Role of Balloons and Stents in Congenital Heart Disease

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No conflict of interest
Balloons in CHD – Initially used in the 80s
Learning curve
Development and refinement of techniques / equipments

Generalized use
Balloons in CHD

- **Valve Stenosis**
  - Pulmonary
  - Aortic
  - Mitral
  - Tricuspid

- **Vessels**
  - Pulmonary artery stenosis
  - Aortic coarctation
  - Systemic vein stenosis
  - Pulmonary vein stenosis

- **Other**
  - Atrial septum
  - Aorto-pulmonary colateral arteries
  - Surgical shunts
  - Conduits / surgical anastomosis
Balloon dilatation in CHD

Ideal angioplasty / valvuloplasty balloon

- Low and smooth profile
- Non compliant
- Smooth and short tapering
- Mounted on small shaft catheters

- Resistant to rupture and tears
- Large central lumen
- Rapid inflation / deflation times
- Short tip
- Smooth folding
Balloon dilatation in CHD

Available equipment

- Angioplasty / valvuloplasty
- Septostomy balloons
- Very high pressure balloons
- Balloon-in-balloon
- Occlusion / sizing balloons
- Cutting balloons
Pulmonary valve dilatation

- Standard treatment in all ages
- Introduced 30 years ago (1982)
- Immediate results similar to surgical valvotomy, (↓ morbidity and mortality)

**Indications**
- Gradient above 50mmHg (lower?)
- Evidence of right ventricular hypertrophy

**Technique**
- Balloon 1.2 - 1.4x the pulmonary valve
- Small rather than large balloons
Pulmonary valve pathology

**Typical stenosis (80-90%)**

- Thin, pliant valve
- Dome-shaped valve
- Post-stenotic dilatation of PA

**Dysplastic valve (10- 20%)**

- Thickened leaflets
- Frequently small annulus
- Small main PA
Pulmonary valve dilatation

Immediate results

- Good immediate results (>95% patients)
- Very low mortality rates
- Improvement in RV function
- Decrease in TV regurgitation

Rao, Heart 1998
Pulmonary valve dilatation

Immediate complications

- Arrhythmias
- Hypotension / collapse
- Blood loss
- RV / tricuspid valve injury
- Pulmonary artery lesions
- Pulmonary valve / annulus disruption

VACA registry

- 0.24% death
- 0.35% major complications

Stranger, Am J Cardiol 1990
Critical neonatal pulmonary valve stenosis

- Critically ill neonates
- Prostaglandin infusion
- Sequential balloon dilatation, starting with a small balloon
  - Wire through the duct → desc Ao
- May require prostaglandin infusion for some days or ductal stenting
Critical neonatal pulmonary valve stenosis

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Pulmonary valve dilatation

Adults

- Single versus Double balloon
- Infundibular reaction!
Pulmonary valve dilatation

Late results

- Recurrent obstruction (5-10%)
- Freedom from reintervention 84% - 95% at 10 years
- Pulmonary regurgitation > mild 10-57%

Risk factors for significant pulmonary regurgitation

- young age
- severe obstruction
- large balloon/valve ratio
- low residual gradient

Berman, CCI 1999
Garty, J Invasive Cardiol 2005
Rao, Heart 1998
Garty, J Invasive Cardiol 2005
Harrild JACC 2010
Indications for balloon dilatation

**Neonatal period**

- Symptoms / signs of heart failure
- Asymptomatic patients with peak to peak gradient $\geq 65\text{mmHg}$

**Children / Adolescents**

- Symptoms / signs of heart failure
- Gradient across the aortic valve $\geq 50\text{mmHg}$
Aortic Valve Stenosis

Wide spectrum of pathology:

**Mild valvular Ao stenosis**
- normal diameter
- fusion of leaflets
- good ventricular function

**Stenotic valve**
- In most cases bicuspid / functionally bicuspid
- “Good left ventricle”

**Severe aortic stenosis**
- variable LV dimensions
- variable function

**Nearly atretic valve**
- Small annulus
- Fibroelastosis
- Small dimension LV

Paris, RA 2011
Aortic Valve Dilatation

Approach

**Retrograde**
- Single balloon
- Two balloons

**Antegrade**
- Usually single balloon

**Combined:** retrograde + antegrade
Complications of balloon dilatation

- **Significant valvular regurgitation**
- **Arterial access complications** (1.5 – 7.5%)
  - Incidence of 1% to 18%
- **Central nervous system embolization** (< 1%)
  - Large ballons ⇒ more regurgitation!
- **Mitral valve damage**
  - Valvar perfuration
- **LV damage / perfuration**
- **Cardiac arrest**
- **Rupture of aortic valve annulus**
Aortic Valve Dilatation

Late results of Balloon dilatation

Midterm Results of Balloon Dilation of Congenital Aortic Stenosis: Predictors of Success

Are Outcomes of Surgical Versus Transcatheter Balloon Valvotomy Equivalent in Neonatal Critical Aortic Stenosis?

Circulation. 2001;104[suppl I]:I-152

Long term results of percutaneous balloon valvoplasty of congenital aortic stenosis: independent predictors of outcome

Heart 2004;90:70-76
Complications during valvuloplasty (n=76)

<table>
<thead>
<tr>
<th>Group</th>
<th>Type</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhythm disorders</td>
<td>Bradycardia</td>
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<tr>
<td>(frequency 53%; incidence 5.0%)</td>
<td>RBBB, LBBB</td>
<td>3</td>
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<tr>
<td></td>
<td>Ventricular tachycardia</td>
<td>4</td>
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<tr>
<td></td>
<td>SVT, atrial flutter/fibrillation</td>
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<tr>
<td></td>
<td>Asystole</td>
<td>7</td>
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<tr>
<td></td>
<td>Ventricular fibrillation</td>
<td>8</td>
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<tr>
<td></td>
<td>AV block, temporary</td>
<td>11</td>
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<tr>
<td></td>
<td></td>
<td>40</td>
</tr>
<tr>
<td>Arterial lesions</td>
<td>Occlusion of femoral artery</td>
<td>15</td>
</tr>
<tr>
<td>(frequency 28%; incidence 2.6%)</td>
<td>Femoral arterial cutdown</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Dissection/occlusion iliac artery</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Intimal lesion in aortic arch</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21</td>
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<tr>
<td>Cardiac lesions</td>
<td>Aortic regurgitation grade III-IV</td>
<td>8</td>
</tr>
<tr>
<td>(frequency 20%; incidence 1.9%)</td>
<td>Myocardial perforation</td>
<td>3</td>
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<tr>
<td></td>
<td>Mitral valve lesions</td>
<td>2</td>
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<tr>
<td></td>
<td>Transitory myocardial ischemia</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Occlusion of RCA</td>
<td>1</td>
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<tr>
<td></td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

Sum of frequencies is 101% and sum of incidences is 9.5% due to statistical rounding. RBB = right bundle branch block; LBBB = left bundle branch block; RCA = right coronary artery.

Freedom from surgery

- p = 0.04
- 70% at 5 years
- 50% at 10 years
Balloons and Stents in CHD

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Use of stents in Congenital Heart Disease

- More predictable results
- Effective dilatation
- Radial force prevents elastic recoil
- Compress dissection flaps against vessel wall
- More effective in long vessel hypoplasia / stenosis
Use of stents in Congenital Heart Disease

- **Balloon expandable stents**
  - Mounted on balloons
  - Expanded at the site of obstruction
  - Size of balloon = expanded stent diameter
  - Redilatation possible

- **Self expanding stents**
  - Lower profile delivery system
  - More flexible
  - Lower radial strength
  - More intimal hyperplasia
  - No further dilatation to accommodate growth
Use of stents in Congenital Heart Disease

**Ideal stent**

- Low stent profile
- Good radial strength
- Flexibility
- High trackability
- Radio-opacity
- Minimal shortening
- No fractures over time

- Full biocompatibility
- No neointimal hyperplasia
- Compatible with MRI
- Possibility of redilatation
- Round and soft edges
- Retrievability / repositioning

...
Pulmonary artery stenosis

Congenital

Post-surgical

Balloon dilatation

Poor results of BD
(immediate / long term)

Better results, but unpredictable
Require overdilatation of PA
Pulmonary artery stenosis

Goals of treatment

- Reduce RV pressure
- Balance pulmonary perfusion
- Improve ventilation / perfusion mismatch
- Prevention of arterial hypoplasia

Indications

- RV pressures >50% systemic
- Lung perfusion < 20%
Pulmonary artery stenosis

Transcatheter interventional approach

- Conventional angioplasty
- High pressure balloons
- Cutting balloons
- Stents
Indications

- Congenital or acquired stenosis at origin of PAs
- Angulation / tenting
- External compression
- Recoil
- Intimal tears
- Recanalization of occluded vessel

Complications (5 to 19%)
- Malposition and embolization
- Jailing of branches
- Stent fracture
- Dissection
- Vessel rupture

O´Laughlin. Circulation 1993
Van Gameren. Eur Heart J 2006
Aortic coarctation
Balloon dilatation of aortic coarctation

**Expected Result**

- Gradient < 20 mmHg (ideally < 5-10 mmHg)
- Increased diameter of coarctation
Balloon dilatation of aortic coarctation

Tearing of intima / media
Aortic coarctation treatment in children, adolescents and adults

**Disadvantages**
- Damage of aortic intima & media
- Possibility of dissection / rupture (specially with aortic wall disease)
- Neurological accidents (rare)
- Residual / recurrent stenosis (5-45%)
- Aneurysm formation (0-30%)

**Advantages**
- Less traumatic than surgery
- Shorter admission
- Lower rate of acute severe complications
- Effective acute results
- No material implanted
Multi-institutional study for stents in CoA

Acute complications / CCISC

- Acute complications: 14.3%
- Death procedure related: 0.3%
- Aortic wall complications: 4.1%
  - Aneurysm: 1.0%
  - Intimal tear: 1.5%
  - Dissection: 1.6%

Risk factors
- pre-stent balloon angioplasty
- age > 40yrs

Forbes TJ. Cath Cardiovasc Interv 2007
## Stents in aortic coarctation

<table>
<thead>
<tr>
<th>Patients</th>
<th>Procedure Mort/Compl</th>
<th>Immed. Gd reduct.</th>
<th>Follow Up (Months)</th>
<th>F - up Gradient</th>
<th>Late Complicat.</th>
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</thead>
<tbody>
<tr>
<td>SuarezLezo</td>
<td>Valencia, Ped Card 05</td>
<td>73 1,3% / 3%</td>
<td>36</td>
<td>24</td>
<td>4% aneur.</td>
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<tr>
<td>C Pedra</td>
<td>S. Paulo, Cath Card Interv 05</td>
<td>21 0 / 5 %</td>
<td>50</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>A Tzifa</td>
<td>Multicenter JACC 06</td>
<td>30 0 / 0</td>
<td>32</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Mahadavan</td>
<td>Cath Card Interv 06</td>
<td>37 0 / 6+13%</td>
<td>25</td>
<td>12</td>
<td>11</td>
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<tr>
<td>Golden</td>
<td>Multicenter, Cath Card Interv 07</td>
<td>588 0,3%/12%</td>
<td>28</td>
<td>28</td>
<td>9% aneur.</td>
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<tr>
<td>T Forbes</td>
<td>Multicenter, Cath Card Interv 07</td>
<td>565/144 0,3%/14,3%</td>
<td>28</td>
<td>12</td>
<td>1 % fracture</td>
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<tr>
<td>Holzer</td>
<td>Multicenter, Cath Card Interv 10</td>
<td>302 0/5%</td>
<td>24</td>
<td>18-60</td>
<td>1 % aneur.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12% reinterv</td>
</tr>
</tbody>
</table>
Stents in aortic coarctation

Large stents!

Cheatham Platinum (NuMED)

Intrastent Maxi LD (EV3)

Advanta V12 (Atrium)

Palmaz XL (J & J)

Andrastent XL and XXL (Andramed)
Advantages

- More predictable results than angioplasty
- Sustained relief of gradient
- Less vascular injury
- Prevents elastic recoil
- Provides radial support of the wall vessel
- Intimal flap adherent to aortic wall reinforcing weakened areas

Disadvantages

- If patient grows, requires redilatation
- Neointima hyperplasia
- Aorta and Vascular access injury (<3%)
- Neurological damage (<1%)
- Neointimal formation
- Aneurysm formation (0-9%)
- Mortality (<1%)
Stents in aortic coarctation

**RESULTS**

*Systolic Blood Pressure*

- 67 patients after stent implantation

**RESULTS**

*Residual gradient at follow up*

- 67 patients after stent implantation

R Anjos, unpublished data
Aneurysms in aortic coarctation

Caused by:

- Intrinsic changes of the arterial wall
- Direct damage by wires / balloons / stents
- Overstretching

Occurrence in:

- Bare stents: 0-9%
- Covered stents: <1%
- Redilatation of stents: 3.6%
- Balloon angioplasty: 0-36%
- Surgery: 0-15%
Aneurysm 4 years after stent implantation. PTFE covered CP stent with resolution.

Images courtesy Grazyna Brzezinska-Rajszys
Bare or covered stent?

Indications

Bare stent
- Young patients
- Simple coarctation
- Discrete lesions
- No aortic wall complications

Covered stent*
- Severe coarctation
- Long segment hypoplasia
- Aneurysm / Pseudoaneurysm
- Fractured stent
- Recoarctation
- Older patients
- Rescue for acute complications
- Primary indication in adult patients

Special considerations*

Children require redilatation, which may be more limited
Risk of spinal injury
May occlude the origin of subclavian artery
Technique

Stenting of the arterial duct combined with banding of the pulmonary arteries and atrial septectomy or septostomy: a new approach to palliation for the hypoplastic left heart syndrome

John L. Gibbs, Christopher Wren, Kevin G Watterson, Stewart Hunter, J R Leslie Hamilton

Stent implantation of the arterial duct in newborns with duct-dependent circulation

M. Schneider, P. Zartner, A. Sidiropoulos*, W. Konertz* and G. Hausdorff†
Stents in duct dependent pulmonary circulation

Stenting of the arterial duct: a new approach to palliation for pulmonary atresia

John L Gibbs, Martin T Rothman, Michael R Rees, Jonathan M Parsons, Mike E Blackburn, Carlos E Ruiz


Stent Implantation in the Ductus Arteriosus for Pulmonary Blood Supply in Congenital Heart Disease

Ina Michel-Behnke, MD, Hakan Akintuerk, MD, Josef Thul, MD, Juergen Bauer, MD, Karl-Juergen Hagel, MD, and Dietmar Schranz, MD

Stenting of the arterial duct in newborns with duct-dependent pulmonary circulation

G Santoro, G Gaio, M T Palladino, C Iacono, M Carrozza, R Esposito, M G Russo, G Caianiello, R Calabrò

Heart 2008;94:925–929.
Developments in technology and operators experience have turned balloons and stents into primary tools in current treatment of CHD.

Clear advantage over surgery and risk / benefit evaluation with objective performance criteria are still missing for many of these techniques.