Percutaneous Aortic Valvuloplasty in 2009 Indications and Results

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Symptomatic aortic stenosis

One of the most common valve lesions in adults ~5% >75 years old

From Ross and Braunwald, Circulation 1968

Natural History of Severe AS
Managed without Surgery.
Aortic Valvuloplasty Course
Washington Hospital Center 1987.
Good Results

CO 3.4, Mean Grad 57, AVA .54

CO 3.6, Mean Grad 17, AVA 1.2

CO 6.2, Mean Grad 100, AVA .62

Sub Optimal Result

CO 6.2, Mean Grad 54, AVA .94
Technical Aspects

Rapid RV Pacing

- Use Large balloon (guided by echo-CT-angio)
- Preclose with 6F Proglide
- Reverse Heparin at end of procedure
**Procedure:**

- Proglide pre closure and 9-13F sheath insertion
- Heparin 10-70 Unit/Kg
- We cross with an AL1.0 5F or JR 4.0 5F using a straight 0.038 inch Terumo wire.
- A pigtail catheter (5F) was exchanged
- Amplatz super stiff ST-1 (1 cm tip) shaped
- Balloon size was determined by analyzing dimensions on echocardiography, aortogram with marker pigtail, and cardiac tomography when available
Procedure:

**Screw in Temporary Pacer**

Medtronic 6416-100 cm 3.5 F Pacer

Pacing at 180 bpm until the blood pressure falls <50 mmHg prior for deployment and to continue pacing until the balloon is fully deflated
BAV is Mandatory Prior to THV Implantation

Pre-THV Preparatory & Diagnostic BAV

Stand Alone BAV

Jena THV (JenaValve Tech)

Perceval THV (Sorin Group)

CoreValve THV (Endoluminal Technology)

Enable THV (ATS)

Paniagua THV

AorTx THV (Hansen Med.)

Direct Flow THV

Lotus THV (Sadra Med.)

Edwards-Sapier THV (Edwards)
Current Technology Limitations:

Standard aortic balloons are currently being used off label
- Provides no understanding of interaction between balloon and annulus at any given inflation diameter and pressure

Current balloons are hindered by the complex aortic valve anatomy

Choosing the appropriate balloon size is guesswork:
- “Is the patient big?” → 22 to 25 mm diameter
- “Is the patient small?” → 20 to 22 mm diameter
- Balloon to LVOT diameter ratio of 0.9 to 1.3
  (Echocardiographic LVOT measurement often inaccurate)
Multiple Adverse Consequences of Current Aortic Valvuloplasty Technology

1. A strong tendency to undersize balloon (do no harm) results in:
   a) Inadequate improvement in AVA in stand alone BAV
   b) Small failure in ability to deliver THV across stenosed aortic valve
   c) Immobile calcified ridges adjacent to annulus are not adequately assessed and prepared
Adverse Consequences of Current Aortic Valvuloplasty Technology

2. Catastrophic consequences can result from overly aggressive dilatation:

Aortic root dissection (occurs in 1-2%)
Balloon Over Inflation
What are the Causes of BAV Procedural Mortality?

210 consecutive BAVs at MHI
June 2003 to July 2008

Procedural mortality

7/210 (3.3%)
- 4 aortic root dissections (2%)
- 1 electrical mechanical dissection
- 1 pulmonary hemorrhage
- 1 hemodynamic collapse (cause unknown)

(MHIF BAV database 210 consecutive patients)
262 patients who underwent 301 BAV procedures among these 29 patients underwent 2 BAV, 8 patients underwent 3 BAV and 2 patients underwent 4 BAV procedures.
Symptomatic aortic stenosis
High risk/non operable

469 patients with severe aortic stenosis screened for TAVI trial

- 107 (22.8%) enrolled in TAVI trial
- 362 (77.2%) not eligible for TAVI trial

382 patients with severe aortic stenosis screened for TAVI trial

- 112 (29.3%) enrolled in TAVI trial
- 270 (70.7%) not eligible for TAVI trial

Ben-Dor AHA 2009
Symptomatic aortic stenosis
High risk/non operable

Erasmus MC: University Medical Center Rotterdam

100 patients with severe aortic stenosis screened for TAVI trial

39 (39%) enrolled in TAVI trial
61 (61%) not eligible for TAVI trial

Causes for ineligibility

- 75 (20.7%) had two reasons for rejection
- 26 (7.1%) had three reasons for rejection
Symptomatic aortic stenosis
High risk/non operable-BAV

Improve symptoms

<table>
<thead>
<tr>
<th></th>
<th>Pre (%)</th>
<th>6m f/u (%)</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>CHF</td>
<td>54</td>
<td>49</td>
<td>ns</td>
</tr>
<tr>
<td>Fatigue</td>
<td>59</td>
<td>61</td>
<td>ns</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>87</td>
<td>71</td>
<td>ns</td>
</tr>
<tr>
<td>NYHA III/IV</td>
<td>71</td>
<td>57</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Angina</td>
<td>53</td>
<td>33</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Syncope</td>
<td>23</td>
<td>12</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

Mansfield Registry Data (n=492)
Symptomatic aortic stenosis
High risk/non operable-BAV

And it improves AVA
Follow up - Median time for follow-up was 181 [56, 436] days.
* Or evaluation of reversibility of severe left ventricular dysfunction/ evaluation of reversibility of severe mitral regurgitation and severe pulmonary hypertension
Delta increase in AVA: First vs. repeat procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Area (Cm²)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First balloon aortic valvuloplasty</td>
<td>0.41</td>
<td>0.003</td>
</tr>
<tr>
<td>Repeat balloon aortic valvuloplasty</td>
<td>0.28</td>
<td></td>
</tr>
</tbody>
</table>
During median (25th, 75th interquartiles) follow-up of 181 [56, 436] days the mortality rate was 131 (50%)
Mortality according to final AVA

- AVA <1 cm²: 36.4 vs. >1 cm²: 57.9
  - P < 0.001

- AVA >40%: 49.7 vs. <40%: 50.9
  - P = 0.7

>1 vs. <1 cm²  >40 vs. <40%
## Predictors for mortality

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Univariate Cox Analysis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.43</td>
<td>1.01-2.01</td>
<td>0.04</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>2.5</td>
<td>1.5-4.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NYHA class IV</td>
<td>2.97</td>
<td>1.9-4.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2.09</td>
<td>1.46-2.98</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sodium level</td>
<td>0.95</td>
<td>0.9-0.99</td>
<td>0.01</td>
</tr>
<tr>
<td>Septal thickness</td>
<td>0.15</td>
<td>0.005-0.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Final aortic valve area</td>
<td>0.46</td>
<td>0.22-0.95</td>
<td>0.03</td>
</tr>
<tr>
<td>Aortic systolic pressure</td>
<td>0.99</td>
<td>0.98-1</td>
<td>0.03</td>
</tr>
<tr>
<td>Delta drop in hematocrit level</td>
<td>1.1</td>
<td>1.06-1.14</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delta rise in creatinine level</td>
<td>1.42</td>
<td>1.22-1.67</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delta rise in troponin level</td>
<td>1.02</td>
<td>1.0-1.03</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Multivariate Cox Analysis</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Renal failure</td>
<td>2.23</td>
<td>1.09-4.54</td>
<td>0.01</td>
</tr>
<tr>
<td>NYHA class IV</td>
<td>4.91</td>
<td>1.88-12.8</td>
<td>0.001</td>
</tr>
<tr>
<td>Pulmonary pressure</td>
<td>1.03</td>
<td>1.01-1.06</td>
<td>0.01</td>
</tr>
<tr>
<td>Delta drop in hematocrit level</td>
<td>1.16</td>
<td>1.04-1.3</td>
<td>0.01</td>
</tr>
</tbody>
</table>
## Complications %

<table>
<thead>
<tr>
<th>Registry</th>
<th>N</th>
<th>Procedural Death</th>
<th>CVA</th>
<th>Tamponade</th>
<th>Severe AR</th>
<th>Vasc</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLBI (674)</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Mansfield Registry (492)</td>
<td>7.5</td>
<td>2.2</td>
<td>2</td>
<td>1</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Cribier (334)</td>
<td>4.5</td>
<td>1.4</td>
<td>0.6</td>
<td>0</td>
<td>13.1</td>
<td></td>
</tr>
<tr>
<td>WHC (262)</td>
<td>1.6</td>
<td>1.9</td>
<td>0.3</td>
<td>1.3</td>
<td>6.9</td>
<td></td>
</tr>
<tr>
<td>Kuntz (219)</td>
<td>4.4</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Agarwal (212)</td>
<td>1.1</td>
<td>0.4</td>
<td>0.4</td>
<td>1.1</td>
<td>13.5</td>
<td></td>
</tr>
<tr>
<td>Safian (170)</td>
<td>3.5</td>
<td>0</td>
<td>1.7</td>
<td>N/A</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Lewin (125)</td>
<td>10.4*</td>
<td>3.2</td>
<td>0</td>
<td>1.6</td>
<td>9.6</td>
<td></td>
</tr>
</tbody>
</table>

* In hospital mortality
# Mortality %

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Procedural Death</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLBI</td>
<td>(674)</td>
<td>3</td>
<td>45</td>
<td>65</td>
<td>77</td>
</tr>
<tr>
<td>Mansfield Registry</td>
<td>(492)</td>
<td>7.5</td>
<td>36</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Cribier</td>
<td>(334)</td>
<td>4.5</td>
<td>24</td>
<td>34</td>
<td>N/A</td>
</tr>
<tr>
<td>WHC</td>
<td>(262)</td>
<td>1.6</td>
<td>42</td>
<td>59</td>
<td>N/A</td>
</tr>
<tr>
<td>Kuntz</td>
<td>(219)</td>
<td>4.4</td>
<td>25</td>
<td>40</td>
<td>47</td>
</tr>
<tr>
<td>Agarwal</td>
<td>(212)</td>
<td>1.1</td>
<td>36</td>
<td>53</td>
<td>72</td>
</tr>
<tr>
<td>Safian</td>
<td>(170)</td>
<td>3.5</td>
<td>36</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Lieberman</td>
<td>(165)</td>
<td>N/A</td>
<td>39</td>
<td>59</td>
<td>75</td>
</tr>
<tr>
<td>Lewin</td>
<td>(125)</td>
<td>10.4*</td>
<td>38</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* In hospital mortality
Hemodynamic Results of BAV

Increase of aortic valve area: 0.3-0.4 cm²
PTAV can be Accomplished with Low Complication Rate

<table>
<thead>
<tr>
<th>Condition</th>
<th>WHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients n=</td>
<td>196</td>
</tr>
<tr>
<td>In-Hospital Mortality</td>
<td>1.6%</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>6.1%</td>
</tr>
<tr>
<td>Severe AI</td>
<td>1.6%</td>
</tr>
<tr>
<td>Stroke (mostly minor)</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

BenDor, Satler, Pichard et al. AHA 09
Survival after PTAV is Low.
Agarwal, Sharma et al. AJC 2005;95:43-7

212 cases
Survival after Single PTAV is Low
WHC: Ben-Dor et al. ACC 09

255 patients excluded from the Partner Trial at WHC

Medical group: higher STS 12.8±7.0 vs. 8.5±5.1, p<0.001 and logistic Euroscore 42.4±22.8 vs. 24.4,
Surgical Group: surgical mortality 3.4%, in hospital mortality 17.04%, and 17.8% discharged to nursing care facilities due to debilitation.
Cause of Death

- **Medical/BAV**
  - N=102
  - Cardiac death: 43.1%
  - Non-cardiac death: 36.2%
  - Unknown death: 20.6%

- **Surgical AVR**
  - N=19
  - Cardiac death: 47.3%
  - Non-cardiac death: 52.6%
  - Unknown death: 0%
Clinical Benefit of BAV

- **Temporary improvement in:**
  - CHF
  - syncope
  - angina.

- **Hypothesis:** “repeated BAV could decrease the rate of death”
  - should we recommend BAV q 3-6 months until definitive therapy is performed?
## 90 year old
Recurrent pulmonary edema.
**EF 20%, 4+ MR, BNP 5,000.**
AVA 0.29 cm². STS 22

## After PTAV
EF improved to 50%
MR decreased to 1-2+

---

**Diagnostic Benefits of BAV**
Patient became eligible for TAVI
Diagnostic Benefit of BAV

Excellent tool to evaluate reversibility of
- LV dysfunction
- MR
- Pulmonary hypertension

WHC.
BAV as a Bridge to AVR

![Graph showing survival rates over time for PAV and PAV + AVR, with a p value of 0.0001.](image)
Indications for BAV

- **Best Indications:**
  - Bridge to AVR.
  - Evaluate for reversibility of severe LV dysfunction and severe MR.

- **Other Indications:**
  - Palliative symptom alleviation.
  - Temporizing for percutaneous AVR.
  - Urgent therapy for patients is severe CHF/shock due to critical AS.
The valve area threshold increased from 0.7 cm² to 1.0 cm².

“Prior to urgent noncardiac surgery” has been eliminated as an indication.

Most importantly, unless operative risk is high, BAV is never indicated.
## ESC Guidelines for Aortic Balloon Valvuloplasty 2007

<table>
<thead>
<tr>
<th>Indication</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>A bridge to surgery in hemodynamically unstable patients who are at high risk for AVR</td>
<td>I</td>
</tr>
<tr>
<td>Palliation in patients with serious comorbid conditions</td>
<td>IIb (level of evidence: C)</td>
</tr>
<tr>
<td>Patients who require urgent noncardiac surgery</td>
<td>IIb (level of evidence: C)</td>
</tr>
</tbody>
</table>

**Additional palliative indications:**
- Expected survival <3 years.
- Age >80, AVR refused
- Cardiogenic shock (due to AS)
BAV not helpful in:

- Extreme LV dysfunction, particularly when unrelated to AS (e.g., scar due to large MI’s).
- Terminal CHF with multiple system failure.
- Severe arch atheroma with high risk of Cerebral embolization.
- Aortic insufficiency $\geq 2+$ at baseline.
- Life-limiting non cardiac illness.
Summary

A. Clinical Benefits of BAV
  • Not a permanent cure
  • Safe procedure
  • Good initial clinical improvement

B. Diagnostic Benefits
  • LV dysfunction reversibility
  • MR and PH reversibility

C. Bridging for AVR: excellent strategy

D. Therapeutic Benefit:
  • Occasionally used for palliative care.
CONCLUSIONS

• BAV will play a central role in the treatment of all nonsurgical AS patients who are candidates for transcatheter therapy.
• Long term survival after BAV is poor.
• A successful valvuloplasty appears to be a final AVA at least $1\text{cm}^2$, which is associated with lower mortality rate.
• Trans catheter or surgical aortic valve replacement should be pursued aggressively if final AVA>$1\text{cm}^2$ is not met.
• This may be especially true in patients who developed restenosis after the first BAV since the second BAV is seldom as successful in reaching that end point.