Branch Pulmonary Artery Stenosis

Long-term Outcomes of Endovascular Stenting

Lee Benson MD
Professor Pediatrics (Cardiology)
Director, Cardiac Diagnostic & Interventional Unit
The Hospital for Sick Children
Toronto, Canada
What do we know

Since the first report in 1988, (Mullins Circulation 1988) acute clinical efficacy has been well established in the setting of PAS.

Over 20 years of clinical experience using a variety of stents, few long-term studies have assessed the modified natural history of the branch vessel & the stent.
What we know

The purpose of stent implantation:

dilate areas of stenosis to diameters matched to the size of the adjacent vessel, avoids vessel disruption

provide structural support to the stenotic area to prevent recoil and compression
What we know

Long-term outcome data is limited, with no serial trials examining the clinical impact beyond 10 years

Potential problems

• neo-intimal proliferation: in-stent stenosis
• limited expansion potential for smaller stents
• side-branch flow limitations & occlusion
• metal fatigue: fractures
What questions can we ask of long-term outcome data?

What is freedom from re-intervention rate?

What are the risk factors for in-stent stenosis, fracture?

Can the stents be redilated reliably?

How does stent management of PAS factor into the clinical treatment algorithms?

What of the adult with CHD....stented as a child?
**What data do we have?**

*Shaffer JACC 1998*

Summarized phase I & II IDE trial ~200 pts: 347 stents implanted over 6 yrs  
Palmaz P308 (12-18mm), P204 (8-10mm)

<table>
<thead>
<tr>
<th>Postoperative branch PA stenoses</th>
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<tbody>
<tr>
<td><strong>Tetralogy of Fallot</strong></td>
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<tr>
<td>s/p RVOT augmentation</td>
<td>55</td>
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<tr>
<td>s/p systemic to PA shunt</td>
<td>17</td>
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<tr>
<td>s/p RV to PA conduit</td>
<td>9</td>
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<tr>
<td>With absent right or left PA</td>
<td>6</td>
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<tr>
<td><strong>Pulmonary atresia</strong></td>
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<td><strong>Transposition of the great arteries</strong></td>
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<tr>
<td>s/p arterial switch operation</td>
<td>7</td>
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<tr>
<td>With VSD, s/p RV to PA conduit</td>
<td>3</td>
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<tr>
<td><strong>Truncus arteriosus</strong></td>
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<td>s/p RV to PA conduit</td>
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<td><strong>VSD</strong></td>
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<td>s/p PA band</td>
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<td><strong>Other diagnoses, s/p systemic to PA shunt</strong></td>
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<tr>
<td>Congenital branch PA stenosis</td>
<td>13</td>
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</table>

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<tr>
<th>Venous stenoses</th>
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<tbody>
<tr>
<td>s/p Fontan and Fontan variants for tricuspid atresia, previous shunts</td>
<td>10</td>
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<tr>
<td>s/p Fontan and Fontan variants (various diagnoses)</td>
<td>12</td>
</tr>
<tr>
<td>s/p Glenn/bidirectional Glenn (various diagnoses)</td>
<td>9</td>
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<tr>
<td>Atrial switch for transposition of the great arteries</td>
<td>7</td>
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<td>Superior vena cava stenosis (various diagnoses)</td>
<td>5</td>
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<td>Systemic venous stenoses</td>
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</table>
What data do we have?

Shaffer JACC 1998

| Age       | 10.5 yrs (6m-43yrs), weight 28 kg (5.3-83kg) |
| FU        | 19±15 months                                |
| P/O PAS   | 136 pts, 237 stents                        |

![Images](chart.png)

- **A**: Gradient - mmHg
  - Pre Stent: n=223
  - Post Stent: n=223
  - Follow-up: n=112
  - Redilation: n=51
  - 51/112

- **B**: Diameter - mm
  - Pre Stent: n=229
  - Post Stent: n=229
  - Follow-up: n=112
  - Redilation: n=98
  - ΔP <10 mmHg

- **C**: RV/FA Ratio
  - Pre Stent: n=127
  - Post Stent: n=127
  - Follow-up: n=62
  - Redilation: n=10
  - >100% in 65%
What data do we have?

Shaffer JACC 1998

$\Delta P$  $\Delta$ Diam  RV/FA

$>200\%$ in $>50\%$
What data do we have?

Shaffer JACC 1998

Perfusion scan: unilateral obstruction
What data do we have?

Fogelman Circulation 1995

55 stents were implanted in 42 children, ~6 years of age
Recatheterized 1 year after implantation

12 stents straddled the orifice of a PA side-branch &
reduced flow in 7 children
What data do we have?

Fogelman Circulation 1995

29 children underwent recatheterization

In 12, various degrees & locations of acquired intraluminal narrowing particularly in areas of diameter mismatch between the stented and nonstented vessels.
What data do we have?

Fogelman Circulation 1995

11 children redilation

Of the 38 children: planned surgery for PAS was avoided in 33 & deferred in 4

Symptomatic improvement was reported in 27, & 15 children remained asymptomatic
What about redilation?

McMahon JACC 2001

Neointimal proliferation:
208 none
8 mild
4 signf (1.8%) -redilated
-May be related to pt age-stn diam
(Schneider Heart 2002, Duke Heart 2003)

Restenosis: 5 of 220 (2%)

Risk factors-
lack of overlap
What about stent fracture?

Breinholt CCI 2008

17 year follow up study

265 pts----583 stents

Fluoroscopy ~4 yrs after implant (395 stents for PAS)

No symptoms

10/395 (2.5%) fractures in proximal PA’s

No embolization. Redilated or restented

Thought due to extra-vascular compression
What about stent fracture?

McElhinney CITY 2008

3 year follow up study 120 pts----166 stents
Fluoroscopy/catheterization

No symptoms
35 stents in 25 patients (21%) fractures in proximal PA's
2 fragment embolizations
Risk: placement close to AAo, large diameter stn, TA, RAA, ASO
Obstruction 28 stn, severe in 11: restented, redilated
Fate of stents placed in a small child
Stanfill CCI 2008

27 of 113 children <24 months stented

Median age 10 months & weight 8 kg

Follow-up ~102 months

Highly 'intervened' group:
   23 children had 35 cardiac surgical procedures,
   16 interventional catheterizations on 12 children.

Indications:
   symptomatic, recurrent vascular obstruction
   severe cyanosis
   failure to wean from cardiopulmonary support
   optimize presurgical hemodynamics
Angiographic success: 27/31 (87%) implants
Procedural success: 31 of the 33 (94%) attempts
13 of the 17 children (15 PA stents) underwent 27 redilations.

6 stents were redilated x1, 6-x2, & 3-x3

At the latest catheterization, ~69 months after index implant there was significant increase in luminal diameters (7 to 9 mm, (p<0.001)
Stenting in small children, provides an important clinical alternative to emergent surgery in the neonate.

Small- to medium-sized stents can be successfully implanted.

Life-saving in many of these children.

The stents can be dilated safely as the child grows.

Planned surgical removal can be performed at a later time.
Are there better stents for infants?

Coronary stents, which in an infant can be life saving have maximal expansion (5mm stent) of ~7 or 8 mm.

Larger Genesis stents can be dilated to adult diameters but have a delivery high profiles not appropriate for infants.
Valeo Biliary Lifestent
(Edwards Lifesciences-Irvine, CA)

Stainless steel triple helical stent with an open cell design

6-10 mm diameters; lengths 18 and 56 mm; premounted balloons (14 atm)

Sheath size is 6 Fr for 6-8mm stented balloons; 7 Fr for the 9-10 mm stented balloons

Less radial strength than premounted Genesis
Serial dilations of the 10X26 mm stent using 12, 14, 15, and 18 mm short length balloons:

Serial dilations of the 10X26 mm stent

Dilated to:

10 mm

12 mm

15 mm

20 mm
What have we learned?

Stent management of PAS is effective with a positive clinical impact, luminal gain maintained in the majority

Redilation is effective as late as 10 years, & the majority will require redilation to accommodate somatic growth

Large diameter stents rarely develop in-stent stenosis due to neointimal proliferation, but are subject to fracture depending on position
Thank You
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