The Current Approach to the Stenotic Aortic and Mitral Valve

TCT 2004

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Presenter Disclosure Information

Name: Igor Palacios

Nothing to Disclose Related to this Presentation
Percutaneous Treatment of Valvular Heart Disease

- **Stenotic Lesions:**
  - Pulmonary balloon valvuloplasty
  - Mitral balloon valvuloplasty
  - Aortic balloon valvuloplasty
  - Tricuspid balloon valvuloplasty

- **Regurgitant Lesions:**
  - Percutaneous aortic valve replacement
  - Percutaneous mitral valve repair/replacement
Aortic Stenosis

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### Aortic Balloon Valvuloplasty

#### Patient Population

- **Number of Patients:** 310 (394 PAV)
- **Age:** 79±1 (35-96) years
- **Female/Male:** 180/130
- **NYHA Class:**
  - Class I: 2%
  - Class II: 8%
  - Class III: 30%
  - Class IV: 53%
  - Shock: 7%

All patients were non or very high surgical candidates for AVR.
Aortic Balloon Valvuloplasty

Associated Comorbid Conditions

- COPD 64 (21%)
- Chronic Renal Failure 64 (21%)
- Peripheral Vascular Disease 54 (17%)
- Cancer 48 (15%)
- Cerebrovascular Disease 48 (15%)
- Others* 112 (38%)

* Liver failure, Hip fracture, GI bleeding, Complications of Diabetes, Alzheimer, Sepsis, Thyroid disease, AIDS.
Aortic Balloon Valvuloplasty

Techniques

- Retrograde technique.
- Transseptal antegrade technique.
- Inoue transseptal antegrade technique.
Aortic Balloon Valvuloplasty
Retrograde Technique
Retrograde PAV
Retrograde PAV
Aortic Balloon Valvuloplasty

Pre-PAV

AVA: 0.6 cm²

Post-PAV

AVA: 1.2 cm²
Pre-PAV AVA = 0.4 cm²
Antegrade PAV Using the Inoue Balloon Technique
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Antegrade PAV Using the Inoue Balloon Technique
Post-PAV AVA = 1.0 cm²
Hemodynamic Changes After PAV

<table>
<thead>
<tr>
<th></th>
<th>Pre-PAV</th>
<th>Post-PAV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Gradient</td>
<td>63</td>
<td>18</td>
</tr>
<tr>
<td>Cardiac Output</td>
<td>3.3</td>
<td>4.7</td>
</tr>
<tr>
<td>AVA</td>
<td>0.4</td>
<td>1.0</td>
</tr>
</tbody>
</table>
Aortic Balloon Valvuloplasty

Mechanism
Aortic Balloon Valvuloplasty

Immediate Outcome

Aortic Gradient (mmHg)

Pre-PAV: 56±1
POST-PAV: 25±1

P <0.0001

AVA (cm²)

Pre-PAV: 0.5±0.1
POST-PAV: 0.9±0.1

P <0.0001
Aortic Balloon Valvuloplasty

Complications

- In-Hospital Mortality: 8.6%
- Vascular Surgery: 9.5%
- Severe AI: 1.5%
- Stroke: 1.2%
- Cholesterol Emboli: 1.0%
Aortic Balloon Valvuloplasty

**Post-PAV AVA**
- Failure: 3%
- ≤ 0.7 cm²: 38%
- 0.7-0.9 cm²: 38%
- ≥ 1.0 cm²: 27%

**Post-PAV AI**
- ≥ 2 Grade: 2%
- < 1 Grade: 28%
- No Changes: 65%

Palacios et al

Cribier et al
Aortic Balloon Valvuloplasty

Natural History of Aortic Stenosis

![Graph showing the natural history of aortic stenosis](image-url)
Aortic Balloon Valvuloplasty

Natural History of Aortic Stenosis in the Elderly

Survival (%)

Control

Severe AS

Time of Follow-up (years)

Aortic Valve Replacement in Octogenarians With Aortic Stenosis

Life Table Analysis

Probability of Survival

Years after AVR
Aortic Balloon Valvuloplasty

Mortality

- AVA ≥ 1.0 cm²
- AVA 0.8 - 0.9 cm²
- AVA < 0.7 cm²

% vs. MONTHS FIU
Aortic Balloon Valvuloplasty

Clinical Restenosis
PAV as a Bridge to AVR

Long Term Survival

![Graph showing survival over time for PAV and PAV + AVR with a p-value of 0.0001]
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
First Human Case Description

Alain Cribier, Circulation 2002 106: 3006-3008
Aortic Balloon Valvuloplasty

Indications

- Non-Surgical Candidates
- Bridge to AVR
- Bridge to Major Non-Cardiac Surgery
- Cardiogenic Shock
- Gorlin Conondrum
- Non Calcified Valves (Congenital AS, Rheumatic AS)
Mitral Balloon Valvuloplasty

Long-Term Results

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Symptomatic patients.
No evidence of left atrium thrombus by TEE.
Adequate mitral valve morphology
  – Echocardiographic assessment (echo-score).
  – Fluoroscopic calcium.
Pre-PMV MR ≤ 2 + (Seller’s classification).
Lack of significant aortic valve or coronary artery disease requiring surgery.
Mitral Balloon Valvuloplasty

Baseline Characteristics

- Number of PMV: 939
- Age (years): 55 ± 15
- Female Gender: 82%
- Atrial Fibrillation: 49%
- Previous Commissurotomy: 16%
- NYHA Class
  - Class I: 2%
  - Class II: 24%
  - Class III: 61%
  - Class IV: 13%

Mitral Balloon Valvuloplasty

Pre-PMV MR

MR 0 + (54.5%)
MR 1 + (39%)
MR 2 + (6%)
MR 3 + (0.5%)

Fluoroscopic Calcium

CALCIUM 1 + (43%)
CALCIUM 2 + (16%)
CALCIUM 3 + (6%)
CALCIUM 4 + (3%)
NO CALCIUM (32%)

Assessment of Mitral Valve Morphology
The MGH - Echocardiographic Score

- Leaflets Rigidity 0 - 4
- Leaflets Thickening 0 - 4
- Leaflets Calcification 0 - 4
- Subvalvular Disease 0 - 4
- Total Score 0 - 16

Low vs. High Mitral Score

Low Score (5)  High Score (9)
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>$\leq 8$</th>
<th>$&gt; 8$</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>634</td>
<td>305</td>
<td></td>
</tr>
<tr>
<td><strong>Mean Echo Score</strong></td>
<td>$7.7\pm2.2$</td>
<td>$10.2\pm1.4$</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Male Gender</strong></td>
<td>14.8%</td>
<td>26.2%</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Mean Age</strong></td>
<td>$51\pm14$</td>
<td>$63\pm14$</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Atrial Fibrillation</strong></td>
<td>44.3%</td>
<td>59.7%</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>NYHA Class IV</strong></td>
<td>7.5%</td>
<td>25.2%</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Calcium $\geq 2+$</strong></td>
<td>10.9%</td>
<td>59.5%</td>
<td>0.0001</td>
</tr>
<tr>
<td><strong>Pre-PMV MR $&gt; 1 +$</strong></td>
<td>5.7%</td>
<td>9.9%</td>
<td>0.004</td>
</tr>
<tr>
<td><strong>Prior Commissurotomy</strong></td>
<td>14.7%</td>
<td>20.3%</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Mitral Balloon Valvuloplasty

PMV Technique

- DOUBLE BALLOON (72%)
- SINGLE BALLOON (2.5%)
- INOUE (25%)
- Mixed (0.5%)

Mitral Balloon Valvuloplasty

The Double Balloon Technique
Mitral Balloon Valvuloplasty

The Inoue Technique
Mitral Balloon Valvuloplasty

The Cribier Technique
Mitral Balloon Valvuloplasty

The Multi-Track technique
Mitral Balloon Valvuloplasty

Immediate Outcome

LV/LA Pre-PMV

LV/LA Post-PMV

MVA= 0.9 cm²  95%

MVA= 2.2 cm²  96%
Mitral Balloon Valvuloplasty

Procedural Success

- Post-PMV Mitral Valve Area ≥ 1.5 cm²
- Post-PMV MR ≤ 2 + (Seller’s Class)
Mitral Balloon Valvuloplasty

Changes in MVA

Pre-PMV
Post-PMV

0.9±0.3
1.9±0.6

P <0.001

Post-PMV MR ≥ 3 +

Patients (%)

Success: 72%

MR 3 +
MR 4 +

9.0
6.3
2.7
Mitral Balloon Valvuloplasty

Unsuccessful PMV

- MR $\geq 3 +$ 33.1%
- MVA $< 1.5$ cm$^2$ 66.9%

Post-PMV MVA

- MVA $\leq 1.0$ cm$^2$ 10.1%
- 1.1-1.4 cm$^2$ 10.1%
- 1.5-1.9 cm$^2$ 34.2%
- $\geq 2.0$ cm$^2$ 38.5%

## Mitral Balloon Valvuloplasty

### Procedural Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>≤ 8</th>
<th>&gt; 8</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Number</td>
<td>634</td>
<td>305</td>
<td></td>
</tr>
<tr>
<td>Pre-PMV MVA</td>
<td>1.0±0.3</td>
<td>0.8±0.3</td>
<td>0.0001</td>
</tr>
<tr>
<td>EBD/A/BSA</td>
<td>3.66±0.5</td>
<td>3.54±0.5</td>
<td>0.001</td>
</tr>
<tr>
<td>Post-PMV MVA</td>
<td>2.0±0.6</td>
<td>1.6±0.6</td>
<td>0.0001</td>
</tr>
<tr>
<td>QP/QS &gt; 1.5:1</td>
<td>5.4%</td>
<td>5.2%</td>
<td>NS</td>
</tr>
<tr>
<td>Post-PMV MR 3 +</td>
<td>5.8%</td>
<td>6.3%</td>
<td>NS</td>
</tr>
<tr>
<td>Post-PMV MR 4 +</td>
<td>2.5%</td>
<td>5.3%</td>
<td>0.03</td>
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<tr>
<td>Procedure Success</td>
<td>79%</td>
<td>56.4%</td>
<td>0.0001</td>
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## Independent Predictors of Success

<table>
<thead>
<tr>
<th>Variables</th>
<th>Odd Ratio</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Larger Pre-PMV MVA</td>
<td>13.05</td>
<td>&lt;0.00001</td>
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<tr>
<td>Less Pre-PMV MR</td>
<td>3.85</td>
<td>&lt;0.00001</td>
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<tr>
<td>Younger Age</td>
<td>3.33</td>
<td>0.006</td>
</tr>
<tr>
<td>No Prior Commissurotomy</td>
<td>1.85</td>
<td>0.00</td>
</tr>
<tr>
<td>Male Gender</td>
<td>1.92</td>
<td>0.00</td>
</tr>
<tr>
<td>Echo-Score ≤ 8</td>
<td>1.69</td>
<td>0.0004</td>
</tr>
</tbody>
</table>

Mitral Balloon Valvuloplasty

Complications

- Procedure Mortality 0.6%
- In-Hospital Mortality 1.9%
- Emergency MVR 1.4%
- Tamponade 0.8%
- Stroke 1.2%

## In-Hospital Adverse Events

<table>
<thead>
<tr>
<th>Echo Score</th>
<th>≤ 8</th>
<th>&gt; 8</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Number</td>
<td>634</td>
<td>305</td>
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</tr>
<tr>
<td>Procedural Death</td>
<td>0.3%</td>
<td>1.3%</td>
<td>0.08</td>
</tr>
<tr>
<td>In-Hospital Death</td>
<td>0.8%</td>
<td>4.3%</td>
<td>0.0006</td>
</tr>
<tr>
<td>Tamponade</td>
<td>0.8%</td>
<td>0.9%</td>
<td>NS</td>
</tr>
<tr>
<td>Emergency MVR</td>
<td>1%</td>
<td>2.3%</td>
<td>NS</td>
</tr>
<tr>
<td>In-Hospital MVR</td>
<td>2.2%</td>
<td>5.7%</td>
<td>0.007</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.1%</td>
<td>1.3%</td>
<td>NS</td>
</tr>
<tr>
<td>AV Block</td>
<td>0.5%</td>
<td>0.7%</td>
<td>NS</td>
</tr>
</tbody>
</table>
Percutaneous Mitral Balloon Valvuloplasty
Long-Term Follow-Up
Percutaneous Mitral Balloon Valvuloplasty
Long-Term Follow-Up

Long-term Follow-up

- Death 110 (13.0%)
- MVR 234 (27.7%)
- Redo-PMV 54 (6.4%)
- Combined Events 398 (47.2%)
- Free of Events 446 (52.8%)
  - NYHA I-II 417 (94%)
  - NYHA III-IV 29 (6.5%)

Time of follow-up 4.2±3.7 (0.5-15) years
### Independent Predictors of Combined Events

<table>
<thead>
<tr>
<th>Variables</th>
<th>Risk Ratio</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Age</td>
<td>1.02</td>
<td>&lt;0.0001</td>
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<tr>
<td>NYHA Class IV</td>
<td>1.35</td>
<td>0.05</td>
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<tr>
<td>Prior Commissurotomy</td>
<td>1.50</td>
<td>0.002</td>
</tr>
<tr>
<td>Echo-Score</td>
<td>1.31</td>
<td>0.03</td>
</tr>
<tr>
<td>Pre-PMV MR $\geq$ 2 +</td>
<td>1.56</td>
<td>0.02</td>
</tr>
<tr>
<td>Post-PMV MR $\geq$ 3+</td>
<td>3.54</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Post-PMV PA</td>
<td>1.02</td>
<td>&lt;0.00001</td>
</tr>
</tbody>
</table>

Mitral Balloon Valvuloplasty
Effect of Echo Score

Mitral Balloon Valvuloplasty
Effect of Echo Score

Long-term Survival

Time of Follow-up (months)
Survival (%)

Echo Score ≤ 8
Total Group
Echo Score > 8

P < 0.0001

Mitral Balloon Valvuloplasty
Effect of Echo Score

Long-term Event Free Survival

Optimal Candidates for PMV

- Age ≤ 55 year old.
- Normal Sinus Rhythm.
- Echocardiographic Score ≤ 8.
- No Fluoroscopic Mitral Valve Calcification.
- Pre-PMV MR ≤ 1 + Seller’s Grade
Follow-up of Optimal Candidates for Percutaneous Mitral Balloon Valvuloplasty

Long-term Follow-up

Survival (%)

Follow-up Time (months)

Survival
Event Free Survival
### PMV vs. Surgical Closed and Open Mitral Commissurotomy

#### Randomized Trials

<table>
<thead>
<tr>
<th></th>
<th>Turi</th>
<th>Reyes/Turi</th>
<th>Farhat</th>
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</thead>
<tbody>
<tr>
<td><strong>PMV</strong></td>
<td>21</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td><strong>CCM</strong></td>
<td>19</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>27±12</td>
<td>30±9</td>
<td>29±12</td>
</tr>
<tr>
<td></td>
<td>29±10</td>
<td>31±9</td>
<td>27±12</td>
</tr>
<tr>
<td><strong>Echo Sc</strong></td>
<td>7.2±1.7</td>
<td>6.7±1.3</td>
<td>6.0±1</td>
</tr>
<tr>
<td></td>
<td>8.4±1.5</td>
<td>7±1.2</td>
<td>6.0±1</td>
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<tr>
<td><strong>MVA Post</strong></td>
<td>1.6±0.6</td>
<td>2.0±0.6</td>
<td>2.1±0.5</td>
</tr>
<tr>
<td></td>
<td>1.6±0.8</td>
<td>2.1±0.6</td>
<td>2.2±0.4</td>
</tr>
<tr>
<td><strong>MVA 7 yr</strong></td>
<td>1.6±0.4</td>
<td>1.9±0.6</td>
<td>1.8±0.3</td>
</tr>
<tr>
<td></td>
<td>1.7±0.6</td>
<td>1.6±0.4</td>
<td>1.8±0.3</td>
</tr>
<tr>
<td><strong>Restenosis</strong></td>
<td>30%</td>
<td>27%</td>
<td>6.6%</td>
</tr>
<tr>
<td></td>
<td>25%</td>
<td>43%</td>
<td>6.6%</td>
</tr>
<tr>
<td><strong>Event Free</strong></td>
<td>91%</td>
<td>78%</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>65%</td>
<td>93%</td>
</tr>
</tbody>
</table>
PMV results in excellent hemodynamic and clinical improvement in the majority of patients with mitral stenosis.

The immediate and long-term outcome of patients undergoing PMV is multi-factorial. The use of the *Echo-Sc* in conjunction with other clinical and morphological predictors of PMV outcome allows identification of patients who will obtain the best outcome from PMV.
• These factors include pre-PMV variables (MVA, history of previous surgical commissurotomy, age and MR) and post-PMV variables (MR ≥ 3 + and PA pressure).

• In hospital complications, immediate and long-term follow-up results are similar to those of open and closed surgical commissurotomy.

• Thus, PMV is the procedure of choice for the treatment of most patients with rheumatic mitral stenosis.