Welcome to the 5th European Bifurcation Club
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Role of lesion preparation in the treatment of bifurcation lesions
Case Review Session

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Role of lesion preparation in the treatment of bifurcation lesions
Case Review Session
Lesion Preparation:
Cosmetic or Curative?

Hypothesis

• Plaque modification before stent deployment may minimize arterial injury and subsequent neointimal proliferation /restenosis:
  – It minimizes plaque shifting between main branch and side branch and thus helps avoiding side branch stenting
  – It gives perfect stent apposition with reduced inflation pressure even if very long stents are deployed
  – With bioabsorbable stents it will be an essential tool to perform complete “vessel repair procedures”
Pre-treatment options and consequences

Options
- CB
- DCA
- Rota

Consequences
- Minimize problems related to plaque shifting
- Treat un-dilatable and resistant lesions (e.g. calcified)
- Facilitate difficult stent delivery
- Dilate precisely

Procedural benefit
Restenosis benefit
PCI Strategy in Complex Lesions

Lessons from Nordic Bifurcation Study

- **Direct stenting**
  - Similar results with 1 and 2 stents (NBS I)
  - In 2 stents trend to lower restenosis in Culotte vs Crush (NBS II)
  - Risk of large uncontrolled dissections
  - And/or not good expanded stent

- **Predilatation + stenting**
  - Pre-treatment
  - Improved stent apposition
  - Similar results with 1 and 2 stents (NBS I)
  - In 2 stents trend to lower restenosis in Culotte vs Crush (NBS II)
  - No large dissections
  - Good stent apposition

- **Stenting +**
  - Post-treatment
  - No benefit of routine kissing postdilation in single stenting (NBS III)
  - No large dissections
**Scoring Balloon Types**

**Cutting Balloon Ultra**

A non-compliant balloon with 3-4 microtomes mounted on its surface.

**Flextome Cutting Balloon**

Improved profile and flexibility.

**Angiosculpt**

A semi-compliant balloon with an external Nitinol shape memory helical scoring edge.

**Possible advantages:**

- Focused force PTCA with “Controlled” dissections
- Stent apposition improvement

**Possible disadvantages:**

- Profile & limited length
Acting Mechanisms of Regular and Cutting Balloons

**Regular balloon**
- Entire balloon surface contact the vessel wall – arterial wall damage
- Multiple rips and tears in media
- Endothelium is completely disrupted, large hematoma has formed due to trauma

**Cutting balloon**
- Injury localized to the scoring sites - reduced trauma
- Media with no visible disruption
- Endothelial layer remains intact
Bifurcation CB Substudy

- Single centre substudy (Nordic Bifurcation Study I, II+ Riga bifurcation registry)
- **Goal:** The safety and efficacy of plaque modification with cutting ballon before main vessel stenting and/or side branch treatment in bifurcation lesion
- **Comparison:** CB vs non-CB interventions in bifurcation lesions
- **End-points:** cardiac death, myocardial infarction, stent thrombosis, target lesion revascularization (TLR), and target vessel revascularization (TVR) after 8 months.
# CB Substudy: 8 Months Outcomes

<table>
<thead>
<tr>
<th></th>
<th>CB</th>
<th>Non-CB</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n= 209</td>
<td>n= 347</td>
<td></td>
</tr>
<tr>
<td>Death, n (%)</td>
<td>7 (3.3)</td>
<td>10 (2.9)</td>
<td>0.802</td>
</tr>
<tr>
<td>MI, n (%)</td>
<td>7 (3.3)</td>
<td>9 (2.6)</td>
<td>0.609</td>
</tr>
<tr>
<td>Non Q-wave MI, n (%)</td>
<td>6 (12)</td>
<td>4 (8)</td>
<td>0.518</td>
</tr>
<tr>
<td>ST, n (%)</td>
<td>5 (2.4)</td>
<td>10 (2.6)</td>
<td>&gt;0.99</td>
</tr>
<tr>
<td>TLR, n (%)</td>
<td>11 (5.3)</td>
<td>38 (11.0)</td>
<td>0.021</td>
</tr>
<tr>
<td>TVR, n (%)</td>
<td>17 (8.1)</td>
<td>48 (13.8)</td>
<td>0.056</td>
</tr>
</tbody>
</table>
Arterial Scoring in LM (including distal bifurcation)

Unprotected LM Registry

615 consecutive patients with unprotected LM disease undergoing PCI at Latvian Center of Cardiology were enrolled into the LM PCI registry since January 2002.

PCI on unprotected LM (IVUS guidance, cutting balloon pretreatment optional, BMS or DES implantation)

Between Feb 2004 and Nov 2005 PCI on unprotected LM (IVUS guidance, cutting balloon pretreatment mandatory, randomization)

BMS n=50

PMS n=53

Intrahospital evaluation

n: 413 (100%)

6 months clinical, angiographic and IVUS follow-up

n: 276 (67%)

36 months clinical, angiographic and IVUS follow-up & OCT

## Lesion Location

<table>
<thead>
<tr>
<th>Location</th>
<th>BMS</th>
<th>DES</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LM</td>
<td>14%</td>
<td>4%</td>
<td>0.087</td>
</tr>
<tr>
<td>Ostium</td>
<td>18%</td>
<td>15%</td>
<td>0.793</td>
</tr>
<tr>
<td>Body</td>
<td></td>
<td></td>
<td>0.173</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>68%</td>
<td>81%</td>
<td></td>
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</tbody>
</table>
3 Years Clinical Results

MACE (death, MI, TLR) free survival

<table>
<thead>
<tr>
<th></th>
<th>BMS (n= 50)</th>
<th>PES (n= 53)</th>
<th>p-value</th>
<th>All (n=103)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total death, n (%)</td>
<td>7 (14.0)</td>
<td>3 (5.7)</td>
<td>0.193</td>
<td>10 (9.7)</td>
</tr>
<tr>
<td>Cardiac death, n (%)</td>
<td>4 (8.0)</td>
<td>3 (5.7)</td>
<td>0.710</td>
<td>7 (6.8)</td>
</tr>
<tr>
<td>Q-MI, n (%)</td>
<td>1 (2.0)</td>
<td>3 (5.7)</td>
<td>0.618</td>
<td>4 (3.9)</td>
</tr>
<tr>
<td>TLR, n (%)</td>
<td>10 (20.0)</td>
<td>3 (5.7)</td>
<td>0.038</td>
<td>13 (12.6)</td>
</tr>
<tr>
<td>TLR-PCI, n (%)</td>
<td>9 (18.0)</td>
<td>3 (5.7)</td>
<td>0.067</td>
<td>12 (1.7)</td>
</tr>
<tr>
<td>TLR-CABG, n (%)</td>
<td>1 (2.0)</td>
<td>0 (0)</td>
<td>0.485</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Total MACE, n (%)</td>
<td>18 (36.0)</td>
<td>7 (13.2)</td>
<td>0.011</td>
<td>25 (24.3)</td>
</tr>
</tbody>
</table>
Patient Characteristics

• 76 years old female admitted with stable angina CCS III on good medical therapy

• Factors of cardiovascular risk: dyslipidemia, arterial hypertension

• Previous history: Myocardial infarction (2007), Peripheral artery disease and lumbar sympathectomy (2008)
Coronary Angiography

Diffusely diseased RCA + severely calcified LAD-D1 stenosis
Intended Strategy for Bifurcation

IVUS guided PCI on LAD-D1 (plaque pre-treatment with cutting balloon + DES stenting)
Equipment

- Femoral approach - 7F Medtronic EBU 3.75
- IVUS guidance
- Choice floppy wires
- Predilatation balloon - Ø 2.5 - 12 mm
- Cutting balloon - Ø 2.75 - 6 mm
- CYPHER stent – Ø 3.0 - 18 mm
Predilatation

Apex 2.5-12 mm pre-treatment

Only after predilatation it was possible to perform IVUS
Baseline IVUS - LAD

MLD 2.22 mm
MLA 5.03 mm²

MLD 1.78 mm
MLA 3.37 mm²

MLD 2.30 mm
MLA 4.85 mm²
Lesion Preparation with Cutting Balloon

CB 2.75 – 6 mm three incisions performed with 7, 9, 11 bar
After CB pretreatment calcium is broken and vessel is ready for stent implantation.

- **CYPHER 3.0-18 mm**
  - Pressure: 13 bar

- **NC 3.5-10 mm**
  - Pressure: 17 bar
Postintervention IVUS - LAD

MLD 2.48 mm
MLA 6.45 mm²

MLD 2.34 mm
MLA 5.85 mm²

MLD 2.89 mm
MLA 7.86 mm²
Conclusions

Good final result, well aposed stent confirmed by IVUS. No side branch flow limitation because of plaque shift which was prevented by lesion pretreatment with CB