Stent Implantation for PPS: Indications, Type of Stents, Technique for Deployment, Complications and Outcome [20]

SCAI Fellow Course – Fall 2014

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(Peripheral) Pulmonary Artery Stenosis: Treatment Options

Preprocedural Considerations

⇒ Individualized approach for each specific patient!
Recommendations for Pulmonary Artery Stent Placement

Class I

1. Primary intravascular stent implantation is indicated for the treatment of significant proximal or distal branch pulmonary artery stenosis when the vessel/patient is large enough to accommodate a stent that is capable of being dilated to the adult diameter of that vessel (Level of Evidence: B).

Class IIa

1. It is reasonable to consider pulmonary artery stent implantation in critically ill postoperative cardiac patients when it has been determined that significant branch pulmonary artery stenosis is resulting in a definite hemodynamic compromise in a patient/vessel of any size, particularly if balloon dilation is unsuccessful (Level of Evidence: B).

2. Primary intravascular stent implantation is reasonable in the treatment of significant stenosis of the main pulmonary artery segment that results in elevation of the RV pressure, provided that the stent definitely will not compromise a functioning pulmonary valve and will not impinge on the pulmonary artery bifurcation (Level of Evidence: B).

Class IIb

1. It may be reasonable to implant small pulmonary artery stents that lack the potential to achieve adult size in small children as part of a cooperative surgical strategy to palliate severe branch pulmonary artery stenosis. These stents may need to be enlarged surgically or removed during a future planned operation (eg, conduit replacement, Fontan completion) (Level of Evidence: C).
Literature review: Inclusion Criteria used for Selecting patient for PA Stenting

RV to systemic ratio
  - Quoted criteria: >50%, >60%, >66%, >75%

Hypertension of other unobstructed pulmonary artery segments (non specified)

Gradient across the stenotic lesion:
  - Quoted criteria: >20mmHg, >30mmHg

Angiographic narrowing
  - Quoted criteria: Qualitatively significant, < 50% of adjacent normal vessel

Complete obstruction of branch PA stenosis

Reduction in perfusion to (R or L) lung
  - Quoted criteria: Qualitatively significant, perfusion <35% of total lung

Clinical symptoms as an adjunct to other criteria (such as exercise intolerance or increasing cyanosis)

Stenosis considered difficult to treat surgically

Failure of balloon angioplasty or surgery to treat the lesion

Combination of above findings
Proximal branch PA stenosis: Indications for intervention (2V)

<table>
<thead>
<tr>
<th>Evidence of Branch PA Stenosis based on one or more of the three criteria (dimension, gradient, perfusion)</th>
<th>Dimension Stenosis in % of normal Vessel (Angio, MRI, CT)</th>
<th>Systolic Gradient (mmHg)</th>
<th>Reduction in Single Lung Perfusion (% of normal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV Pressure</td>
<td>&lt;60%</td>
<td>&gt;20mmHg</td>
<td>&lt;90%</td>
</tr>
<tr>
<td>➢ 2/3 systemic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV pressure</td>
<td>&lt;50%</td>
<td>&gt;25mmHg</td>
<td>&lt;85%</td>
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<tr>
<td>➢ 1/3 systemic and &lt; 2/3 systemic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV Pressure</td>
<td>&lt;40%</td>
<td>&gt;30mmHg</td>
<td>&lt;80%</td>
</tr>
<tr>
<td>&lt; 1/3 systemic</td>
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</table>
Inclusion criteria for PA stenting in a 1-ventricle circulation

Problem: Even less data than for 2-ventricle patients (virtually zero studies, few cases mixed with 2V patients)

➤ Branch pulmonary artery stenosis with the stenotic lesion being < 60% of the diameter of the adjacent normal vessel (based on Angiography, MRI, or CT).

➤ Branch pulmonary artery stenosis with the stenotic lesion being < 75% of the diameter of the adjacent normal vessel (based on Angiography, MRI, or CT) and additional reproducible mean gradient across stenotic lesion of 2mmHg or more.
Success of balloon angioplasty limited due to elastic recoil (less when using cutting balloons)

Stents theoretically reduce traumatic injury to PA vessel wall (avoid overexpansion)

Stents can address longer segment stenoses
(Peripheral) Pulmonary Artery Stenosis: Pros and Cons of Percutaneous Stenting

**Pros:**
- No/less recoil
- No need for overexpansion
- Better distal control than intraop stents (biplane angiography, accurate measurements, good roadmaps)
- Suited for external compression / kinks / long-segment stenosis
- No need for sternotomy or CPB

**Cons:**
- Technically demanding (size does matter)
- Longer procedure and fluoro times
  - Hemodynamic effects of long sheaths/stiff wires
  - Need for redilations in children
  - Stent associated problems (fractures, instent stenosis)
(Peripheral) Pulmonary Artery Stenosis: Pros and Cons of Intraoperative Stenting

**Pros**
- Size doesn't matter
- Avoid ‘curves and bends’
- No need for stiff wires and long sheaths
- Suited for external compression / kinks
  - Potential for stent modification
  - Better control of potential vascular complications
  - Advantage in unstable patients
  - Low fluoro and procedure times

**Cons**
- Direct visual deployment ➔ distal wire and stent position more difficult to assess
- Need for redilations in children
- Stent associated problems
(Peripheral) Pulmonary Artery Stenosis: Intraoperative PA Stents – Endoscopic Guidance
Intraoperative PA Stents: Direct Vision with Endoscopy
**Desirable Stent Characteristics**

- Excellent crimpability
- High degree of flexibility
- Adequate radial strength
- Fracture resistant
- Expansibility to adult size
- Minimal stent shortening
- Lowest possible stent profile
- Non-traumatic leading edges
- Facilitates access to jailed branch vessels
Coronary Stents

Numerous types, diameters, length

Usually premounted

Examples:
- Multi-Link Vision [Abbott]
- Multi-Link Ultra [Abbott]

Struts can potentially be fractured with (ultra) high pressure balloons
(Small) Diameter Stents

Palmaz Genesis (Cordis)
- Maximum diameter:
  - Medium: 8mm
  - Large: 10-12mm
- Available length:
  - Medium: 12, 15, 18, 24mm
  - Large: 29, 39, 59, 79mm
- Unmounted
- Premounted (OptaPro, Slalom) (5-10mm)
- 5-7Fr sheath

Palmaz Blue (Cordis)
- Maximum diameter: 7mm
- Available length: 15, 17, 20, 25mm
- Premounted on Slalom (4-7mm)
- 5Fr sheath

Formula 418 (Cook)
- Maximum diameter: 8mm
- Available length: 12, 14, 20, 24, 30mm
- Premounted (5-8mm)
- 5-6Fr sheath
- Open cell
Large Diameter Stents

Maximum diameter ~18mm

Different types:

- Genesis XD (Cordis)
- Mega LD (eV3)
- IntraStent Doublestrut LD (eV3)
Large Diameter Stents

Genesis XD
- Maximum diameter 18mm
- Length: 19, 25, 29, 39, 59mm
- Low profile
- Stent shortening at 18mm:
  - 22%/2910
  - 16%/3910
Large Diameter Stents

Mega LD stent (ev3):
- Maximum diameter 18mm
- Length: 16, 26, 36mm
- Rounded edges
- Open cell design (5 cells)
- Minimal stent shortening
- 9Fr per label

IntraStent Doublestrut LD (ev3):
- Maximum diameter 18mm
- Length: 16, 26, 36, 56, 76mm
- Rounded edges
- Open cell design
- Minimal stent shortening
- Flexible, reduced radial strength
- 8Fr per label
Extra-large Diameter Stents

- **Palmaz XL (Cordis):**
  - Maximum expanded diameter 25+ mm
  - Lengths range between 30-50 mm
  - Very stiff, very good radial strength, poor flexibility

- **Max LD stent (eV3):**
  - Maximum expanded diameter 25 mm
  - Good radial strength
  - Open cell design (6 cells)
  - Minimal stent shortening
  - Length: 16, 26, 36mm 11Fr per label

- **CP 8-zig stent (NuMED):**
Extra-large Diameter Stents: The CP Stent

- 0.013 platinum / iridium wire
- Arranged in Zig-pattern
- Rounded edges
- Laser welded at each joint
- Over brazed with 24 karat gold
- Number of Zigs variable (expansion, stent shortening)
  - 8 Zigs: expansion up to 25mm
  - 8 Zigs: stent shortening ~ 35% at 24mm
- Variable number of rows - length: 5.6mm/row
- Length 16, 22, 28, 34, 39, 45
## Large and Extra-Large Diameter Stents

<table>
<thead>
<tr>
<th>Name</th>
<th>Material</th>
<th>Max Diameter (mm)</th>
<th>Available length (mm)</th>
<th>Profile</th>
<th>Radial Force</th>
<th>Flex</th>
<th>Short</th>
<th>Non traumatic edges</th>
<th>Crimp</th>
<th>Cells</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genesis XD (Cordis)</td>
<td>Stainless steel</td>
<td>18</td>
<td>19, 25, 29, 39, 59</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>-</td>
<td>0</td>
<td>++</td>
<td>Closed</td>
</tr>
<tr>
<td>Palmaz XL (Cordis)</td>
<td>Stainless Steel</td>
<td>25+</td>
<td>31, 40, 50</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>Closed</td>
</tr>
<tr>
<td>IntraStent DoubleStrut LD (EV3)</td>
<td>Stainless Steel</td>
<td>18</td>
<td>16, 26, 36, 56, 76</td>
<td>+</td>
<td>-</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>0</td>
<td>Open</td>
</tr>
<tr>
<td>Mega LD (EV3)</td>
<td>Stainless steel</td>
<td>18</td>
<td>16, 26, 36</td>
<td>0</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>0</td>
<td>Open</td>
</tr>
<tr>
<td>Max LD (EV3)</td>
<td>Stainless steel</td>
<td>25</td>
<td>16, 26, 36</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>-</td>
<td>Open</td>
</tr>
<tr>
<td>Cheatham Platinum 8z (NuMED)</td>
<td>Platinum / Iridium + Gold</td>
<td>25</td>
<td>22-45</td>
<td>-</td>
<td>++</td>
<td>0</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>Closed</td>
</tr>
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</table>
### Self-expandable Stents

<table>
<thead>
<tr>
<th>Protégé (eV3)</th>
<th>Precise (Cordis)</th>
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<tbody>
<tr>
<td>Diameter: 5-14mm</td>
<td>Diameter: 5-10mm</td>
</tr>
<tr>
<td>Length, 20, 30mm +</td>
<td>Length, 20, 30, 40mm</td>
</tr>
<tr>
<td>6Fr sheath</td>
<td>6Fr sheath</td>
</tr>
<tr>
<td>0.035” wire</td>
<td>0.018” wire</td>
</tr>
<tr>
<td>80 cm delivery cath</td>
<td>135cm delivery cath</td>
</tr>
</tbody>
</table>
Covered C-P Stent (NuMED)

CP Stent
Covered with ePTFE
Upsize sheath by 4Fr
Advanta V12 (Atrium)

Premounted
Covered with PTFE
Fairly low profile
Shortening!

Small:
- Diameter: 5-10mm (expandable up to 12mm)
- Length: 16, 22, 38, 59mm
- 6-7Fr sheath

Large:
- Diameter: 12-16mm (expandable up to 22mm)
- Length: 29, 41, 61mm
- 9-11Fr sheath

Delivery cath: 80- and 120cm
iCast Covered Stent (Atrium)

Diameters 5-10mm
Length: 16, 22, 38, 59
6-7Fr sheath
Balloons RBP 12 Atm
38 and 59mm stents can be post-dilated to 12mm
Delivery cath: 80- and 120cm

316L laser-cut stainless steel
Covered with ePTFE
Balloon Angioplasty and Stenting of Branch Pulmonary Arteries
Adverse Events and Procedural Characteristics: Results of a Multi-Institutional Registry

Ralf J. Holzer, MD, MSc; Kimberlee Gauvreau, ScD; Jacqueline Kreutzer, MD; Ryan Leahy, MD; Joshua Murphy, MD; James E. Lock, MD; John P. Cheatham, MD; Lisa Bergersen, MD, MPH

Background—Pulmonary artery (PA) balloon angioplasty and/or stenting (PA rehabilitation) is one of the most common procedures performed in the cardiac catheterization laboratory, but comprehensive and consistently reported data on procedure-related adverse events (AE) are scarce.

Methods and Results—Data were prospectively collected using a multicenter registry (Congenital Cardiac Catheterization Project on Outcomes). All cases that included balloon angioplasty and/or stent implantation in a proximal or lobar PA position were included. Multivariate analysis was used to evaluate for independent predictors of AE and need for early reintervention. Between February 2007 and December 2009, 8 institutions submitted details on 1315 procedures with a PA intervention. An AE was documented in 22% with a high severity (level 3 to 5) AE in 10% of cases. Types of AE included vascular/cardiac trauma (19%), technical AE (15%), arrhythmias (15%), hemodynamic AE (14%), bleeding via endotracheal tube/reperfusion injury (12%), and other AE (24%). AE were classified as not preventable in 50%, possibly preventable in 41%, and preventable in 9%. By multivariate analysis, independent risk factors for level 3 to 5 AE were presence of ≥2 indicators of hemodynamic vulnerability, age below 1 month, use of cutting balloons, and operator experience of <10 years. Reintervention during the study period occurred in 22% of patients undergoing PA rehabilitation.

Conclusions—PA rehabilitation is associated with a 10% incidence of high-level severity AE. Hemodynamic vulnerability, young age, use of cutting balloons, and lower operator experience were significant independent risk factors for procedure-related AE. (Circ Cardiovasc Interv. 2011;4:00-00.)

Key Words: congenital heart disease ■ pulmonary artery stenosis ■ cardiac catheterization ■ adverse events
Inclusion:

- Angioplasty and/or stent placement in a lobar and/or proximal branch PA
- \(\Rightarrow\) 1,315 cases (969 pts)

Three subgroups:

- Proximal therapy \(\text{ }(n=789)\)
- Lobar therapy \(\text{ }(n=226)\)
- Mixed therapy \(\text{ }(n=300)\)
## Procedural Data

**Type of case:**
- Elective: 85%
- Non-elective add-on: 14%
- Emergent: 1%

**Hybrid procedure:** 2%

**Within 30 days of surgery:** 9%

**4 or more previous cath:** 31%

**Inotropica support:** 8%

**ECMO support:** 1%
<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>Total</th>
<th>Proximal</th>
<th>Lobar</th>
<th>Mixed</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
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<td></td>
</tr>
<tr>
<td>Balloon angioplasty (&lt;8 atm)</td>
<td>348 (26)</td>
<td>178 (23)</td>
<td>71 (31)</td>
<td>99 (33)</td>
<td>&lt;0.001</td>
</tr>
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<td>Balloon angioplasty (&gt;= 8 atm)</td>
<td>565 (43)</td>
<td>225 (29)</td>
<td>139 (62)</td>
<td>201 (67)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cutting balloon angioplasty</td>
<td>221 (17)</td>
<td>19 (2)</td>
<td>86 (38)</td>
<td>116 (39)</td>
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<td>Stent angioplasty</td>
<td>314 (24)</td>
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<tr>
<td>Premounted Stent</td>
<td>224 (17)</td>
<td>114 (14)</td>
<td>41 (18)</td>
<td>69 (23)</td>
<td>0.003</td>
</tr>
<tr>
<td>Non-Premounted Stent</td>
<td>262 (20)</td>
<td>222 (28)</td>
<td>11 (5)</td>
<td>29 (10)</td>
<td>&lt;0.001</td>
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<tr>
<td>Covered Stent</td>
<td>9 (1)</td>
<td>4 (1)</td>
<td>2 (1)</td>
<td>3 (1)</td>
<td>ns</td>
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<tr>
<td>5 or more interventions</td>
<td>122 (9)</td>
<td>1 (&lt;1)</td>
<td>32 (14)</td>
<td>89 (30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Interventions on both PAs</td>
<td>462 (35)</td>
<td>200 (25)</td>
<td>73 (32)</td>
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<tr>
<td>Non-PA Interventions</td>
<td>523 (40)</td>
<td>379 (48)</td>
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</table>
### Procedural data

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<td><strong>N (%)</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Total</strong></td>
<td>1222</td>
<td></td>
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Outcome of PA stenting
50 patients

Long term follow-up with cath at: 7.2 ± 4.3 yrs post-stenting

43 survivors (mean age at stenting 12.6 ± 7.1; Wt 24.7 ± 12.7 kg)

Final repeat catheterizations were performed in 36 patients (55 stents) 7.2 +/- 4.3 years post stent insertion

Higher initial gradient and smaller balloons were assoc. with a final stent diam <14 mm

Conclusion: Stent implants for PA stenoses provide effective long-term improvement in vessel caliber.
Stenting in Bifurcation Stenosis

49 pts; median age 10.9 yrs (1-43 yrs)

Significant improvement in vessel diameter, PG and RVP

One death due to severe pulmonary hemorrhage

F/U data on 38 pts (mean duration 6.3 6 4.1 years, range 1.2–13.1 years)

Thirty pts underwent repeat catheterizations, 26 requiring further interventions: 15 had balloon angioplasty alone and 11 had additional stents placed.
PA Stenting in Adults

12 Pts
23 stents (15 procedures)
6 Pts required bilateral stents
3 Stent embolizations – all had significant PI
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Procedures with Adverse Events

- 324 Adverse events in 1315 cases
- Max Level 1-2 adverse events in 10% of cases
- Level 3-5 in 12% of cases, Level 5 (death) in 0.15%
Level of Adverse Events

- Level 1: N=2, 1%
- Level 2: N=36, 11%
- Level 3: N=143, 45%
- Level 4: N=107, 34%
- Level 5: N=30, 9%
Adverse Events by Preventability

- **Proximal**
  - Not Preventable (ns): 50%
  - Poss. Preventable (ns): 30%
  - Preventable (ns): 20%

- **Lobar**
  - Not Preventable (ns): 70%
  - Poss. Preventable (ns): 30%
  - Preventable (ns): 10%

- **Mixed**
  - Not Preventable (ns): 60%
  - Poss. Preventable (ns): 40%
  - Preventable (ns): 20%
<table>
<thead>
<tr>
<th>Adverse Event Details</th>
<th>Total (n=324)</th>
<th>Proximal (n=174)</th>
<th>Lobar (n=61)</th>
<th>Mixed (n=89)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular / Cardiac Trauma</td>
<td>60 (19)</td>
<td>20 (11)</td>
<td>14 (23)</td>
<td>26 (29)</td>
<td>0.001</td>
</tr>
<tr>
<td>Technical AEs</td>
<td>50 (15)</td>
<td>40 (23)</td>
<td>2 (3)</td>
<td>8 (9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>49 (15)</td>
<td>32 (18)</td>
<td>11 (18)</td>
<td>6 (7)</td>
<td>0.04</td>
</tr>
<tr>
<td>Hemodynamic AEs</td>
<td>45 (14)</td>
<td>24 (14)</td>
<td>10 (16)</td>
<td>11 (12)</td>
<td>ns</td>
</tr>
<tr>
<td>Reperfusion Injury / ETT bleed</td>
<td>40 (12)</td>
<td>9 (5)</td>
<td>12 (20)</td>
<td>19 (21)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vascular Entry Site AE</td>
<td>34 (10)</td>
<td>22 (13)</td>
<td>5 (8)</td>
<td>7 (8)</td>
<td>ns</td>
</tr>
<tr>
<td>Sedation / Anesth. / Airway</td>
<td>12 (4)</td>
<td>5 (3)</td>
<td>3 (5)</td>
<td>4 (4)</td>
<td>ns</td>
</tr>
<tr>
<td>Other</td>
<td>34 (10)</td>
<td>22 (13)</td>
<td>4 (7)</td>
<td>8 (9)</td>
<td>ns</td>
</tr>
<tr>
<td>Adverse Event Details</td>
<td>Total (n=324)</td>
<td>Proximal (n=174)</td>
<td>Lobar (n=61)</td>
<td>Mixed (n=89)</td>
<td>P-Value</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>----------------</td>
<td>------------------</td>
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<td>--------------</td>
<td>---------</td>
</tr>
<tr>
<td>Vascular / Cardiac Trauma</td>
<td>60 (19)</td>
<td>20 (11)</td>
<td>14 (23)</td>
<td>26 (29)</td>
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<tr>
<td>Technical AEs</td>
<td>50 (15)</td>
<td>40 (23)</td>
<td>2 (3)</td>
<td>8 (9)</td>
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</tr>
<tr>
<td>Arrhythmias</td>
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## Risk factors for level 3-5 AE

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<tr>
<th>Predictor</th>
<th>Incidence of all AE</th>
<th>Univariate</th>
<th>Multivariate Analysis</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Predictor Present</td>
<td>Predictor Not Present</td>
<td>P Value</td>
</tr>
<tr>
<td>Emergent or non-elective cases</td>
<td>17/92 (18)</td>
<td>57/700 (8)</td>
<td>0.004</td>
</tr>
<tr>
<td>Use of inotropic support at start</td>
<td>7/44 (16)</td>
<td>67/748 (9)</td>
<td>0.175</td>
</tr>
<tr>
<td>Age &lt; 1 month</td>
<td>5/20 (25)</td>
<td>69/772 (9)</td>
<td>0.032</td>
</tr>
<tr>
<td>Weight &lt; 5kg</td>
<td>8/58 (14)</td>
<td>66/734 (9)</td>
<td>0.238</td>
</tr>
<tr>
<td>Date since last surgery &lt; 30d</td>
<td>12/60 (20)</td>
<td>62/732 (8)</td>
<td>0.009</td>
</tr>
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<td>5/40 (13)</td>
<td>69/752 (9)</td>
<td>0.411</td>
</tr>
<tr>
<td>Number previous catheterizations &gt;= 4</td>
<td>28/254 (11)</td>
<td>46/538 (9)</td>
<td>0.295</td>
</tr>
<tr>
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</tr>
<tr>
<td>Complex 2V and Suprasystemic RVp</td>
<td>8/67 (12)</td>
<td>66/725 (9)</td>
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</tr>
<tr>
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</tr>
<tr>
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<td>58/613 (9)</td>
<td>16/179 (9)</td>
<td>0.885</td>
</tr>
<tr>
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<td>10/171 (6)</td>
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<tr>
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<td>41/417 (10)</td>
<td>0.627</td>
</tr>
<tr>
<td>Cutting balloon angioplasty</td>
<td>21/167 (13)</td>
<td>53/625 (8)</td>
<td>0.133</td>
</tr>
<tr>
<td>Premounted stent</td>
<td>15/134 (11)</td>
<td>59/658 (9)</td>
<td>0.417</td>
</tr>
<tr>
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<td>21/178 (12)</td>
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<td>0.241</td>
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Risk factors for reperfusion injury

Acute changes in distal PA pressures of more than 150%

Acute changes in mean distal PA pressure of more than 20mmHg

Arnold et al, Am J Cardiol, 1988
(Peripheral) Pulmonary Artery Stenosis: Complications of Percutaneous Stenting

- Embolization, migration, malposition
- Jailing of adjacent vessels
- Refractory pulmonary edema / reperfusion injury
- Intimal proliferation and re-stenosis
- Stent thrombosis
- Need for re-dilation
- Balloon angioplasty related complications (rupture, dissection)
## Effect of Operator Experience Adjusting With CHARM – Type of AE

<table>
<thead>
<tr>
<th>Experience (yrs)</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5</td>
<td>1.98</td>
<td>(1.31, 2.99)</td>
<td>0.001</td>
</tr>
<tr>
<td>5 to 24.9</td>
<td>1.00</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>≥25</td>
<td>1.27</td>
<td>(0.67, 2.42)</td>
<td>0.46</td>
</tr>
</tbody>
</table>
PA Rehab – Early Reinterventions
(C3PO Registry)

Median f/u 16 months (1d to 35 months)

346 reinterventions

215/969 (22%) patients

- 15% just one reintervention
- 8% more than 1 reintervention

Median time to reintervention 181 days (1 to 896 days)
# PA Rehab (C3PO Registry)

## Independent Predictors for Early Reintervention

<table>
<thead>
<tr>
<th></th>
<th>Number</th>
<th>Any 3-5 AE (%)</th>
<th>P-value</th>
<th>P-value</th>
<th>OR (95% CI)</th>
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</thead>
<tbody>
<tr>
<td><strong>Weight</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5kg</td>
<td>90</td>
<td>47 (52)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>26.9 (15.9, 49.1)</td>
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<tr>
<td>5 &lt; 25kg</td>
<td>534</td>
<td>133 (25)</td>
<td>&lt;0.001</td>
<td></td>
<td>5.95 (3.65, 9.75)</td>
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<tr>
<td>25 &lt; 75kg</td>
<td>286</td>
<td>31 (11)</td>
<td>0.11</td>
<td></td>
<td>1.61 (0.90, 2.87)</td>
</tr>
<tr>
<td>&gt;= 75kg</td>
<td>59</td>
<td>4 (7)</td>
<td>---</td>
<td></td>
<td>1.00</td>
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<tr>
<td><strong>Location of PA rehab</strong></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>Proximal (+/- lobar)</td>
<td>670</td>
<td>98 (15)</td>
<td>---</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Lobar (+/- proximal)</td>
<td>133</td>
<td>52 (39)</td>
<td>&lt;0.001</td>
<td></td>
<td>5.59 (3.91, 8.00)</td>
</tr>
<tr>
<td>Mixed (Proximal AND lobar)</td>
<td>166</td>
<td>65 (39)</td>
<td>&lt;0.001</td>
<td></td>
<td>4.26 (3.34, 5.42)</td>
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<tr>
<td><strong>Bilateral Interventions</strong></td>
<td>299</td>
<td>89 (30)</td>
<td>&lt;0.001</td>
<td>0.03</td>
<td>1.39 (1.03, 1.88)</td>
</tr>
<tr>
<td>&gt;= 500 cases/center/year</td>
<td>862</td>
<td>277 (32)</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>2.59 (1.83, 3.66)</td>
</tr>
</tbody>
</table>

*Holzer et al, Circ Interv, 2011*
459 pts had PA stents (1989-2006)
54 pts had subsequent cardiac surgery
Surgical manipulation was done in 33 % PAs; 66 % stents were untouched
Catheter reintervention was similar between the surgically manipulated and untouched groups
Factors associated with future catheter reintervention: having the stent transected longitudinally and patched and a lower weight at the time of stent placement.

Conclusions: Surgical manipulation does not alter the need for future reintervention and catheter re-intervention may be more likely when the stents are transected longitudinally and patched.
General Technical Considerations for PA Stenting
Technical considerations for PA stenting

Angiography – 3D!!! ➔ without accurately profiling the lesion you are off to a bad start!!

Wire position

Wire position

Wire position

Do NOT rush during balloon inflation

Error distally rather than proximally

Remember that you have to come back (and that time no wire will be in place)

Do not create a subsequent problem by using “small boy” stents as much as possible!!

Use of appropriate (long) sheaths

If amenable (diameter wise) consider starting with cutting BA even if you know that you will stent

Have a plan B!
Isolated Proximal PA stenting
8 year female – s/p repair TOF PA
8 year female – s/p repair TOF PA
Lobar branch PA stenting
8 year female – s/p repair TOF PA (incl unifocalization)
8 year female – s/p repair TOF PA (incl unifocalization)
8 year female – s/p repair TOF PA (incl unifocalization)
8 year female – s/p repair TOF PA (incl unifocalization)
Stenting of bifurcation lesions
- Kissing stents
- Flower blossom
- Double open cell
12 months male – s/p TOF repair (with conduit)
12 months male – s/p TOF repair (with conduit)
12 months male – s/p TOF repair (with conduit)
12 months male – s/p TOF repair (with conduit)
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12 months male – s/p TOF repair (with conduit)
12 months male – s/p TOF repair (with conduit)
17 year female – s/p TOF repair
17 year female – s/p TOF repair
17 year female – s/p TOF repair
2 week female – s/p Truncus Repair
2 week female – s/p Truncus Repair
2 week female – s/p Truncus Repair
3 month female – s/p Truncus Repair and LPA stent
3 month female – s/p Truncus Repair and LPA stent
8 months female HLHS – s/p comp II
8 months female HLHS – s/p comp II
8 months female HLHS – s/p comp II
8 months female HLHS – s/p comp II
PA stenting in a single ventricle
5 year male – complex single V - s/p Fontan
5 year male – complex single V - s/p Fontan
5 year male – complex single V - s/p Fontan
5 year female – complex single V s/p Glenn
5 year female – complex single V s/p Glenn
5 year female – complex single V s/p Glenn
Early catheter interventions 2 days after abnormal exit angio

5 months, male, HLHS, s/p comprehensive Stage II
Conclusions

PA rehab is not only one of the most common procedures we perform in the cath lab, but also one of the most challenging with a considerable learning curve.

Make use of your senior colleagues and the CT surgeon!!

In contrast to procedures like ASD closure, most patients will over time have multiple PA interventions and you have to think about future interventions at the time of the procedure.

Adverse events are not uncommon and one needs to be prepared to deal with all those when engaging in PA rehab procedures.