DEBATE: Zilver PTX Stents Are Effective For Long Or Calcified SFA Lesions: But All Other SFA Lesions Should Be Treated With Drug Eluting Balloons (DEBs)

Faculty Disclosure

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For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
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DEB in SFA Evidence: Proof-of-Concept

7 Trials / 6 DEB Technologies; 6-month LLL (Primary Endpoint)

Evidence from DEB Trials
Long-term Freedom from TLR

Significant and sustained TLR reduction up to 5 years

**FEMPAC 2Y**

- **IN.PACT vs. PTA**
  - 2-Year Outcomes IN.PACT SFA Pivotal RCT
  - 331 Patients RCT (IN.PACT Admiral vs. PTA)
    - Primary Patency: 78.9% vs. 50.1% (p<0.001)
    - Clinically driven TLR: 9.0% vs. 27.8% (p<0.001)
    - No PTX related adverse Events

**THUNDER 5Y**

IN.PACT Global Long Lesion Cohort vs. Zilver PTX

Long Lesion Cohort

Kaplan-Meier Estimate of Primary Patency

- **IN.PACT Global Long Lesion Cohort**
  - 364.0 ± 86.1
  - Zilver PTX
  - 149.3 ± 81.1
IN.PACT Global Long Lesion Imaging Cohort: Primary Patency in Non-stented Subgroup

Consistent clinical outcomes with the IN.PACT® Admiral® DCB across studies and complex femoropopliteal lesions.

Calcium may present a challenge for DCBs
Calcium is a barrier to optimal drug absorption\(^1,2\)

<table>
<thead>
<tr>
<th>Lesion Length (cm)</th>
<th>IN.PACT SFA (DCB Arm)</th>
<th>IN.PACT Global</th>
<th>IN.PACT Global Long Lesion Imaging Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N= 220</td>
<td>N= 655</td>
<td>N=157</td>
</tr>
<tr>
<td>CD-TLR</td>
<td>2.4%</td>
<td>8.7%</td>
<td>6.0%</td>
</tr>
<tr>
<td>CD-TVr</td>
<td>4.3%</td>
<td>5.5%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>1.4%</td>
<td>3.8%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Target Limb Major Amputation</td>
<td>0.0%</td>
<td>0.3%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

DAART = Directional Atherectomy + Anti-Restenotic Therapy

• Mechanically re-canalize the vessel without overstretching
• Remove the perfusion barrier
• Reduce the likelihood of bail-out stenting and preserve the native vessel

Potential Benefit of DA Prior to DCB
DEF AR Reaffirms the value of luminal gain achieved by DA

What is the Impact of Luminal Gain with DAART? What is the impact on patient outcomes?

Potential Benefit of DA Prior to DCB
DEF AR suggests DAART better than DCB alone in long or calcified lesions

5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care

<table>
<thead>
<tr>
<th>Treatment</th>
<th>5-Year Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilver PTX</td>
<td>66.4%</td>
</tr>
<tr>
<td>Standard Care</td>
<td>43.4%</td>
</tr>
</tbody>
</table>

p < 0.01

Optimal PTA + BMS

At 5 years, Zilver PTX demonstrates a 43% reduction in restenosis compared to standard care.

IN.PACT DCB vs. DES in long SFA lesions

- 228 Patients Retrospective, Propensity score Analysis
- Non significant difference between IN.PACT DEB and Zilver PTX in long SFA lesions
- Prov Stent rate post DEB = 18.3%


The BIM Demonstrates Potentially Substantial Savings From Use of Drug-Based Therapies

- DES and DCB least costly index procedure strategies over 24 months
- Per patient savings:
  - € 561 for DCB vs. PTA index procedure
- Potential total savings/yr:
  - For hypothetically assumed 25,000 cases per year treated with DCB instead of PTA in German healthcare system
  - ~ € 14 M savings

The BIM Demonstrates Potentially Substantial Savings From Use of Drug-Based Therapies

Summary

DEB vs. Zilver PTX DES in SFA-Revascularization

- DEB angioplasty achieves at least as good results as DES in TASC A & B de novo lesions (Level 1 of evidence)
- DEB ± DA should be considered as first line strategy in the treatment of TASC C & D femoro-popliteal lesions with a length up to 25 cm (IN.PACT global & DEFINITIVE AR) because outcomes are at least as good as with DES
- DEB angioplasty is as cost-effective as DES without the expense of a permanent implant