Recorded Live Case: IN.PACT AV Access Drug Coated Balloon

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Relevant Disclosures

Dr. Holden is a member of the Medtronic Peripheral Arterial Advisory Board

Dr. Holden is a Clinical Investigator on Medtronic devices

No other relevant disclosures

Disclosures

Speaker name: Andrew Holden, MBChB, FRANZCR, EBIR

I have the following potential conflicts of interest to report:

☒ Consulting – Medical Advisory Board: Medtronic, Gore, Boston Scientific
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)
☐ I do not have any potential conflict of interest
IN.PACT ADMIRAL AV Access Product Specifications

DCB Components

**Balloon (Based on 0.035” IN.PACT Admiral)**
- 4.0 – 12.0 mm diameters
- 40, 60, 80, 120, 150 mm lengths
- 40*/80/130 cm shaft

**Paclitaxel**
- Proven anti-proliferative drug
- 3.5 μg/mm²

**Sheath Compatibility**
- 5-7 French

**Pressure Characteristics**
- Nominal pressure 8 ATM
- Rated burst pressure 14 ATM

* 40 cm shaft - unique feature of IN.PACT AV Access catheter
IN.PACT AV Access 12-Month Primary Effectiveness Endpoint

Log-rank p-value < 0.001

Target Lesion Primary Patency

Time After Index Procedure (Days)

Number at risk

0 180 360

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

IN.PACT AV DCB
Standard PTA

Δ 17.2%
Δ 19.0%

65.3%
46.3%
IN.PACT AV Access 12-Month Access Circuit Patency

Log-rank p-value < 0.001

Time After Index Procedure (Days)

Number at risk

170
160
118
83
70
42

IN.PACT AV DCB
Standard PTA

% Patency

100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%

\( \triangle 22.3\% \)
\( \triangle 20.1\% \)

55.1%
35.0%
Edited Live Case – Case Presentation

- 72 year old male
- Long-standing type-2 diabetic - on insulin
- History of hypertension, gout, peripheral neuropathy
- Diabetic nephropathy
- Left hand dominant
- Right brachiocephalic AV access created 9.25.16
- Hemodialysis commenced 2.9.17
- Juxta-anastomotic stenosis treated with POBA 11.23.17
- Presented with decreased blood flow in AV access 4.13.18
## IN.PACT AV Access Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Demographics</th>
<th>IN.PACT AV DCB (n=170)</th>
<th>Standard PTA (n=160)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs) (mean ± SD)</td>
<td>65.8 ± 13.1</td>
<td>65.5 ± 13.4</td>
<td>0.837</td>
</tr>
<tr>
<td>Male</td>
<td>65.9% (112/170)</td>
<td>63.1% (101/160)</td>
<td>0.646</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td><strong>91.2% (155/170)</strong></td>
<td><strong>94.4% (151/160)</strong></td>
<td><strong>0.295</strong></td>
</tr>
<tr>
<td><strong>Hyperlipidemia</strong></td>
<td><strong>54.1% (92/170)</strong></td>
<td><strong>52.5% (84/160)</strong></td>
<td>0.825</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>2.4% (4/170)</td>
<td>3.8% (6/160)</td>
<td>0.532</td>
</tr>
<tr>
<td>Type 1</td>
<td>60.6% (103/170)</td>
<td>65.0% (104/160)</td>
<td>0.427</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>100.0% (170/170)</td>
<td>100.0% (160/160)</td>
<td>&gt; 0.999</td>
</tr>
<tr>
<td>Carotid Artery Disease</td>
<td>4.1% (7/170)</td>
<td>8.8% (14/160)</td>
<td>0.114</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>22.9% (39/170)</td>
<td>24.4% (39/160)</td>
<td>0.796</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>35.9% (61/170)</td>
<td>38.8% (62/160)</td>
<td>0.649</td>
</tr>
<tr>
<td>Peripheral Artery Disease</td>
<td>19.4% (33/170)</td>
<td>15.1% (24/159)</td>
<td>0.312</td>
</tr>
<tr>
<td>Smoker - Current</td>
<td>11.2% (19/170)</td>
<td>16.3% (26/160)</td>
<td>0.201</td>
</tr>
<tr>
<td>- Former</td>
<td>37.6% (64/170)</td>
<td>28.1% (45/160)</td>
<td>0.079</td>
</tr>
<tr>
<td>Previous AV Access Endovascular Procedure</td>
<td>74.1% (126/170)</td>
<td>75.0% (120/160)</td>
<td>0.900</td>
</tr>
</tbody>
</table>

DCB, drug-coated balloon  
PTA, percutaneous transluminal angioplasty
## IN.PACT AV Access Clinical Characteristics

<table>
<thead>
<tr>
<th>Clinical Characteristics</th>
<th>IN.PACT AV DCB (n=170)</th>
<th>Standard PTA (n=160)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Presenting Clinical Symptoms Indicating AV Access Dysfunction</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased Blood Flow</td>
<td>63.5% (108/170)</td>
<td>55.0% (88/160)</td>
<td>0.118</td>
</tr>
<tr>
<td>Elevated Venous Pressures</td>
<td>15.9% (27/170)</td>
<td>20.0% (32/160)</td>
<td>0.389</td>
</tr>
<tr>
<td>Unexplained Reduction in Hemodialysis Dose (Kt/V)</td>
<td>2.9% (5/170)</td>
<td>3.1% (5/160)</td>
<td>1.000</td>
</tr>
<tr>
<td>Abnormal Recirculation Values</td>
<td>1.2% (2/170)</td>
<td>3.1% (5/160)</td>
<td>0.271</td>
</tr>
<tr>
<td>Swollen Extremity or Aneurysm Formation</td>
<td>6.5% (11/170)</td>
<td>5.6% (9/160)</td>
<td>0.820</td>
</tr>
<tr>
<td>Elevated Negative Arterial Pre-pump Pressures</td>
<td>8.2% (14/170)</td>
<td>9.4% (15/160)</td>
<td>0.846</td>
</tr>
<tr>
<td>Unexplained Reduction of Dialysis Efficiency</td>
<td>3.5% (6/170)</td>
<td>5.0% (8/160)</td>
<td>0.590</td>
</tr>
<tr>
<td>Abnormal Physical Findings (thrill, murmur, arm swelling, etc)</td>
<td>43.5% (74/170)</td>
<td>44.4% (71/160)</td>
<td>0.912</td>
</tr>
<tr>
<td>Abnormally High BUN</td>
<td>0.0% (0/170)</td>
<td>1.3% (2/160)</td>
<td>0.234</td>
</tr>
<tr>
<td>Other</td>
<td>4.1% (7/170)</td>
<td>3.1% (5/160)</td>
<td>0.772</td>
</tr>
</tbody>
</table>
The entire access circuit, from the AV anastomosis to the superior vena cava should ideally be imaged, particularly to exclude occult central venous stenoses.
Edited Live Case

IN.PACT AV IDE Trial clinical cases – utilized IN.PACT AV balloon not available in Europe
Edited Live Case – Post-procedure Outcome

- Dialysis commenced immediately post-procedure
- Blood flow and venous pressures normal at 6 months
- Duplex US satisfactory at 3 and 6 months
- Routine AV access contrast study at 8 months satisfactory

12.12.18
Conclusions

- Stenosis is a major challenge to AV access circuit patency
- The IN.PACT AV Access IDE RCT has, for the first time shown a highly significant target lesion and access circuit patency compared to plain balloon angioplasty
- HP balloon angioplasty followed by DCB angioplasty holds considerable promise in improving AV access patency and dialysis patients quality of life
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