n=154)
G. Pedrazzini

Clara Hospital Basel, Switzerland (n=132)
B. Hornig

Cardiovascular Center Zürich, Switzerland (n=59)
O. Bertel

State Hospital Chur, Switzerland (n=56)
P. Bonetti

Ospedale Civile, Legnano, Italy (n=41)
S. De Servi

Gentofte University Hospital, Copenhagen, Denmark (n=402)
S. Galatius

State Hospital Lucerne, Switzerland (n=337)
P. Erne

Triemli Hospital Zürich, Switzerland (n=264)
F. Eberli

University Hospital Innsbruck, Austria (n=199)
H. Alber

State Hospital St. Gallen, Switzerland (n=174)
H. Rickli

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