Current Optimal Treatment Of Aortic Coarctation: When Endo, When Open: Bare vs. Covered Stents: Which Covered Stent Is Best: Precautions And Long-Term Results

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Potential conflicts of interest
Speaker’s name: Elchanan Bruckheimer

- Consulting (Maquet Getinge, NH)
- Consulting (Bentley, Germany)

Repair of Coarctation
- Surgical repair is effective with low procedural mortality and morbidity
- Stent implantation is effective with very low procedural mortality and low morbidity
- Both methods are complicated long term by hypertension, reintervention for stenosis and aneurysm formation due to abnormal wall with post stenotic dilation, cystic medial necrosis, calcification…
- Potential advantages of covered vs. bare stents vs. angioplasty to prevent AWI
  - reduction of the extent of intimal tear
  - creation of longitudinal framework for endothelial growth
  - control over integrity of vessel wall at coarc and below
  - usefulness when aneurysm is present or there is a risk

are suggested by the data but not proven – especially long term

Aortic Wall Injury Related to Endovascular Therapy for Aortic Coarctation

Jacqui T. Truex, MD; Thomas R. Jones, MD; Daf B. McElhinney, MD

- Aortic rupture after endovascular treatment for CoA, including angioplasty alone, bare metal stenting, and primary covered stent therapy… the incidence is substantially <1%.
- Acute aneurysm formation was 0% to 13% after angioplasty, 0% to 5% after bare metal stent placement, and <1% after covered stent placement. The reported incidence and natural history of AWI during follow-up after endovascular therapy in CoA varies considerably, likely secondary to ascertainment and reporting biases and inconsistent definitions.
- Although AWI after endovascular treatment of CoA seems to be declining in frequency, it remains one of the most important potential adverse outcomes. Long-term surveillance for new AWI and monitoring of existing AWI is mandatory, with institution of appropriate treatment when necessary.

Coarctation of Aorta - Covered Stents

Covered stents – need to consider:
- Vascular access damage due to large delivery systems
  - 12mm - Atrium, Bentley 9Fr
  - CP 11-12Fr
- Stent Integrity
  - CP - Platinum-Iridium – Fractures
  - Atrium - SS – Infolding
  - Bentley – CoCr – Strong radial force
- Covering Integrity
  - CP - incomplete sealing of leaks
  - Atrium, Bentley – complete cover
COAST I: [BARE]

A total of 105 patients underwent attempted implantation of an uncovered stent, with 104 successes. All patients experienced immediate reduction in upper-to-lower extremity blood pressure difference.

- There were no serious AEs and no deaths.
- Four patients were found to have small aortic aneurysms on angiography following compliance testing. All were clinically stable. NuMED Covered CP stents were implanted for CoA therapy and to prevent further AWI. One patient developed a localized dissection after CP stent implant with perhaps a small aneurysm at its upper margin.
- One CP stent migrated distally.
- 2 serious access site complications

COAST II: [COVERED]

A total of 158 patients with 83 having pre-existing AWI.

- Complete coverage of pre-existing AWI was achieved in 76 of 83 patients (92%); 7 patients had minor endoleaks.
- Four patients experienced important access site vascular injury.
- There were no acute AWI, repeat interventions, or deaths.
- Conclusions: The CCPS can effectively treat and potentially prevent AWI associated with CoA. Access site arterial injury is the most common important complication. Longer-term follow-up is necessary to define mid- and late-term outcomes.

**Advanta V12LD CoArc Trial**

70 patients with a diagnosis of native or recurrent coarctation of the aorta enrolled prospectively for stent implantation.

<table>
<thead>
<tr>
<th></th>
<th>Before Implantation Mean ± SD</th>
<th>After Implantation Mean ± SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AscAo systolic blood pressure (mmHg)</td>
<td>114.2 ± 24.0</td>
<td>111.0 ± 24.7</td>
<td>0.27</td>
</tr>
<tr>
<td>DescAo systolic blood pressure (mmHg)</td>
<td>78.7 ± 17.6</td>
<td>105.0 ± 23.9</td>
<td>&lt;0.0001</td>
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<tr>
<td>Mean peak gradient(mmHg)</td>
<td>35.8 ± 16.0</td>
<td>5.4 ± 7.8</td>
<td>&lt;0.0001</td>
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<tr>
<td>Mean minimal lumen diameter (mm)</td>
<td>5.5 ± 3.6</td>
<td>13.1 ± 3.2</td>
<td>&lt;0.0005</td>
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**Efficacy using Advanta™ V12 (CoArc Study) as Measured by Blood Pressure**

<table>
<thead>
<tr>
<th></th>
<th>Baseline Mean ± SD (n)</th>
<th>Discharge Mean ± SD (n)</th>
<th>1 Year Mean ± SD (n)</th>
<th>2 Year Mean ± SD (n)</th>
<th>3 Year Mean ± SD (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Extremity SBP (mmHg)</td>
<td>144.3±17.7 (70)</td>
<td>128.5±16.9 (68)</td>
<td>123.5±14.7 (66)</td>
<td>125.3±14.8 (66)</td>
<td>128.5±15.2 (63)</td>
</tr>
<tr>
<td>Lower Extremity SBP (mmHg)</td>
<td>107.9±23.9 (66)</td>
<td>124.7±19.4 (67)</td>
<td>119.6±20.6 (65)</td>
<td>124.2±20.8 (65)</td>
<td>123.9±17.8 (61)</td>
</tr>
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A reduction in the systolic gradient was sustained throughout 3 years of follow up.

**CoArc: CT and V12 related MAVE**

- 61 follow up CT scans [86%] at ~12 months post procedure
  
<table>
<thead>
<tr>
<th>CIA at 12 months F/U</th>
<th>MILD in stent CoA Diameter (mm)</th>
<th>Proximal Arch Reference (mm)</th>
<th>CoA/Dia ratio</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.25 +/- 2.08</td>
<td>15.29 +/- 2.89</td>
<td>0.91 +/- 0.10</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
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</table>

- MAVE acute 1.4% - 1 femoral artery occlusion - Mx
- MAVE 12 months 4.3%
  - 1 aortic hematoma treated with a second stent
  - 1 patient had a small aneurysm at distal edge of treated with a second stent 2 months later

- At 12 months there was no new AWI on CT
- 3 patients had late (>1 yr) stent in folding requiring re-intervention
  - 2 of which were urgent

**Bentley Aortic BeGraft**

9 yr old girl with native CoA treated with BeGraft
Bentley Aortic BeGraft

10 yr old girl with CoA s/p endovascularitis and aneurysm

Bentley Aortic BeGraft

CoA endovascularitis, aneurysm s/p CP covered with leak treated with BeGraft

Bentley BeGraft for CoA

- 22 pts [18M, 4F] , median age 17.3 yrs [5.7-38.1] , weight 62.1kg [19.2-104.7]
- CoA [9 native, 6 surgical repair, 8 stent, 2 with aneurysms Tx CP stent]
- BeGraft Aortic [12 or 14mm] via a 9-11Fr, femoral artery, implanted and post dilated through the delivery sheath.
- Systolic peak gradient decreased from 15.3±7.0 to 3.5 ±3.1mmHg [p=0.001]
- CoA diameter increased from 9.2±3.5 to 15.7±0.2mm [p=0.0001].
- There was no acute aortic wall injury nor other immediate complications
- 2 patients underwent successful occlusion of the pre-existing aneurysms.
- At median follow up of 14.2 [1.5-22.4] months all patients are alive and well with normal femoral pulses and are normotensive.

Conclusions

- Surgery is the primary choice of intervention in patients who endovascular stenting is not possible [infants and small children]
- Covered stents are safe and effective for acute treatment of coarctation of the aorta and associated with less AWI than BMS and balloon angioplasty
- Reintervention for further dilation is often required
- Choice of covered stent - need to consider
  - Delivery system – sheath size
  - Maximal diameter of stent
  - Stent integrity - fracture / infolding
  - Covering integrity - incomplete sealing of leaks
- Long term follow up imaging is essential