Update of Evaluation of DCBs: When Are They Worthwhile and Advantages of Different DCBs

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Is There a Class Effect or Are There Differences?

On the Bench and in Animals They Are Not the Same

• Vary on consistency drug amount
• Vary on coating consistency
• Vary on drug forms on balloon
• Vary on size of particulates

On the Bench and in Animals They Are Not the Same

Concentration

2.0 ug/mm²

2.5 ug/mm²

2.0 ug/mm²

On the Bench and in Animals They Are Not the Same

Gary M Ansel MD.
Conflicts of Interest

• Consultant
  - Abbott Vascular
  - Boston Scientific
  - Cordis Corporation
  - Medtronic
  - WL Gore
  - CR Bard
  - Primacea
  - Reflow Medical

• Equity
  - Embolitech
  - Primacea
  - Fellow medical

November 2018
On the Bench and in Animals
They Are Not the Same

DCB Animal comparison at 28 days
- All DCBs showed improvement over PTA
- MLD maintained most optimally
- Stellarex
- Lowest variability Stellarex


On the Bench and in Animals
They Are Not the Same

PREVEIL DCB Feasibility Study

<table>
<thead>
<tr>
<th>Device</th>
<th>Patients</th>
<th>Plasma Paclitaxel (mg)</th>
<th>Tmax (hr)</th>
<th>Cmax (ng/mL)</th>
<th>AUC0-last (ng/mL*hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surmodics SurVeil DCB EFS</td>
<td>13</td>
<td>1.3 – 3.6</td>
<td>2.25 ± 2.5</td>
<td>3.76 ± 3.2</td>
<td></td>
</tr>
<tr>
<td>Bard Lutonix</td>
<td>22</td>
<td>1.0 – 5.0</td>
<td>5.10 ± 3.2</td>
<td>8.39 ± 4.0</td>
<td></td>
</tr>
<tr>
<td>Medtronic IN.PACT Admiral</td>
<td>24</td>
<td>2.8 – 16.8</td>
<td>5.74 ± 2.7</td>
<td>29.44 ± 3.8</td>
<td></td>
</tr>
</tbody>
</table>

Three subjects had insufficient data to complete the analysis and are excluded from descriptive statistics

Levant 2 Subset (serum); data from PMA P130024 SSED
IN.PACT SFA Trial Sub-Study (plasma); data from PMA P140010 SSED

Difference Between DCB’s?

DCB Patency Results in Device Approval Trials

Levant 2

What Populations Are They Effective and How Long?
Calcium: Appears to be a Barrier to Drug Penetration

2. Tepe G. ISET 2014

IN.PACT SFA Trial Through the Years

4. Schneider P. VIVA 2017
5. Laird VIVA 2018

IN.PACT SFA Trial: Freedom From CD-TLR Through 5 Years

The tale of three populations!

APPROVAL TRIALS
- Lots of exclusions
- Typically Claudicants
- Up to moderate Ca
- Advanced CTO
- No adjunctive devices
- Patients that follow up
- Core lab adjudication

REGISTRY PATIENTS
- Fewer exclusions
- Broader patient class to IV
- More Ca
- More complex CTO
- Runoff present
- Adjunctive devices
- Increased patient loss
- Some core lab adjudication

REAL WORLD PATIENTS
- Few exclusions
- Includes many CLI patients
- Includes severe Ca
- Long CTO
- Borderline to poor runoff
- Frequent adjunctive devices
- Rare core lab

IN.PACT Global Study: Standard vs. Wider Use

Outcomes Across IN.PACT Clinical Studies

<table>
<thead>
<tr>
<th>Lesion Length (cm)</th>
<th>Standard Use (N=281)</th>
<th>Wider Use (N=1125)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD-TLR</td>
<td>2.4%</td>
<td>8.7%</td>
</tr>
<tr>
<td>CD-TVR</td>
<td>4.2%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>1.4%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Target Limb Major Amputation</td>
<td>0.0%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Provisional stent rate</td>
<td>7.3%</td>
<td>14.7%</td>
</tr>
</tbody>
</table>

IN.PACT Global Long Lesion Imaging Cohort: Results across IN.PACT Clinical Studies

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