Percutaneous Aortic Valvuloplasty: Long-Term Survival

Angioplasty Summit – Seoul April 27, 2007

James R. Margolis MD
Carmen Paez MD, Kevin Coy MD, Edward Freeman PhD
Miami International Cardiology Consultants
Miami, Florida
Background

• Although Aortic Valve Replacement (AVR) is a surgical procedure with low surgical mortality and excellent long-term results, there exists a large cohort of patients who represent high-risk for AVR or are frankly inoperable.
• Most of these patients are managed medically with a concomitant inexorable downhill course and very high mortality.
• Percutaneous Aortic Valve Replacement (PAVR) shows great promise for this cohort of patients.
• However, PAVR is some years from being available to the general public.
• In the meantime, we need a treatment for the high-risk and inoperable patients that will serve as a bridge to PAVR when it is finally available.
31.8% did not undergo intervention, despite NYHA class III/IV symptoms

Do patients with valvular heart disease receive treatment according to established guidelines?

- 92 hospitals from 25 countries
- 5,001 patients from April-July, 2001
Aortic Valve Replacement

Hospital Mortality

In-Hospital Mortality (percent)

Year


AVR + CABG

AVR

Society of Thoracic Surgeons Database, 2005 [www.sts.org]
Operative Mortality / Comorbidity
Euro Heart Survey on Valvular Heart Disease

1231 Patients operated in 92 centers from April to July 2001

Mortality

% 20 30 40

EuroScore

16% of patients

2 3 4 5 6 7 8 9 10_11 >11
Introduction

• For more than twenty years, Percutaneous Balloon Aortic Valvuloplasty (PBAV) has been an effective treatment for short-term palliation of signs and symptoms of critical aortic stenosis in patients who are not candidates for aortic valve replacement.

• Because of a prohibitively high restenosis rate, this procedure fell into disfavor soon after its introduction in 1985.

• Although the procedure was generally abandoned after 1990, some centers including our own have continued to perform it on a regular basis for true “no option” patients.

• We have observed that hemodynamic restenosis does not always correlate with clinical recurrence in these elderly patients who are otherwise limited by age and co-morbid disease.
Methods

• In order to assess the magnitude and duration of palliation in this population, we have retrospectively examined the clinical course of patients who underwent PBAV in our center during the past six years.
• No formal prospective criteria were followed in the determination of suitability for AVR.
• All patients were referred by cardiologists and/or cardiac surgeons from outside our institution.
• All were functional classes 3 and 4.
Methods, cont.

• All patients were deemed by their referring physicians to be unsuitable candidates for aortic valve replacement.

• In general, patients were felt to be too old or too frail for AVR, or were rejected on the basis of significant co-morbidities such as advanced pulmonary disease or cancer.

• In support of the accuracy of this assessment, two patients in the cohort had AVR subsequent to early clinical recurrence following apparently successful and uncomplicated PBAV.
  – One patient died immediately post-operatively, and the second patient died within one month.
Technique

• All efforts were made to keep procedures as short and simple as possible.
• Patients were fully evaluated prior to the procedures.
  – All with echocardiography.
  – Many with prior diagnostic cardiac cath.
• If coronary angioplasty was necessary, this was done as a separate procedure.
• Right heart catheterization and cardiac output measurements were not routinely performed.
• Overriding principle was that in these elderly very sick patients complications could be minimized by minimizing procedure time and avoiding all but essential procedural components.
• Most procedure times were kept under 30 minutes.
Technique

• All procedures were performed from a retrograde approach using a single balloon.
• Balloon sizes varied from 18 mm to 23 mm.
• A single 20 mm balloon was used for the majority of procedures.
• Some procedures were started with an 18 mm balloon followed by a 20 mm balloon.
• Occasional procedures were started with the 20 mm balloon with subsequent step-up to a 23 mm balloon.
• In most cases an effort was made to rupture the balloon, but this technique was not uniformly applied.
Cohort

- 38 symptomatic patients with Critical Aortic Stenosis.
- Ages 65-95 (mean age 80).
- Follow-up 3-78 months (mean 42 months) after PBAV.
- 19 men and 19 women.
- All patients were functional classes 3 and 4.
- All were prohibitively high-risk for Aortic Valve Replacement (AVR).
- Initial decision that a patient was not a surgical candidate was never made by the physician performing the valvuloplasty procedure.
- Vast majority of patients were referred for specific purpose of aortic valvuloplasty.
Assessment of Risk

• Logistic Euroscore
  – Range 14.0% - 84.1%
  – Mean 57.5%
  – Median 62%

• STS Predicted Risk
  – Range 14.2% - 79.2%
  – Mean 39.7%
  – Median 35%
## Comparative Risk vs. PAVR

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Logistic Euroscore (%)</th>
<th>STS Score (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancouver (CE)*</td>
<td>28.0</td>
<td></td>
</tr>
<tr>
<td>Revival (CE)*</td>
<td>33.3</td>
<td>13.0</td>
</tr>
<tr>
<td>Leipzig (CE)*</td>
<td>27.1</td>
<td></td>
</tr>
<tr>
<td>CoreValve</td>
<td>25.5</td>
<td></td>
</tr>
<tr>
<td>PBAV</td>
<td>57.5</td>
<td>39.7</td>
</tr>
</tbody>
</table>

*Cribier-Edwards Valve
*Transapical
Results

• Pre-PBAV all patients were functional classes 3 and 4.
• All procedures were initially successful and uncomplicated.
• Two patients (5%) died during hospitalization.
  – One from ischemic bowel.
  – One from renal failure.
• One patient died at 11 days outside of hospital from unknown cause (30 day mortality 8%).
• Two patients had AVR within 3 months after PBAV.
  – Both died shortly after surgery.
Results, cont.

- After 36-months there were 19 deaths (5 non-cardiac).
- Mortality was 19% at 6 months, 31% at 12 months, 46% at 24 months, and 52% at 36 months.
- Four patients have survived more than 4 years and 2 have survived more than 5 years – all without re-intervention.
- Eight patients (21%) required re-interventions, 7 between 6 and 12 months after initial PBAV.
- Three patients had 2 re-interventions; one had 3 re-interventions.
- Need for re-intervention did not appear to affect survival.
Pre-operative Risk vs. Mortality

• There was a loose correlation between Logistic Euroscore and mortality.
  – Most patients with Euroscores > 70 died in the first year.

• However:
  – Two patients with Euroscores of 80 and 69 were alive at 3 and 4 years respectively.
  – Several patients with Euroscores in 50 – 69 range survived more than two years.
Comparison to PAVR
Retrograde Approach: Vancouver (n=45)

30-Day Mortality

- Log. Euroscore
- Mortality
- Patient 1-23
- Patient 24-46

Mortality (%)

John Webb et al. ACC 2006
# Mortality

<table>
<thead>
<tr>
<th>Cohort</th>
<th>30 Day (%)</th>
<th>6 Month (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancouver (CE)*</td>
<td>12.1</td>
<td>ca. 20</td>
</tr>
<tr>
<td>Revival (CE)*</td>
<td>7.3</td>
<td>14.8</td>
</tr>
<tr>
<td>Leipzig** (CE)*</td>
<td>6.6</td>
<td>14.1</td>
</tr>
<tr>
<td>CoreValve Gen II</td>
<td>12.7</td>
<td>19.0</td>
</tr>
<tr>
<td>PBAV</td>
<td>8.1</td>
<td>18.9</td>
</tr>
</tbody>
</table>

*Cribier-Edwards Valve
**Transapical
Survival

![Graph showing survival over days with a declining trend](image-url)

- **X-axis**: Days (30, 180, 365, 730, 1095)
- **Y-axis**: Survival (Percent)
- The graph illustrates a decreasing survival rate over time.
Transcatheter AVR*:
The Vancouver Experience

50 consecutive patients; all patients > 6 months follow-up and 30 patients >1 year follow-up

Event Free Survival (%)

Survival function

Days

0 30 60 90 120 150 180 210 240 270 300 330 360 390 420 450

0.0 0.2 0.4 0.6 0.8 1.0

Log-rank p-value 0.09

Days

Second 25 patients
First 25 patients

*Cribier – Edwards Valve

Courtesy of J. Webb via Martin Leon
Conclusions

• Whether these are good or bad results depends on whether one believes that a glass is half-empty or half-full.
• In this cohort of elderly symptomatic patients with critical aortic stenosis, who were prohibitively high-risk for AVR, 50% survived three or more years, and only a minority required re-intervention.
• The fact that the two patients who crossed over to AVR died peri-operatively lends credence to the high-risk nature of this cohort.
• These data suggest that in the absence of a surgical alternative PBAV is a reasonable palliative procedure for patients with end-stage aortic stenosis.
Speculation

• It is difficult to compare this cohort to those who have undergone PAVR.
  – The valvuloplasty patients were generally sicker (Logistic Euroscores 58% vs. 30%).
  – PAVR patients have comparable early mortalities with a trend toward more durable results.

• As equipment and technique improve, PAVR will undoubtedly emerge as the superior procedure.

• Until PAVR becomes more generally available, PBAV can bridge the gap between ineffective medical management and definitive AVR in these very sick high-risk patients.