Valve-sparing repair with intraoperative balloon dilation in tetralogy of Fallot: Mid-term results
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No Disclosures
Valve-sparing repair with intraoperative balloon dilation

• Implemented at our BCH since 2007

• **Technique**
  – Infundibulotomy
    • VSD closure, muscle bundle resection
    • Infundibular (non-transannular) patch
  – MPA patch augmentation
  – Pulmonary valve commissurotomy
  – Pulmonary valve annulus dilation
    • Balloon inflation to 120 - 140% of measured annulus diameter
      • 1 unit increase in annulus z-score
Methods

• Retrospective review of all ToF-PS pts who underwent valve-sparing repair with IBD under 1 year of age (2007 - 2015)
  • Excluded pts: ToF/PA, ToF/MAPCAs, ToF/CAVC

Study Endpoints:

Early

• Residual Lesion Score - pulmonary stenosis (discharge echocardiogram)
  • RVOT peak gradient: Class 1: 0 - 20mmHg, Class 2: 20 - 40mmHg, Class 3: >40mmHg

• Pulmonary valve reintervention for residual stenosis
  • Multi-variable regression analysis - risk factors for valve reintervention

Late

• Mid-term pulmonary valve competency

• RV remodeling - chamber size
**Baseline patient characteristics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number (%) or Median (Interquartile range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Number</td>
<td>162</td>
</tr>
<tr>
<td>Age at primary repair, days</td>
<td>98 (73, 98 days)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>5.4 (4.6, 6.1 kg)</td>
</tr>
<tr>
<td>Pulmonary valve annulus z-score</td>
<td>-2.2 (-2.4, -1.8)</td>
</tr>
<tr>
<td>Chromosomal anomaly / genetic syndrome</td>
<td>19 (12%)</td>
</tr>
<tr>
<td>Prior pulmonary valve intervention</td>
<td>9 (6%)</td>
</tr>
</tbody>
</table>
Pulmonary valve characteristics

Study cohort: N = 162

Valve morphology

- Bicuspid: 76%
- Unicuspid: 9%
- Tricuspid: 15%

Valve leaflet appearance

- Normal: 60%
- Thickened/Dysplastic (40%)
Early outcome 1: Residual Lesion Score - pulmonary stenosis

RVOT peak gradient - Discharge echo

- (0 - 20mmHg)
- (20 - 40mmHg)
- (>40mmHg)

Number of Patients

- Class 1: 35%
- Class 2: 56%
- Class 3: 9%
Reinterventions for residual RVOT stenosis

N = 30/162 (19%)

- Pulmonary valve: N = 25
- Branch PA: N = 1
- Subvalvar: N = 4
Early outcome 2: Pulmonary valve reintervention for residual stenosis

N = 25 (15%)

Timing of first reintervention

Type of reintervention

Number of Reinterventions

- Catheter-based: 24
- Surgical: 10
# Risk factors for early pulmonary valve reintervention

Multivariable regression analysis (N = 162, N events = 25, $R^2 = 0.21$)

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
<th>$p$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary valve annulus z-score ≤ -2.45</td>
<td>4.47</td>
<td>1.24, 16.09</td>
<td>0.036</td>
</tr>
<tr>
<td>Younger age at primary repair (per 30 day decrease)</td>
<td>1.72</td>
<td>1.28, 2.33</td>
<td>0.001</td>
</tr>
<tr>
<td>Residual Lesion Score - pulmonary stenosis</td>
<td></td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>Class 1 (0 - 20 mmHg)</td>
<td>Ref</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 2 (20 - 40 mmHg)</td>
<td>2.69</td>
<td>0.76, 9.49</td>
<td></td>
</tr>
<tr>
<td>Class 3 (&gt;40 mmHg)</td>
<td>10.59</td>
<td>2.64, 42.4</td>
<td></td>
</tr>
</tbody>
</table>
Late outcome 1: pulmonary valve competence

Median follow-up = 2.5 yrs (range: 0.6 - 8.5 yrs)

Freedom from $\geq$ moderate PR

Time since valve-sparing repair, years

No. at risk 162 94 76 58 41 22 14 8 1
Risk factors for pulmonary regurgitation

Multivariable regression analysis (N = 162, N events = 71)

- **Pulmonary valve annulus z-score**
  - Hazard ratio = 2.31

- **Thickened/dysplastic valve leaflet**
  - Hazard ratio = 1.67
Late outcome 2: RV chamber size - Matched cohort analysis

Valve-sparing repair (IBD)
2007 - 2015
N = 162

Transannular repair*
1997 - 2006
N = 179

1:1 Matching
- Preop PV annulus z-score
- Age at primary repair

IBD = intraoperative balloon dilation

Time-adjusted analysis
(linear mixed effects model)

*Same inclusion criteria
Late outcome 2: RV chamber size

N = 53 per

RV EDA (cm²)*

*Indexed to BSA
Conclusions

- Patients with annular z score less than -2.45 and those under 3 months of age experience higher rates of early reintervention for residual pulmonary valve stenosis.

- Valve-sparing repair with IBD is associated with development of progressive pulmonary regurgitation:
  - Significant annular hypoplasia, thickened/dysplastic leaflets are risk factors for early onset pulmonary regurgitation.

- Extent of RV dilation was not significantly different compared to transannular patch technique:
  - Further prospective studies required (cardiac MRI).
Pulmonary valve characteristics in ToF
ToF: Valve leaflet histology

Histologic examination of (A) a normal PV, and (B) a dysplastic PV in ToF: At histology, the dysplastic PV in ToF shows enlargement of spongiosa, fragmentation of fibrosa, and fibrotic thickening of the free edge (magnification 31, elastic fiber Van Gieson staining).

Vida et al, JTCVS, 2015; 149: 1358-63
Pulmonary valve morphology and reintervention for residual stenosis

All valve-sparing repair cases at BCH - 2007-2015 (N = 207):

Pulmonary valve reintervention, N = 32

Freedom from reintervention

<table>
<thead>
<tr>
<th>Time since Surgery, yrs</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unicuspid</td>
<td>18</td>
<td>9</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Bicuspid</td>
<td>151</td>
<td>99</td>
<td>75</td>
<td>61</td>
<td>46</td>
<td>34</td>
<td>26</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Tricuspid</td>
<td>38</td>
<td>28</td>
<td>24</td>
<td>20</td>
<td>17</td>
<td>14</td>
<td>9</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

Unicuspid
Bicuspid
Tricuspid
p=0.013

Unicuspid 18 9 4 4 2 2 1 1 0
Bicuspid 151 99 75 61 46 34 26 20 6
Tricuspid 38 28 24 20 17 14 9 4 1
Pulmonary valve annulus remodeling post valve-sparing repair

\[
p = <0.001
\]
Valve annulus growth vs. healthy children