Transcatheter Therapy for Coarctation of the Aorta: The Results of Our Efforts

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No conflicts relevant to this presentation
Supporters of the CCISC

B Braun
Cook
Gore
Medtronic

NuMed
Siemens
St Jude Medical
PediaVascular
Safety and Efficacy: The Data

Tough to make fair comparisons in the contemporary literature due to evolution in treatment

Surgery 70 years / Transcatheter 25 years

Stent CCISC, COAST
Surgical: literature, CCISC

CCISC = Congenital Cardiovascular Interventional Study Consortium
COAST = COA rctation Stent Treatment STUDY
Stent Placement versus Surgery for Coarctation of the Thoracic Aorta

976+3 Studies
Remove duplicates

743
Screen titles and abstracts for obvious irrelevance

18
Secondary Screening:
Multiple reports of Same study Cohort

“We planned ……”

5
Full text review for eligibility

0
Stent /Surgery
Current Realities

- 99.1% of patients in the CCISC Consortium with recurrent coarctation of the aorta, regardless of the location or complexity underwent transcatheter therapy

- The vast majority would agree that surgery remains the “gold standard” in neonates (though stent treatment has been used in selective neonates with complex aortic obstruction)

- Covered stents (CP) have only recently become available in the United States
“Pseudo” Meta Analysis
Surgery versus Balloon Angioplasty

• 9 Studies of 625 pts; 378 Sx / 245 BA
• No Difference in Post intervention gradient – Immediate, Mid-term Long term

• BA more short-term reCoa: OR 0.25 [0.12-0.54]
• BA less severe complications: OR 2.67 [1.37-5.21]
• BA more aneurysm formation OR 0.12 [0.04-0.34]

Pediatric Cardiac Care Consortium
1982 - 2007

• 7860 pts had a coa repair reported 1982-2007: 70% isolated coarctation
 45% were done in first 30 days

• Hypoplastic arch 4.6%; Mortality 10.6%

• Mortality of isolated coa 2.0%

  Operative year was a significant variable

STS-CHSD
2006-2010

• 2705 pts/95 centers with Isolated Coa +/- TAH
• 75% < 1 year of age at time of repair
• 90% End to end / Extended end to end

• Operative Mortality 1%
• Complications in 25%
• No long term follow-up

RM Ungerleider et al. JTCVS
Evolution of Surgical Repairs by Decade
Mayo Clinic Experience of over 800 patients

Surgical Repairs by Age
CCISC Experience in Native Coarctation

Years at Surgery

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Tube Graft</th>
<th>Subclav Flap</th>
<th>Patch</th>
<th>End-to-End</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 to 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 to 12</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>12 to 16</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>&gt; 16</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# CCISC Surgery / Stent Data

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Surgery (n = 99)</th>
<th>Balloon (n = 144)</th>
<th>Stent (n = 349)</th>
<th>p-value (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years; mean ± SD)</td>
<td>9.4±8.7</td>
<td>9.0±8.0</td>
<td>16.4±10.9</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Weight (kg; mean ± SD)</td>
<td>33.6±22.7</td>
<td>30±21</td>
<td>53.5±24.1</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Male (vs. Female %)</td>
<td>70%</td>
<td>64%</td>
<td>67%</td>
<td>0.715</td>
</tr>
<tr>
<td>Pre-Intervention Right-arm Sys. BP (mmHg; mean ± SD)</td>
<td>136±19</td>
<td>138±23</td>
<td>142±21</td>
<td>0.009*</td>
</tr>
<tr>
<td>Pre-Intervention ULG (mean ± SD)</td>
<td>36±21</td>
<td>43±23</td>
<td>40±23</td>
<td>0.167</td>
</tr>
<tr>
<td>Coarctation Location (%)</td>
<td></td>
<td></td>
<td>0.004*</td>
<td></td>
</tr>
<tr>
<td>Isthmus</td>
<td>82%</td>
<td>95%</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>48%</td>
<td>63%</td>
<td>72%</td>
<td></td>
</tr>
<tr>
<td>Proximal</td>
<td>34%</td>
<td>32%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Transverse Aorta</td>
<td>12%</td>
<td>2%</td>
<td>9%</td>
<td></td>
</tr>
<tr>
<td>Complex</td>
<td>5%</td>
<td>2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Abdominal/Thoracic Aorta</td>
<td>0%</td>
<td>2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Bicuspid Aortic Valve (%)</td>
<td>46%</td>
<td>46%</td>
<td>41%</td>
<td>0.351</td>
</tr>
<tr>
<td>Shone</td>
<td>0%</td>
<td></td>
<td>1%</td>
<td>0.580</td>
</tr>
<tr>
<td>Other CHD Diagnosis (%)</td>
<td>11%</td>
<td>5%</td>
<td>9%</td>
<td>0.564</td>
</tr>
</tbody>
</table>

* P-value < 0.05
Any Difference in Efficacy?
Acute Blood Pressure Changes

Pre vs Post Clinical BP’s-Surgery (n=99)

Pre vs Post Clinical BP’s-Stent (n=349)
Any Difference in Efficacy?
Comparisons at Intermediate Follow-up

Clinical Parameters
- Normal BP
- Anti-Hypertensive Meds
- ULG < 10 mmHg
- ULG < 15 mmHg

Percent Patients
- Surgery (48)
- Stent (169)
- COAST Stent (87)
## CCISC Complications Data

### Table 3: Acute Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Surgery (n = 99)</th>
<th>Balloon (n = 144)</th>
<th>Stent (n = 349)</th>
<th>p-value (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Intervention Right-arm Sys. BP (mmHg; mean ± SD)</td>
<td>119 ± 14</td>
<td>118 ± 15</td>
<td>124 ± 16</td>
<td>0.013*</td>
</tr>
<tr>
<td>Discharge ULG (Mean ± SD)</td>
<td>5.1 ± 17.2</td>
<td>10.3 ± 12.9</td>
<td>4.1 ± 13.6</td>
<td>0.643</td>
</tr>
<tr>
<td>Discharge ULG ≤10 mmHg (%)</td>
<td>72%</td>
<td>56%</td>
<td>78%</td>
<td>0.288</td>
</tr>
<tr>
<td>Discharge ULG ≤15 mmHg (%)</td>
<td>79%</td>
<td>69%</td>
<td>84%</td>
<td>0.228</td>
</tr>
<tr>
<td>Any Complications (%)</td>
<td>19.2%&lt;sup&gt;1&lt;/sup&gt;</td>
<td>9.8%</td>
<td>2.0%</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Aortic Wall Complications (%)</td>
<td>UK&lt;sup&gt;2&lt;/sup&gt;</td>
<td></td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>Balloon Rupture (%)</td>
<td>n/a</td>
<td>0.0%</td>
<td>0.3%</td>
<td></td>
</tr>
<tr>
<td>Stent Migration (%)</td>
<td>n/a</td>
<td>n/a</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>Femoral (%)</td>
<td>UK&lt;sup&gt;2&lt;/sup&gt;</td>
<td>0.0%</td>
<td>0.6%</td>
<td></td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Severe/Prolonged Hypertension</td>
<td>2%</td>
<td>0%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Length of Stay in days (mean/median)</td>
<td>6.1 / 5.0</td>
<td>3.6 / 1.0</td>
<td>2.4 / 1.0</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

<sup>1</sup> Complications experienced by surgical patients are: severe/prolonged hypertension, atrial fibrillation, stroke, chylothorax, and vocal cord paralysis.

<sup>2</sup> "UK" indicates unknown as these types of complications are not routinely evaluated for surgical patients.

* P-value < 0.05
Evolution of Stent Complications

Acute Complication Trend in Stenting Coarctation of the Aorta

- Prior Jan 2002 (n=312)
- Post Jan 2002 (n=275)
- CCISC Prospective (n=551)

Percentage

- All Comp
- Aortic Wall Comp
- Technical Comp
Aneurysms
Aneurysm Formation Following Surgical Coarctation Repair

Type A Aneurysm

Associated with bicuspid aortic valve

Local Aneurysm @ Coarctation Site

Aneurysm Formation Following Surgical Coarctation Repair Meta Analysis

Overall aneurysm rate for all repairs 9%

End-to-End Anastomosis lowest risk for developing aneurysms (3%; 0-26.8%)
  • “Simple Coarctation” of the aorta

Patch: highest risk for aneurysms (14%; 3-51.7%)

Tube graft: (6%; 0-10.7%)
  • Higher for Type A aneurysms and dissections

## CCISC Results

Intermediate Integrated Imaging F/u mean 36.2 months (18.1-92)

### Table 5b: Intermediate Follow-up Outcomes by Integrated Imaging

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Surgery (n = 29)</th>
<th>Balloon (n = 16)</th>
<th>Stent (n = 106)</th>
<th>p-value (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Complications¹</td>
<td>20.7%</td>
<td>43.8%</td>
<td>10.4%</td>
<td>0.202</td>
</tr>
<tr>
<td>Aortic Wall Injury (%)</td>
<td>10.3%</td>
<td>43.8%</td>
<td>4.7%</td>
<td>0.368</td>
</tr>
<tr>
<td>Dissection / Intimal Tear (%)</td>
<td>0.0%</td>
<td>6.3%</td>
<td>1.0%</td>
<td>1.000</td>
</tr>
<tr>
<td>Aneurysm (%)</td>
<td>10.3%</td>
<td>43.8%</td>
<td>3.8%</td>
<td>0.169</td>
</tr>
<tr>
<td>Coarct / Dao ≥ 0.6</td>
<td>88.5%</td>
<td>93%</td>
<td>90.7%</td>
<td>0.716</td>
</tr>
<tr>
<td>Any Re-obstruction</td>
<td>17.2%</td>
<td>18.8%</td>
<td>9.4%</td>
<td>0.257</td>
</tr>
<tr>
<td>Mild²</td>
<td>6.9%</td>
<td>18.8%</td>
<td>6.6%</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>6.9%</td>
<td>0%</td>
<td>0.9%</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>3.5%</td>
<td>0%</td>
<td>1.9%</td>
<td></td>
</tr>
</tbody>
</table>

¹ Defined as any moderate to severe reobstruction, aortic wall injury (aneurysm, dissection, intimal tear) or stent fracture.

² Mild reobstruction was not considered as a complication in our analysis.

* P- value < 0.05
COAST Trial

• Aneurysm formation
  – 4/112 (3.5%) Acutely, 2 received Covered Stents
  – 1 noted at 12 month f/u, received Covered Stent
Aneurysm Formation

Location

For aneurysms at the coarctation site, *only* aneurysms located at the *greater curvature* of the aortic arch or “down stream” in the anterior aorta for Type A dissections have shown progression at intermediate follow-up.
Aneurysm Location

Dacron Patch Repair

Greater curvature of the arch

10 cm
Aneurysm Location

“Down Stream” anterior aorta
Stent Aneurysm Location

6 months
How about Re-obstruction?
## CCISC Results

### Re-intervention

**Table 6: Re-intervention**

<table>
<thead>
<tr>
<th></th>
<th>Surgery (n = 99)</th>
<th>Balloon (n = 144)</th>
<th>Stent (n = 349)</th>
</tr>
</thead>
<tbody>
<tr>
<td># Patients with any re-Intervention Procedures</td>
<td>8 (8%)</td>
<td>20 (14%)</td>
<td>81 (23%)</td>
</tr>
<tr>
<td># Patients with planned procedures</td>
<td>2</td>
<td>4</td>
<td>59</td>
</tr>
<tr>
<td># Patients with unplanned procedures</td>
<td>6 (6%)</td>
<td>16 (11%)</td>
<td>22 (6.3%)</td>
</tr>
<tr>
<td>Time to first planned re-intervention, yrs</td>
<td>6.8 ± 8.7</td>
<td>1.6 ± 1.7</td>
<td></td>
</tr>
<tr>
<td>Time to first unplanned re-intervention, yrs</td>
<td>2.9 ± 2.0</td>
<td>3.0 ± 1.4</td>
<td></td>
</tr>
</tbody>
</table>
What do we mean by Complex Aortic Arch?  
(This is a take home message)

• Any coarctation of the aorta with associated aortic aneurysm  
  — By far most common (CCISC 2003 to June 2015)

• Narrowing of the aortic arch that includes transverse arch hypoplasia (TAA:Desc Aor ratio < 0.6)  
  — Distant second

• Interrupted aortic arch/tortuosity

• Long segment coarctation (> 5 mm in length) described by some surgical papers

• Anyone over the age of 21 yrs with any type of coarctation of the aorta, regardless of anatomy
Stents in Complex Aortic Arches Survival

Summary

• Transcatheter therapy is here to stay
• Acute complications seem to favor transcatheter treatment of native coarctation of the aorta
• Planned Re-interventions similar for transcatheter and surgery at 1 and 3 year follow-up
• Aneurysm appears to favor Stent over Surgery, especially when end-to-end repair can’t be performed
• Adults are always “complex”
• House of God Rule #10: If you don’t take a temperature: You can’t find a fever