Challenges in AV Access Maintenance: Treating the Cephalic Arch

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Disclosures
Jeffery Hull, MD

I have the following potential conflicts of interest to report:

- Consulting: Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest
Cephalic Arch Challenges
Central Venous Stenosis

- CVS present in 51% of AVF and AVG patients
- 19.4% (97/500) Symptomatic
- Relationship between Symptoms and Collaterals
- Grading system 0-3 based on size, density and number

Cephalic Arch Challenges

Stenosis

- Calviculopectoral fascia
- Deltopectoral fascia
- External restriction results in increased pressure and turbulence

Cephalic Arch Challenges

Causes:

- 4 zones of the cephalic arch
- External compression
- Neointimal hyperplasia
Cephalic Arch Challenges
Stenosis

- Biomechanical factors can cause stenosis in addition to compression
- High flow
- WSS and curve of arch

Cephalic Arch Treatment
High Flow Fistulas

- 19 Patients with CVO
- Fistulae with controlled flow
- Radial artery when possible or small brachial anastomosis
- Flow 415-910 mL/min
- 42% (8/19) developed Edema

AV Access Continuum of Care
Preserve Future Targets and Extend Current Access Longevity

Preoperative Evaluation, Screening & AVF Creation (Open or Percutaneous)

AVF Access Maintenance and Salvage
- PTA
- DCB
- Endovascular Graft

Open Revision Transposition
Jump Graft
Costoclavicular Bypass

Abandonment
IN.PACT AV Access Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion 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>Lesion Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De Novo</td>
<td>30.0% (51/170)</td>
<td>30.6% (49/160)</td>
<td>0.905</td>
</tr>
<tr>
<td>Restenotic</td>
<td>70.0% (119/170)</td>
<td>69.4% (111/160)</td>
<td></td>
</tr>
<tr>
<td>Target Lesion Location</td>
<td></td>
<td></td>
<td>0.310</td>
</tr>
<tr>
<td>Arterial Inflow</td>
<td>2.4% (4/170)</td>
<td>4.4% (7/160)</td>
<td></td>
</tr>
<tr>
<td>Anastomosis</td>
<td>25.9% (44/170)</td>
<td>25.0% (40/160)</td>
<td></td>
</tr>
<tr>
<td>Swing Point</td>
<td>8.2% (14/170)</td>
<td>7.5% (12/160)</td>
<td></td>
</tr>
<tr>
<td>In Cannulation Zone</td>
<td>14.7% (25/170)</td>
<td>7.5% (12/160)</td>
<td></td>
</tr>
<tr>
<td>Venous Outflow</td>
<td>31.2% (53/170)</td>
<td>33.1% (53/160)</td>
<td></td>
</tr>
<tr>
<td>Cephalic Arch</td>
<td>17.6% (30/170)</td>
<td>22.5% (36/160)</td>
<td></td>
</tr>
</tbody>
</table>

DCB, drug-coated balloon; PTA, percutaneous transluminal angioplasty
1. Target lesion location was site-reported
2. Lesion definitions:
   - **Arterial Inflow**: treated segment is isolated to the arterial side
   - **Anastomosis**: treated segment crosses or meets the AV anastomosis
   - **Swing Point**: treated segment includes the curved segment of mobilized vessel
   - **In Cannulation Zone**: treated segment is isolated to straight segment of vessel where cannulation is performed
   - **Venous Outflow**: treated segment is in basilic vein (non-mobilized) or distal to the cephalo-axillary junction
   - **Cephalic Arch**: treated segment includes curved segment of cephalic vein as the vein crosses between the pectoralis major and deltoid muscles

IN.PACT AV DCB is approved in the United States, Canada, and Japan for treatment, after appropriate vessel preparation, of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.
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Lookstein, R.  VIVA 2020

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>IN.PACT AV DCB</th>
<th>Standard PTA</th>
<th>Difference [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion Type</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>De Novo (51/49)</td>
<td>90.7% (39/43)</td>
<td>75.6% (34/45)</td>
<td>15.1% [-0.1%, 30.4%]</td>
</tr>
<tr>
<td>Restenotic (119/111)</td>
<td>78.9% (86/109)</td>
<td>52.4% (54/103)</td>
<td>26.5% [14.2%, 38.8%]</td>
</tr>
</tbody>
</table>

**Favors PTA**  **Favors DCB**
<table>
<thead>
<tr>
<th>Covered Stents</th>
<th>DCB</th>
<th>BMS</th>
</tr>
</thead>
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<tr>
<td>Covered Stents</td>
<td>IN.PACT Admiral™ DCB</td>
<td>IN.PACT AV DCB</td>
</tr>
<tr>
<td>DCB</td>
<td>IN.PACT</td>
<td>IN.PACT</td>
</tr>
<tr>
<td>BMS</td>
<td>Luotonix™ 035</td>
<td>IN.PACT AV Wallstent™ endoprosthesis</td>
</tr>
</tbody>
</table>

**Author**
- Kitrou [1]
- Falk [2]
- Vesely [3]
- Dolmatch [4, 5]
- Haskal [6]
- Yang [7]
- Katsanos [8, 9]
- Lucev [10]
- Trerotola [12, 13]
- Lookstein [14, 15]
- Hoffer [16]
- Shemesh [17]

**Study Device**
- Covered Stent
- Fluency™ Plus stent graft
- Viabahn™ endoprosthesis
- Covera
- Flair™ stent graft
- N/R
- IN.PACT Admiral™ DCB
- Prospective RCT
- Prospective RCT
- Prospective RCT
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**# Patients**
- 64
- 275
- 293 (Graft:145, PTA:148)
- 280 (Graft:142, PTA:138)
- 190
- 98
- 40
- 62
- 64
- 285 (DCB:141, PTA:144)
- 330 (DCB:170, PTA:160)
- 34
- 25

**Access Type**
- AVG
- AVG/AVF (ISR)
- AVG
- AVG
- AVF
- AVF
- AVF
- AVG

**Endpoint**
- Primary Patency
- Access Circuit Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency
- Primary Patency

**6-mo Results**
- PTA: 4.5% p<.001
- PTA: 34.2% p=0.006
- PTA: 47.9% p=.001
- PTA: 23% p<.001
- PTA: 27.8%
- PTA: 25% p<0.001
- PTA: 61.3%;p=0.016
- PTA: 65%;p=.76 PTA: 63% p=0.057
- PTA: 59.0% p<0.001
- PTA: 128 day

**12-mo Results**
- PTA: 21.2% p<.001
- PTA: 7.8%
- PTA: 5% p<0.001
- PTA: 35% p=0.045
- PTA: 46.3% p=0.001
- BMS: 0, p=0.0023

**24-mo Results**
- PTA: 10.4% p<.001
- PTA: 24.4% p=0.087

**Results are not directly comparable. Primary patency rates may be defined differently. Information provided is for illustration purposes only, and may differ in head-to-head comparison.**

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IN.PACT Admiral DCB is approved for treatment of obstructive lesions of arteriovenous dialysis fistulae in the European Union. Please consult the approved product labeling and indications for use for your region or country as indicated within the respective product manual.

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4. Dolmatch B. LINC 2020; Leipzig, Germany.
5. Dolmatch B. CIRSE; 2020; Virtual.
15. Holden A. LINC 2020; Leipzig, Germany.
Edge Stent Subclavian Vein Occlusion

Images courtesy Jeffrey Hull, MD
Ellipsys System Fistula May 2016
Prolonged Bleeding October 2017
Low Flow Arch Stenosis June 2020
Target Lesion Primary Patency Through 12 Months

Log-rank p-value < 0.001

Time After Index Procedure (Days)

Number at risk

170 130 83
160 101 55

IN.PACT AV DCB
Standard PTA

Holden, A. LINC 2020
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<td><strong>Target Lesion Location</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Arterial Inflow (4/7)</td>
<td>75.0% (3/4)</td>
<td>50.0% (3/6)</td>
<td>25.0% [-33.3%, 83.3%]</td>
</tr>
<tr>
<td>Anastomosis (44/40)</td>
<td>84.6% (33/39)</td>
<td>50.0% (19/38)</td>
<td>34.6% [15.1%, 54.1%]</td>
</tr>
<tr>
<td>Swing Point (14/12)</td>
<td>83.3% (10/12)</td>
<td>75.0% (9/12)</td>
<td>8.3% [-24.0%, 40.7%]</td>
</tr>
<tr>
<td>In Cannulation Zone (25/12)</td>
<td>78.3% (18/23)</td>
<td>63.6% (7/11)</td>
<td>14.6% [-18.4%, 47.7%]</td>
</tr>
<tr>
<td>Venous Outflow (53/53)</td>
<td>81.6% (40/49)</td>
<td>70.2% (33/47)</td>
<td>11.4% [-5.6%, 28.4%]</td>
</tr>
<tr>
<td>Cephalic Arch (30/36)</td>
<td>84.0% (21/25)</td>
<td>50.0% (17/34)</td>
<td>34.0% [11.9%, 56.1%]</td>
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Brachiocephalic Fistula
Prolonged Bleeding

Images courtesy Jeffrey Hull, MD
High Bifurcation Ulnarcephalic Fistula
Prolonged Bleeding
**Cephalic Arch**

**Summary of Challenges**

- Unique anatomy prone to external compression and intimal hyperplasia
- Intimal hyperplasia can be reduced with lower flow and paclitaxel
- Stenting has issue with small size, subclavian vein stenosis and permanent implant

**Other options:**

- Costoclavicular bypass
- Cephalic turndown