DCB + BMS is not a DES

Fabrizio Fanelli, MD, EBIR

Professor of Radiology
Director Vascular and Interventional Radiology Department
"Careggi " University Hospital
Florence - Italy
Disclosures

• Consultant / Speaker / Proctor / Advisory Board

  – AstraZeneca
  – Bayer
  – Bolton
  – Boston Scientific
  – Cook
  – Cordis

  – CR Bard
  – Medtronic
  – Shockwave Medical
  – Spectranetics
  – Volcano
  – W.L. Gore & Associates
Background

Treatment of the whole lesion.

- **DES**  
  Continuous mechanical effect on the arterial wall, increasing vessel scaffolding + prolonged antiproliferative drug effect

- **DCB + BMS**  
  DCB + provisional spot BMS  
  Sub-optimal PTA. Selective stent implantation

- **DCB + BMS**  
  DCB + full BMS
Drug Eluting Stent

Zilver PTX
Cook

Eluvia
Boston Scientific
5-year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care

At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to BMS.
24-mos Primary Patency (PSVR < 2.5)
Eluvia

Primary Patency Rate vs Months Since Index Procedure

<table>
<thead>
<tr>
<th>Months</th>
<th>0</th>
<th>1</th>
<th>6</th>
<th>12</th>
<th>24</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patency</td>
<td>100</td>
<td>100</td>
<td>98.2</td>
<td>96.4</td>
<td>83.5</td>
<td>77.9</td>
</tr>
<tr>
<td>Cumulative Failed</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>9</td>
<td>12</td>
</tr>
<tr>
<td>Cumulative Censored</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>At Risk</td>
<td>57</td>
<td>56.5</td>
<td>56</td>
<td>54</td>
<td>52</td>
<td>45</td>
</tr>
</tbody>
</table>

83.5%
Disadvantages

- Long metallic struts
- Fracture rate / metallic fatigue
- No-stent zone

DES  

DCB + BMS
<table>
<thead>
<tr>
<th>DES</th>
<th>DCB + BMS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td></td>
</tr>
<tr>
<td>Prolonged drug release</td>
<td>✓</td>
</tr>
<tr>
<td>Limit stent coverage</td>
<td>✗</td>
</tr>
<tr>
<td>Stent only in more critical area</td>
<td>✗</td>
</tr>
</tbody>
</table>
The “DEBELLUM” – Lower limb multilevel treatment with drug eluting balloon – randomized trial: 1-year results

F. Fanelli, A. Cannavale, M. Corona, P. Lucatelli, A. Wlderk, F. M. Salvatori

Aim. The aim of the present paper was to make a report of the 12-month clinical outcomes of the DEBELLUM (Drug-Eluting-Balloon-Evaluation-for-Lower-Limb- multi-level-treatment) randomized trial.

Unit of Vascular and Interventional Radiology
Department of Radiological Sciences
“Sapienza” University of Rome, Rome, Italy


Single center RCT
60 pts. (1:1)
de novo fem-pop lesions

1. PTA vs. In.Pact Admiral DCB
2. Primary BMS + PTA vs. Primary BMS + In.Pact Admiral DCB
advantage of stent implantation more evident in small vessel diameter
SELF-EXPANDING NITINOL STENTS COMBINED WITH DCB:
TREATMENT RATIONALE AND CLINICAL EVIDENCE

B. PATRICE MWIPATAYI, MMed, FCS (SA), FRACS
Department of Vascular Surgery, RPH, University of Western Australia Perth
RHYS DANIEL, MBChB, B.Eng (ChemEng)
JACKIE WONG, BSc, MPH

LINC 2017
Multi-center, Single-arm study

65 lesions

Mean length 187.6 mm
TASC C & D: 96%
CTO: 80.4%

Pulsar 18 (Biotronik)

Paseo 18 Lux (Biotronik)

<table>
<thead>
<tr>
<th></th>
<th>6 mos</th>
<th>12 mos</th>
<th>24 mos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Restenosis</td>
<td>98%</td>
<td>94.1%</td>
<td>88.2%</td>
</tr>
<tr>
<td>Freedom from CD-TLR</td>
<td>96.1%</td>
<td>94.1%</td>
<td>88.2%</td>
</tr>
</tbody>
</table>
Short-term Results of the RAPID Randomized Trial of the Legflow Paclitaxel-Eluting Balloon With Supera Stenting vs Supera Stenting Alone for the Treatment of Intermediate and Long Superficial Femoral Artery Lesions

Sanne W. de Boer, MD¹, Daniel A. F. van den Heuvel, MD¹, Debbie A. B. de Vries-Werson, MPA², Jan Albert Vos, MD, PhD¹, Bram Fioole, MD, PhD³, Damnis Vroegindeweij, MD, PhD⁴, Otto E. Elgersma, MD, PhD⁵, Rudolph P. Tutein Nolthenius, MD⁶, Jan M. M. Heyligers, MD, PhD⁷, Gerlof P. T. Bosma, MD, PhD⁷, Bernart de Leeuw, MD⁸, Lee H. Bouwman, MD, PhD⁹, Dittmar Böckler, MD, PhD¹⁰, Dmitriy I. Dovzhanskiy, MD¹¹, Floris W. F. Vos, MD¹², Ted W. F. Vink, MD¹³, Pieter G. A. Hooijboer, MD¹⁴, Rutger J. Hissink, MD¹⁵, and Jean-Paul P. M. de Vries, MD, PhD²

Journal of Endovascular Therapy 2017, Vol. 24(6) 783–792

Drug-eluting balloon in peripheral intervention for the superficial femoral artery: the DEBATE-SFA randomized trial (drug eluting balloon in peripheral intervention for the superficial femoral artery).

Liistro F¹, Gotti S², Porto I³, Angioli P³, Ricci L⁴, Ducci K³, Falsini G³, Ventoruzzo G³, Turini F³, Bellandi G³, Bolognese L³.

JACC Cardiovasc Interv. 2013 Dec;6(12):1295-302
Biolux – 4EVER

Physician-Initiated, prospective, multi-center, controlled trial

120 pts.

Mean lesion length: 83.3 mm
CTO: 33.3%

- Passeo 18 Lux (Biotronik)
- Pulsar 18 (Biotronik)
12-mos Primary Patency

105 pts.

89.3%
Conclusions

- Combination of DCB with a BMS shows a pretty good outcome
- Encouraging patency rate
- Few data available with limited follow-up
- No big difference between DCB + BMS and BMS + DCB. Still «open question»
Paclitaxel-coated balloon plus bare metal stent vs. sirolimus-eluting stent in de novo lesions: an IVUS study

Dieter Fischer¹*, MD; Bruno Scheller², MD; Arnd Schaefer¹, MD; Gunnar Klein¹, MD; Michael Böhm², MD; Yvonne Clever², MD; Bodo Cremers², MD

EuroIntervention 2012;8:450-455

- 55 pts. From PEPCAD III randomized
  - 26 pts: DES (Cypher)
  - 29 pts: DCB + BMS
- 9-mos. F.U. angiographic and IVUS evaluation
<table>
<thead>
<tr>
<th></th>
<th>DCB/BMS (n=29)</th>
<th>DES (n=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent area, mm$^2$</td>
<td>5.65±1.52</td>
<td>6.25±1.72</td>
<td>n.s.</td>
</tr>
<tr>
<td>Neointimal hyperplasia (stent CSA-lumen CSA), mm$^2$</td>
<td>1.08±0.53</td>
<td>0.69±0.49</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Instent stenosis, % of stent CSA</td>
<td>19.7±8.8</td>
<td>11.0±6.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent malapposition, n</td>
<td>2</td>
<td>4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Symmetric expansion index (min/max stent diameter)</td>
<td>0.90±0.02</td>
<td>0.89±0.04</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
# 9-mos. IVUS evaluation

<table>
<thead>
<tr>
<th></th>
<th>DCB/BMS (n=29)</th>
<th>DES (n=26)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent area, mm$^2$</td>
<td>5.65±1.52</td>
<td>6.25±1.72</td>
<td>n.s.</td>
</tr>
<tr>
<td>Neointimal hyperplasia (stent CSA-lumen CSA), mm$^2$</td>
<td>1.08±0.53</td>
<td>0.69±0.49</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>In-stent stenosis, % of stent CSA</td>
<td>19.7±8.8</td>
<td>11.0±6.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent malaposition, n</td>
<td>2</td>
<td>4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Symmetric expansion index (min/max stent diameter)</td>
<td>0.90±0.02</td>
<td>0.89±0.04</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
### 9-mos. IVUS evaluation

<table>
<thead>
<tr>
<th></th>
<th>DCB/BMS (n=29)</th>
<th>DES (n=26)</th>
<th>$p$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent area, mm$^2$</td>
<td>5.65±1.52</td>
<td>6.25±1.72</td>
<td>n.s.</td>
</tr>
<tr>
<td>Neointimal hyperplasia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(stent CSA-lumen CSA), mm$^2$</td>
<td>1.08±0.53</td>
<td>0.69±0.49</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Instent stenosis, % of stent CSA</td>
<td>19.7±8.8</td>
<td>11.0±6.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent malapposition, n</td>
<td>2</td>
<td>4</td>
<td>n.s.</td>
</tr>
<tr>
<td>Symmetric expansion index</td>
<td>0.90±0.02</td>
<td>0.89±0.04</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
D.G. 67-y. Male
Heavy smoker, hypertension
Right <50 mt claudication
Admiral (Medtronic) 4 mm

In.Pact Admiral (Medtronic) 5 mm
Inf. Time 3 min.

Admiral (Medtronic) 5x60 mm
Inf. Time 5 min.
Zilver PTX
6x60 mm
(Cook)
Zilver PTX
6x60 mm
(Cook)

12-mos F.U.
Safety of Zilver PTX Drug-Eluting Stent Implantation Following Drug-Coated Balloon Dilation in a Healthy Swine Model

Sho Torii, MD, PhD\(^1\), Kazuyuki Yahagi, MD\(^1\), Hiroyoshi Mori, MD\(^1\), Emanuel Harari, MD\(^1\), Maria E. Romero, MD\(^1\), Frank D. Kolodgie, PhD\(^1\), Brandt Young, PhD\(^2\), Anthony Ragheb, PhD\(^2\), Renu Virmani, MD\(^1\), and Alok V. Finn, MD\(^1\)

Journal of Endovascular Therapy 2018, Vol. 25(1) 118–126

20 swine

1-3-6 mos

Vessel integrity

Hystological parameters

In.Pact DCB 5x40mm

Zilver PTX

Advance 35 LP

Zilver PTX
SMC Loss

3-mos Transmural SMC loss score:
- DCB+DES: 3.3
- BA+DES: 2.5  \( p=0.04 \)
Downstream effects and arteriolar changes of skeletal muscle due to paclitaxel

Histological section–based analysis of downstream non-target organs (skeletal muscle and coronary band)

Fibrinoid necrosis and/or inflammation in small arteries and arterioles only in the DCB+DES group at 1 and 3 months.
Thrombotic emboli were observed in 1 section of the DCB+DES group at 1 month and 1 section at 3 months but none in the BA+DES.
with consistent trends between groups at all time points. Medial smooth muscle cell loss peaked at 1 month and was not statistically different between groups at any time point, although the loss was greater in the DCB+DES group. Sections with arterioles exhibiting paclitaxel-associated fibrinoid necrosis in downstream tissues were observed exclusively in the DCB group at 1 month (14.3% of sections) and 3 months (11.5%). **Conclusion:** This preclinical study suggests that Zilver PTX stent implantation is a safe strategy after DCB angioplasty and might be considered for patients who require stenting after DCB treatment.
Conclusions

- Combination of DCB with a BMS shows a pretty good outcome
- Encouraging patency rate
- Few data available with limited follow-up
- No big difference between DCB + BMS and BMS + DCB. Still «open question»
- Data are still supporting the use of DES especially in long-term
- Selection must take in consideration lesion characteristics
- Too many «open questions» (DCB before or after, spot vs. full stenting, etc)
- DCB + DES is a promising alternative
DCB + BMS is not a DES

Fabrizio Fanelli, MD, EBIR

Professor of Radiology
Director Vascular and Interventional Radiology Department
"Careggi " University Hospital
Florence - Italy