A Paclitaxel-Eluting Balloon for Bifurcation Lesions: ‘Early Clinical Observations’

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Disclosure Statement of Financial Interest

I, Pieter Stella, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.
Background

- Stents have become very popular and widely used
- DES is more effective in preventing in-stent restenosis
- However: Concern about long term safety of DES
  Permanent implant
  Live-long dual antiplatelet therapy?
  Not always easy in real challenging anatomy . . .

ic: BIFURCATIONS
Bifurcations

- Bifurcation lesion intervention is performed in about 8-15% of PCI at most centers
- Most of these lesions are complex (type C of ACC/AHA class)
- Technically challenging with higher learning curve
- PCI of these lesions requires higher number of devices
- Higher MACE and higher restenosis
Various Techniques for Stenting Bifurcation Lesions

Bifurcation Lesion

- **Main vessel**

- **Stent+PTCA**
  - Stent+stent ("Y" or "V")
  - Stent+stent ("T stenting")
  - Stent+stent ("reverse-T")

- **Stent+stent ("Culotte")**

- **Provisional ‘T’**
Restenosis following Bifurcation Sirolimus-Eluting Stents for De Novo Narrowings

6-Months Follow-Up (N = 58; 65 Lesions)

Angiographic restenosis (n=44)
- Main branch 9.1%
- Side branch 13.6%
- Overall 22.7%
MV and SB Stenting vs. Optional SB Stenting Using Sirolimus-Eluting Stents in Bifurcation Lesions: NORDIC Bifurcation Study

Procedure-Related Biomarker Elevation

![Bar chart showing procedure-related biomarker elevation](chart.png)

- **MV (n = 153)**
  - > 3 elevation: 8%
  - > 5 elevation: 4%
  - > 10 elevation: 3%

- **MV + SB (n = 126)**
  - > 3 elevation: 18%
  - > 5 elevation: 13%
  - > 10 elevation: 5%

**Statistical Significance**

- **P = 0.011**
- **P = 0.008**
- **P = NS**
Where would DEB fit in?

- Ease of the procedure
- No scaffolding of the SB ostium required
- No crushing of DES-material \((\text{polymer} / \text{drug})\)
- Significant decrease in dual antiplatelet therapy
- Dilatation of small diameter coronary artery (SB) with better long-term results
DIOR™ Technology:

Paclitaxel loading/ balloon surface: 3 µg/mm²

Coating method: nano porous balloon surface, paclitaxel micro crystals (following dimethilsulfate treatment)

Protection of wash off effect: drug hidden within the balloon folds

Balloon inflation time recommended: 35-45 sec. @ nominal balloon pressure
Drug Eluting Balloon in Bifurcation Trial “DEBIUT“

1. Randomised prospective multi centre, 9 month angiographic FU, 5 Years clinical FU
2. Provisional T stenting technique
3. Dual antiplatelet therapy arm I + III for 3 months
4. Non sponsor driven
Drug Eluting Balloon in Bifurcation Trial “DEBIUT“

Registry: (June – August 2007)

- 20 pts
- Clinical FU 4 months (± 1)
- Sequential predilatation MB / SB
- Followed by BMS in MB
- Final kissing with regular balloons
- Clopidogrel stopped in all @ 3 months after index procedure
### “DEBIUT“ - registry

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Characteristics</strong></td>
<td><strong>$n = 20$</strong></td>
</tr>
<tr>
<td>Age (years [range])</td>
<td>68 (41 – 78)</td>
</tr>
<tr>
<td>Male sex, $n$ (%)</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Current or ex-smoker, $n$ (%)</td>
<td>15 (75)</td>
</tr>
<tr>
<td>Hypercholesterolemia, $n$ (%)</td>
<td>16 (80)</td>
</tr>
<tr>
<td>Hypertension, $n$ (%)</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Diabetes mellitus, $n$ (%)</td>
<td>6 (30)</td>
</tr>
<tr>
<td>Previous myocardial infarction, $n$ (%)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Previous CABG, $n$ (%)</td>
<td>5 (25)</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>49</td>
</tr>
<tr>
<td>Glycoprotein IIb/IIIa inhibitor use, $n$ (%)</td>
<td>4 (20)</td>
</tr>
<tr>
<td><strong>Lesion characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>LAD/diagonal, $n$ (%)</td>
<td>17 (85)</td>
</tr>
<tr>
<td>LCX/OM, $n$ (%)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>LM/LAD/LCX, $n$ (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>RCA/RCA-PL/RCA-PD, $n$ (%)</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>
## Drug Eluting Balloon in bifurcation Trial “DEBIUT”

<table>
<thead>
<tr>
<th>Medina classification type: (proximal main branch, distal main branch, and side branch involvement)</th>
<th>Number of patients $(n = 20)$ $(n %)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1</td>
<td>12 (60)</td>
</tr>
<tr>
<td>1.1.0</td>
<td>2 (10)</td>
</tr>
<tr>
<td>1.0.1</td>
<td>4 (20)</td>
</tr>
<tr>
<td>0.1.1</td>
<td>2 (10)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QCA</th>
<th>Main branch</th>
<th>Side branch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length (mm)</td>
<td>15.5 +/- 5.0</td>
<td>4.2 +/- 2.8</td>
</tr>
<tr>
<td>Stent length (mm)</td>
<td>19.0 +/- 6.0</td>
<td>-</td>
</tr>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>3.0 +/- 0.6</td>
<td>2.4 +/- 0.4</td>
</tr>
</tbody>
</table>

100 % successful  
No MACE , no SAT
Conclusions

- Preliminary results look very promising: ‘safe & easy’
- Long term results in de novo unknown
- Indications mainly in difficult anatomy??
- First results “DEBIUT“: TCT 2008
Some cases if time allows . . .
Patient Case DEBIUT Registry
Patient Case DEBIUT Registry
Patient Case DEBIUT Registry
Patient Case DEBIUT Registry