Neonatal Aortic Stenosis Is a Surgical Disease

Really in 2015?...........

Lee Benson MD

The Hospital for Sick Children

Toronto, Canada
Disclosures:

Proctor: Percutaneous pulmonary valve: Medtronic
How do you think I feel?
How do you think I feel?
How do you think I feel?
What can we agree upon?

- AS is relentlessly progressive over time
- Balloon & surgical aortic valvuloplasty can improve isolated AS
- A valve with severe AS will never be normal, hence all treatments are palliative
- Once a valve is replaced, the child requires lifelong re-operations
- The longer the child can keep their own valve with reasonable function, the better (i.e. aortic valve replacement should be delayed as long as possible)
What is the best initial treatment strategy for isolated neonatal aortic valve stenosis?

A simple view of this question is:

What method (BAV or SAV) for a single procedure yields the best gradient reduction without producing severe AI?

Or, a more longer term view:

What lifelong strategy will allow preserved native valve function with the lowest morbidity & mortality for eventual valve replacement surgeries?
The Hospital for Sick Children, Toronto approach

- At initial presentation, severe AS* is treated with BAV with the goal to reduce the $\Delta P$ to an acceptable level (mild to moderate $\Delta P$), without inducing significant AI.

- For recurrent AS: repeat BAV in the absence of significant AI.

- If significant AI develops: manage medically then refer to surgery.

(*aortic annulus z-score $\geq -3$)
3-week old, wt 3.2 kg,
Echo: thickened valve leaflets, BAV, trivial AI, normal annulus (7.9mm) gradient peak/mean/P-P: 104/65/87 mmHg.
Concentric LVH. Good biventricular systolic function.

Admitted day of procedure. Procedure time 90 minutes,

Echo: after BV. Thickened dysplastic BAV with improved leaflet mobility. Gradient peak/mean/P-P: 20/8/4 mmHg.
Mild central AI. Qualitatively good biventricular function.

HOME THE NEXT DAY
Strengths of BV

- Allows hemodynamic assessment of cardiac & AV function
- Precise measurement of $\Delta P$
- Dilation of valve to within a mm
- Ability to reassess and re-dilate during a single procedure......without added risk!
- Not limited to patient size
- Not limited by how sick the infant is (severe LV dysfunction, multi-organ failure...)
Strengths of BV

- Duh... it’s minimally invasive!!
- Less pain
- No scar
- Fewer iatrogenic complications (e.g. nosocomial infections from central lines, chest tubes, etc.)
- Less time in hospital for patient
- Less time off work for parents
- Lower costs to payers & society overall
Drawbacks of BV Approach

- Some risk of femoral artery injury
- It is a “blind” procedure (we don’t “see” the valve and precisely what is happening to it)
- But…it doesn’t seem to matter

Blessed are those who have not seen yet believe
John 20:29
Catheter intervention or surgery?
Problems in comparison

- Published data consists of small series of neonates: either surgical or balloon
- No prospective randomized studies
- Considerable variability in anatomical & clinical features
- Different outcome variables
- Due to improvements in surgical & cath techniques, long-term follow-up data are difficult to interpret
- Few reports comparing surgical & balloon interventions, retrospective series
  lack of adjustments for differences between groups
Let's look at some data:
Contemporaneous experience with opposing strategies for critical AS in 2 centres over 3 decades:
  surgical *vs.* balloon valvuloplasty

<table>
<thead>
<tr>
<th></th>
<th>SV n=27</th>
<th>BV n=52</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (days)</td>
<td>7.9</td>
<td>7.3</td>
<td>.79</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>3.3</td>
<td>3.5</td>
<td>.29</td>
</tr>
<tr>
<td>Annulus (mm)</td>
<td>6.5</td>
<td>6.42</td>
<td>.81</td>
</tr>
<tr>
<td>ΔP (mmHg)</td>
<td>61</td>
<td>90</td>
<td>.003</td>
</tr>
<tr>
<td>Cusp #</td>
<td>2.5</td>
<td>2.4</td>
<td>.36</td>
</tr>
<tr>
<td>LVEDD (mm)</td>
<td>20.1</td>
<td>18.9</td>
<td>.45</td>
</tr>
<tr>
<td>Balloon (% annulus)</td>
<td>0.96±0.12</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Clamp time (min)</td>
<td>14.3±5.07</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Follow up (years)</td>
<td>12.9±6.17</td>
<td>11.2±4.05</td>
<td></td>
</tr>
</tbody>
</table>
Let's look at some data:
Contemporaneous experience with opposing strategies for critical AS in 2 centres over 3 decades:
surgical vs. balloon valvuloplasty

Brown et al 2012 ATS
SAV=surgical aortic valvotomy
BAD=balloon aortic dilation

Surgical Transvalvar Operative Procedure
Mortality

- Late survival established by 1-year following the procedure.
- The apparently greater early mortality in the SV group not statistically significant.
- No significant independent predictors of early or late mortality when adjusting for age, weight, sex, presence of duct dependent circulation, or echocardiographic findings.

92% vs. 81% (ns)
- At 5 years the freedom from re-intervention was 52% (BV) vs. 78% (SV) but the trend was not significant, \( p=0.09 \).
- At 10 years, freedom re-intervention rates also non-significant (\( p=0.60 \)).
The overall risk for re-intervention was highest in the first months after either intervention & declined to its lowest point in the first 4 years (HR of 5) at which point the risk steadily increased over the course of the follow up.
Need for Ross or AVR during follow-up

Need for a Ross

- There was no important difference between BV and SV, p=0.32.
Need for Ross or AVR during follow-up

Need for an AVR

- There was no important difference between BV and SV, \( p=0.32 \).

- In the intermediate term, there was a greater likelihood of AVR in the BV group than the SV group, but this did not reach statistical significance \( p=0.06 \) and at 10 years this trend was completely abolished, \( p=0.86 \).
The most appropriate management of critical aortic stenosis (AS) remains controversial. Balloon valvotomy (BV) and open valvotomy (OV) are firmly established as effective initial treatments with encouraging survival benefits. Improved early results are based rather on a better understanding of the limits of biventricular repair than on the method of treatment. Valvotomy of any kind is a palliative procedure, and reintervention remains frequent. Nevertheless, long-term preservation of the native aortic valve seems to depend on the method used and on the morphology of the aortic cusps [1–12].
The Long-Term Outcome of Open Valvotomy for Critical Aortic Stenosis in Neonates

Viktor Hraška, MD, Nicodeme Sinzobahamvya, MD, Christopher Haun, MD, Joachim Photiadis, MD, Claudia Arenz, MD, Martin Schneider, MD, and Boulos Asfour, MD

Results

Early Mortality and Results

There were 3 (8.8%) early deaths. Two patients with low cardiac output died on the first postoperative day. A third another patient required a Ross-Konno procedure 7 days after the OV, due to progressive heart failure. The hemodynamic instability required delayed sternal closure in 7 patients, 5 of whom needed peritoneal dialysis. The mean length of ventilation was 108 ± 133 hours (range, 12 to 696 hours). All of the remaining 30 surviving
The Long-Term Outcome of Open Valvotomy for Critical Aortic Stenosis in Neonates

Viktor Hraška, MD, Nicodeme Sinzobahamvya, MD, Christopher Haun, MD, Joachim Photiadis, MD, Claudia Arenz, MD, Martin Schneider, MD, and Boulos Asfour, MD

Re-operation

9 children needed a 2nd OR

4 children a 3rd OR (AVR)

Overall 10 children underwent 16 operations
What about the impact of valve morphology?

Re-operation

Hraška 2012
What about the impact of valve morphology?

Aortic Valve Morphology Is Associated With Outcomes Following Balloon Valvuloplasty for Congenital Aortic Stenosis

CCI 2013

Event free-survival
What about the impact of valve morphology?

Aortic Valve Morphology Is Associated With Outcomes Following Balloon Valvuloplasty for Congenital Aortic Stenosis

Shiraz A. Maskatia, MD, Henri Justino, MD, Frank F. Ing, MD, Matthew A. Crystal, MD, Raphael J. Mattamal, BS, and Christopher J. Petit, MD

CCI 2013

Freedom from:

- Functionally Bicuspid

Re-intervention/Tx/Death

AVR
Strengths & drawbacks of STOP

- Limited in patient size (e.g. <2kg?)
- Limited in how sick patient is
- Cardiopulmonary by-pass
  inflammatory injury
  myocardial injury
  on & off pump to re-due STOP
- Limited times to re-due STOP for recurrent stenosis

Hraška 2006
Strengths & drawbacks of STOP

- Duh... it’s maximally invasive!!
- More pain
- More scar
- More iatrogenic complications (nosocomial infections, central lines, chest tubes, etc.)
- More time in hospital for the child
- More time off work for parents
- Higher costs to payers & society overall
Strengths & drawbacks of STOP

- Valve commissures are incised under direct vision to tailor repair as required.
- Additional valve repair techniques are possible (leaflet shaving, augmentation, re-suspension, etc).

- Does this matter??
Their surgical approach to neonates at that time was a transapical blunt dilation of the aortic valve with serial Hegar dilators (Cooper Surgical, Inc., Trumbull, Connecticut).

This of course would be a very similar approach physiologically to a transcatheter balloon dilation.

The rationale for this was that, “the aortic valve in neonates is frequently dysplastic, making identification of the commissures with an open approach using bypass difficult and imprecise.”

Their comment here was that the results from the closed surgical approach (in neonates) were satisfactory and not substantially different from those patients undergoing balloon dilation. The better results with surgical valvotomy were limited to the study population of older children.

*Carl Backer JACC 2013*
So what does this & the literature say:

There is equivalence for both techniques in intermediate & longer term survival (Zeevi 1989, Crowley 2001, Mosca 1995, Zain 2006, McCrindle 2001)

Re-intervention rates are high with both approaches, and with longer-term follow up equivalent (Gaynor 1995, Gildein 1996, Alexiou 2001)

Higher rates of AI have been observed with BV, but restenosis higher with SV (McCrindle 2001, Drury 2005)

The development of AI is the dominate driver for re-intervention, and the direct visual inspection may reduce the incidence in some valves ......but at what cost - morbidity
‘…we should be careful not to decide a priori that one approach is better than the other.

…….there are clearly many patients who may be better served by initial balloon dilation.

There is some advantage to avoiding a sternotomy if the patient is going to require multiple re-operations perhaps eventually culminating in aortic valve replacement and/or a Ross procedure.

As we improve our knowledge of how to care for these patients collaboration between the interventional cardiologist and the surgeon continues to be of paramount importance.’
Thank You
Balloon dilation at presentation................TAVI for AVR

AS may in the future NOT BE a surgical disease
"If a cluttered desk is a sign of a cluttered mind, Of what then is an empty desk a sign?"

~ Albert Einstein