The Case for Stenting Coarctation of the Aorta

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John Moore MD, MPH

The following relationships exist related to this presentation:

COAST I and II Site PI

Off label use of products will be discussed in this presentation.
Coarctation of the Aorta

**BACKGROUND**

- 7% CHD
  - Males, Turner’s, Whites
- Associated cardiac conditions:
  - BAV, AS, VSD, PDA,
  - Shone’s, HLSH
  - Complex Heart Disease
Pathology of Coarctation

- Thickened ridges of intima and media
- Protrude posteriorly and laterally resulting in narrowing of lumen
- Distal disruption of elastic tissue and cystic medial necrosis
Clinical Classification

- “Milder” Coarctation with better developed isthmus
- Presents later with HTN, claudication, HA, chest pain, sudden death
- Associated with: aneurysms, aortic dissection, chronic HTN, cardiomyopathy, stroke, aortic valve disease
- Appropriate for Stenting
Clinical Classification

Also Associated with:

Cerebral Aneurysms:

Adult Type
Aneurysms in Coarctation

ICA’s found in 10.3% (2.3% of Gen Pop)
Surgery: The time-tested "Gold Standard"
First Report: 1945

- Developed Nearly Simultaneously
- Crafoord (Sweden) 1944
- Gross (Boston) 1945

Crafoord, J Thorac Surg, 1945
Gross, N Engl J Med, 1945
Survival with Coarctation

Natural History

Campbell, BHJ, 1970

Natural History after “successful Surgery”

Bobby, BHJ, 1991
- Class I indication for Stenting **Recurrent Coarctation** (general agreement)
- Class IIa indication for Stenting **Native Coarctation** (weight of evidence and opinion favors)
- Level of Evidence: B (data from single trial and non-randomized studies)

Feltes, Circulation, 2011
CONCLUSIONS AND RECOMMENDATIONS

Although treatment of coarctation of the aorta with balloon-expandable endovascular stents is technically challenging, it is a relatively safe and extremely effective treatment modality when used carefully in appropriate patients. It is clear that further research including universal follow-up imaging is necessary to determine incidence of and risk factors for various complications. Disclosure and analysis of this data will dictate guidelines for safer and more successful procedures.

In the meantime, our recommendations are as follows: 1) Surgery is the treatment of choice for all native coarctation and balloon angioplasty is the treatment of choice for most recurrent coarctation in infants and children less than a year of age. 2) Between the ages of 1 year and the time when the child reaches a weight of 30–35 kg (usually 9–11 years of age for boys and girls), there is insufficient data to determine whether surgical intervention or balloon angioplasty is preferable for native lesions. It is likely that balloon angioplasty is the treatment of choice in this age group for recurrent coarctations. 3) In children weighing more than 35 kg who have not yet reached adult size, it is likely that the treatment of choice for native and recurrent lesions should be endovascular stent placement, as it has been demonstrated that these can be further enlarged at a later time to accommodate somatic growth of the patient. 4) In adult-sized adolescents and adult patients, stent placement is the treatment of choice for all lesions, native and recurrent. 5) In adults of advanced age, and in young adults with known vasculitis or other conditions associated with vasculopathy, of which Turner syndrome is one [28], particular care should be taken in stent placement, as these patients carry a high relative risk of life-threatening complications.

Stents Available in US

Ev3 Max LD

CP Stents
First Report: 1995

- Suarez de Lezo (Spain)
- (Developed Simultaneously in US)

Am Heart J, 1995
Endovascular Stents for Coarctation of the Aorta: Initial Results and Intermediate-Term Follow-Up

- 34 patients
- Mean f/u 29 months

Hamdan, J Am Coll Cardiol 2001
153 patients

Median f/u 2.5 years

Qureshi, Cardiol Young 2007
Prospective Registry Study, 34 centers

302 patients (2000-2009)

21% completed Long-Term FU (>18 mo)

Holzer and CCISC invest. CCVI, 2010
No long-term survival data!

Initial and Six-Year Results of Stent Implantation for Aortic Coarctation in Children.

Thanopoulos BD, Giannakoula G, Giannopoulos A, Galdo F, Tsaoussis GS.
Department of Interventional Paediatric Cardiology, Iatrikon Medical Center, Athens, Greece.

Abstract

Although stenting has been used as a treatment option for aortic coarctation (CoA) at increasingly younger ages, limited information is available on the long-term follow-up of stent implantation for CoA in pediatric patients. A total of 74 patients with CoA (mean age 8 ± 3 years) underwent stent implantation; 42 were treated for isolated native CoA and 32 for recurrent CoA. A total of 87 stents were implanted (bare metal stents in 71 patients and covered stents in 3 patients). Redilation of a previously implanted stent was performed in 32 patients. Immediately after stenting, the peak systolic pressure gradient decreased from 68 ± 16 mm Hg to 8 ± 5 mm Hg (p <0.05), and the CoA diameter increased from 5 ± 3 mm to 16 ± 3 mm (p <0.05). The most important procedural complication was aneurysm formation in 1 patient that was successfully treated with implantation of a covered stent. No early or late deaths occurred and no evidence was found of late aneurysm formation during a follow-up period of 6 years. Late stent fracture was observed in 3 patients. At the end of follow-up, no cases of recoarctation were identified on multislice computed tomography or magnetic resonance imaging, and 67 (85%) of the 74 patients were normotensive, receiving no medications. In conclusion, stent implantation is an effective and safe treatment alternative to conventional surgical management for the treatment of CoA in selected pediatric patients.
Summary of Data from Combined Series on Stenting Coarctation

- Approximately 1500 cases published to date
- Majority of Cases have been teenagers and adults
- Complete abolishment of resting systolic gradient in > 95%
- Restenosis does not appear to be a problem except as it pertains to “growth”
- Major complications rare, reported mortality << 1%, need for emergency surgery < 1%, late aneurysm in < 4 %
- Clinical F/u Limited
Comparison of Surgical, Stent, and Balloon Angioplasty Treatment of Native Coarctation of the Aorta

An Observational Study by the CCISC (Congenital Cardiovascular Interventional Study Consortium)

Thomas J. Forbes, MD,* Dennis W. Kim, MD, PhD,† Wei Du, PhD,* Daniel R. Turner, MD,*† Ralf Holzer, MD,‡ Zahid Amin, MD,¶ Ziyad Hijazi, MD,¶ Abdolrahim Ghasemi, MD,§ Jonathan J. Rome, MD,∥ David Nykanen, MD,# Evan Zahn, MD,# Collin Cowley, MD,** Mark Hoyer, MD,†† David Waight, MD,## Daniel Gruenstein, MD,§§ Alex Javois, MD,‖‖ Susan Foerster, MD,¶¶ Jacqueline Kreutzer, MD,¶¶ Nancy Sullivan, MS, CCRC,* Asra Khan, MD,* Carl Owada, MD,*** Donald Hagler, MD,††† Scott Lim, MD,§§§ Joshua Canter, MD,‖‖‖ Thomas Zellers, MD,¶¶¶ and the CCISC Investigators

Detroit, Michigan; Atlanta, Georgia; Columbus and Akron, Ohio; Tehran, Iran; Philadelphia and Pittsburgh, Pennsylvania; Chicago and Oak Lawn, Illinois; Orlando and Miami, Florida; Salt Lake City, Utah; Indianapolis, Indiana; Minneapolis and Rochester, Minnesota; St. Louis, Missouri; Fresno, California; Dallas, Texas; Charlottesville, Virginia; and Washington, DC
Comparison of Surgical, Stent, and Balloon Angioplasty Treatment of Coarctation of the Aorta

- Only “Head to Head” Comparative Study
- Prospective multi-center (36) observational study with patient enrollment between 2002 to 2009
- 350 patients > 10 Kg with Coarctation of Aorta
- 217 stent, 72 surgery, (61 angioplasty)
- Baseline, Acute, Short-term (3-18 months) and intermediate term (> 18 months) efficacy and safety data
## Demographics and Hemodynamic Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>Surgery</th>
<th>Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)</td>
<td>55*</td>
<td>35</td>
<td>30</td>
</tr>
<tr>
<td>R Arm BP (mm Hg)</td>
<td>143</td>
<td>137</td>
<td>138</td>
</tr>
<tr>
<td>Baseline ULG</td>
<td>40</td>
<td>37</td>
<td>43</td>
</tr>
<tr>
<td>Acute ULG</td>
<td>4.9</td>
<td>7.7</td>
<td>10.3</td>
</tr>
<tr>
<td>Short-term ULG</td>
<td>0.9</td>
<td>1.2</td>
<td>9.9*</td>
</tr>
<tr>
<td>Intermediate ULG</td>
<td>1.9</td>
<td>-1.4</td>
<td>5.5</td>
</tr>
</tbody>
</table>

* P < .05

Forbes et al, JACC 2011
### Imaging Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>Surgery</th>
<th>Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute (Any) Re-obstruction</strong></td>
<td>15 %</td>
<td>19 %</td>
<td>32 %*</td>
</tr>
<tr>
<td><strong>Intermediate (Any) Re-obstruction</strong></td>
<td>14 %</td>
<td>19 %</td>
<td>19 %</td>
</tr>
<tr>
<td><strong>Intermediate (Mod or Severe) Re-obstruction</strong></td>
<td>1.8 %*</td>
<td>12.6 %</td>
<td>0 %*</td>
</tr>
</tbody>
</table>

* P < .05

Forbes et al, JACC 2011
<table>
<thead>
<tr>
<th></th>
<th>Stent</th>
<th>Surgery</th>
<th>Angioplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Median LOS</strong></td>
<td>1.0 day</td>
<td>5 days*</td>
<td>1.0 day</td>
</tr>
<tr>
<td><strong>Procedural AE’s (Any)</strong></td>
<td>2.3 %</td>
<td>18 %*</td>
<td>9.8 %</td>
</tr>
<tr>
<td><strong>Short-Term Aortic Wall Injury</strong></td>
<td>3.1 %*</td>
<td>11.5 %</td>
<td>14.3 %</td>
</tr>
<tr>
<td><strong>Med-Term Aortic Wall Injury</strong></td>
<td>7.1 %</td>
<td>12.5 %</td>
<td>43.8 %*</td>
</tr>
</tbody>
</table>

* P< .05

Forbes et al, JACC 2011
# Reintervention

<table>
<thead>
<tr>
<th></th>
<th>Surgery (n = 72)</th>
<th>Balloon (n = 61)</th>
<th>Stent (n = 217)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with reintervention</td>
<td>4</td>
<td>6</td>
<td>44</td>
</tr>
<tr>
<td>Patients with planned procedures</td>
<td>0</td>
<td>2</td>
<td>35</td>
</tr>
<tr>
<td>Patients with unplanned procedures</td>
<td>4</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Time to first planned reintervention, yrs</td>
<td>NA</td>
<td>1.43 ± 1.70</td>
<td>1.14 ± 1.15</td>
</tr>
<tr>
<td>Time to first unplanned reintervention, yrs</td>
<td>2.24 ± 2.23</td>
<td>1.28 ± 1.43</td>
<td>2.84 ± 1.43</td>
</tr>
</tbody>
</table>
Stenting of Aortic Coarctation and Exercise-Induced Hypertension in the Young

Enrico De Caro, MD, Isabella Spadoni, MD, Roberto Crepaz, MD, Michele Saitta, MD, Gianluca Trocchio, MD, Calevo MG, PhD, and Giacomo Pongiglione, MD

Results:

Seventeen patients formed the surgery-group, while 15 patients the stent-group. Patients in surgery-group were younger at coarctation repair and with a longer follow-up than those in stent-group. No difference was present regarding age, body surface area, gender, and presence, and degree of mildly hypoplastic aortic segments between the two groups as well as between patients with or without EIH. EIH was found in 35% of surgery-group patients and in 33% of stent-group patients. PSG and MSG were similar in the patients with or without EIH.
Study Conclusions: CoA Stenting does not appear to effect cardiac work or BP differently than surgery

Coogan, CCVI, 2011
Conclusions:
Stenting compared to Surgery

- It goes without saying..... (Comfort, Cosmetics, Cost favor stenting)
- Acute procedural results are similar
- Procedural Morbidity and AE’s favor stenting
- Planned reintervention more common in stenting
- “Medium” term outcome of stenting appears similar to surgery
- For Long-term comparative outcomes, stay tuned to CCISC!