Mechanical vs. Bioprosthetic Aortic Valve Replacement: Time to Reconsider?

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Disclosures

• None relevant to this presentation
FIGURE 1. Percentage use of bioprosthetic valves relative to mechanical valves from 1997 through 2006. Bioprosthetic valve use increased progressively during 10 years. Asterisk indicates $P < .000001$. 
ACQUIRED CARDIOVASCULAR DISEASE: AORTIC VALVE

National trends in utilization and in-hospital outcomes of mechanical versus bioprosthetic aortic valve replacements

Abby J. Isaacs, MS, Jeffrey Shuhaiber, MD, Arash Salemi, MD, O. Wayne Isom, MD, and Art Sedrakyan, MD, PhD
Increase in the use of bioprosthetic valves from 15 to 74% in young patients (from 50 to 69 years old) between 1997 and 2012 in New York state.
German Heart Surgery Report 2016: The Annual Updated Registry of the German Society for Thoracic and Cardiovascular Surgery

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2016 88% bioprosthetic
Explaining the shift

• “Anti” – Anti –coagulation
  – Many young patients refuse long-term anticoagulation
  – Elderly patients are at high risk when receiving anticoagulation.
• Reoperation to replace a failed bioprosthetic can be accomplished with minimal morbidity and mortality.
• Newer generation tissue valves are expected to provide longer reoperation-free survivals.
• “We can always do a valve in valve”
### ACC/AHA 2017 Guidelines

<table>
<thead>
<tr>
<th>Level</th>
<th>Quality</th>
<th>Recommendation</th>
<th>Description</th>
<th>2014 Recommendation</th>
<th>MODIFIED: LOE updated from B to B-NR. The age limit for mechanical prosthesis was lowered from 60 to 50 years of age.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C</td>
<td></td>
<td>A bioprosthesis is <strong>recommended</strong> in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired.</td>
<td>2014 recommendation remains current.</td>
<td></td>
</tr>
<tr>
<td>IIa</td>
<td>B-NR</td>
<td>An aortic or mitral mechanical prosthesis is <strong>reasonable</strong> for patients less than 50 years of age who do not have a contraindication to anticoagulation (141,149,151,155–157).</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
SAVR & TAVR Volumes

STS/ACC TVT Registry Database as of 3-1-18
Questions

• Should we be using mechanical valves at all?
• If we accept universal bioprosthetic implant
• One of the biggest predictors of SVD is post implant Gradient
  • Both of which are better in TAVR (SURTAVI, PARTNER, NOTION)
• Should we be implanting surgical valves at all?
  • Should everyone just get a TAVR?
The other options

- Mechanical AVR
- Ross operation
- Aortic valve repair
What is a reasonable expectation for valve life?
SVD: Comparison between surgical valves using freedom from reoperation

Valve-Related Reoperation, Structural Valve Deterioration, and Endocarditis

• Ten-year freedom from reoperation was 97.0% and 99.6% for the Hancock II and Perimount, respectively ($P \neq 0.2$).

• In total, 11 reoperations (Hancock II (10) | Perimount, (1)) occurred in this cohort. Structural valve deterioration (Hancock II, 97.5% 1.1%; Perimount, 97.2% 1.9% at 10 years; $P \neq 0.6$).

• Prosthetic valve endocarditis were not different between valve types.

Freedom from reoperation:
Ten reoperations were observed among Hancock II patients and 1 reoperation was observed among Perimount patients.
Surgical bioprostheses long-term follow-up: Based on freedom SVD

Freedom from SVD by age groups:

Expected valve durability (median survival time without SVD) was 17.6 for the younger (60) and and 22.1 years for the 60 to 70 years group

Edwards Perimount

What causes a bioprosthetic valve to fail?
Antimineralization treatment and patient-prosthesis mismatch are major determinants of the onset and incidence of structural valve degeneration in bioprosthetic heart valves.

Mean age: 73.8 years
EOAi <0.85 cm²/m²
All AVR

Valve durability

Willem Flameng et al. JTCVS 2014; 147:1219-24
Bioprosthetic Aortic Valve Durability: A Meta-Regression of Published Studies

Ann Thorac Surg 2017
Bioprosthetic Aortic Valve Durability: A Meta-Regression of Published Studies

Ann Thorac Surg 2017
Long-term follow-up of surgical bioprothesis: Newer Definition of SVD

Structural Valve Deterioration (SVD) and Reoperation for SVD

Strict echocardiographic assessment:

• severe aortic stenosis (mean gradient > 40 mm Hg) or

• severe aortic regurgitation (effective regurgitant orifice area > 0.30 cm², vena contracta > 0.6 cm)

• even in asymptomatic patients
Assuming 15 years/valve, what will it look like for a 50 yo?

- 50 yoa, bioprosthetic SAVR
- 65 TAVR Valve in Valve
- 80 TAVR Valve in Valve in Valve
What if durability of valve is really 10 years?

- 50 yoa, bioprosthetic SAVR
- 60 yoa, Valve in Valve TAVR
- 70 yoa, Valve in Valve in Valve TAVR
- 80 yoa, Valve in Valve in Valve in Valve TAVR
“We can always place a transcatheter valve...”

- Assumptions:
  - The initial bioprosthetic is large enough to accommodate a TAVR without high gradients
    - Inspirus
  - Proximity of valve to coronary ostia and other anatomic factors will allow TAVR implantation without complication
  - You will only need one more intervention in your lifetime
    - Sparse data on Valve in Valve
    - No Data on Valve in Valve in Valve
  - The TAVR will go smoothly
Mechanical Versus Bioprosthetic Aortic Valve Replacement in Middle-Aged Adults: A Systematic Review and Meta-Analysis

Dong Fang Zhao, BA, Michael Seco, BMedSc, MBBS, James J. Wu, BMusStudies, James B. Edelman, MBBS(Hons), PhD, Michael K. Wilson, MBBS, Michael P. Vallely, MBBS, PhD, Michael J. Byrom, MBChB, PhD, and Paul G. Bannon, MBBS, PhD

Sydney Medical School, University of Sydney, Sydney; Baird Institute of Applied Heart and Lung Surgical Research, Sydney; Cardiothoracic Surgery Unit and Institute of Academic Surgery, Royal Prince Alfred Hospital, Sydney; and Australian School of Advanced Medicine, Macquarie University, Sydney, Australia
Ages 50-70

Fig 5. Overall Kaplan-Meier survival curves based on reconstructed individual study data. Aggregated survival curves for bioprosthetic valve (blue lines) compared with mechanical valve (red lines) after aortic valve replacement in patients aged (A) 50 to 70 years; (B) 60 to 70 years; and (C) less than 65 years. (CI = confidence interval; HR = hazard ratio.)

HR 1.13
(95% CI 0.89-1.45)
P=0.32
Ages 60-70

HR 0.87
(95% CI 0.66-1.15)
P=0.32
Ages < 65

HR 1.47
(95% CI 1.10-1.96)
P=0.01
• For 50-70 mortality equal, suggests the bleeding and thrombotic complications favor tissue valve.
• Less than 65 group favored mechanical
  • Larger percentage of 50 year olds and lower...mean 50.
Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Andrew B. Goldstone, M.D., Ph.D., Peter Chiu, M.D., Michael Baiocchi, Ph.D., Bharathi Lingala, Ph.D., William L. Patrick, M.D., Michael P. Fischbein, M.D., Ph.D., and Y. Joseph Woo, M.D.
A Patients 45–54 Yr of Age

Hazard ratio, 1.23 (95% CI, 1.02–1.48)
P = 0.03

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Biologic</th>
<th>Mechanical</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1187.1</td>
<td>2421.7</td>
</tr>
<tr>
<td></td>
<td>745.1</td>
<td>1548.1</td>
</tr>
<tr>
<td></td>
<td>406.7</td>
<td>853.8</td>
</tr>
<tr>
<td></td>
<td>98.0</td>
<td>300.0</td>
</tr>
</tbody>
</table>

Years

Probability of Death
CONCLUSIONS

The long-term mortality benefit that was associated with a mechanical prosthesis, as compared with a biologic prosthesis, persisted...
Table 2  Considerations for implanting a mechanical or bioprosthetic aortic valve

<table>
<thead>
<tr>
<th>Patient characteristic</th>
<th>Consider favouring mechanical valve</th>
<th>Consider favouring bioprosthetic valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt;60</td>
<td>✗</td>
<td></td>
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<tr>
<td>Age 60–70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;70 years</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Age &lt;60 but life expectancy &lt;10 years</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Age &lt;60 but pregnancy wish</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Age &lt;60 but hazardous occupation (e.g. sports, mining, stunt(wo)man, etc)</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Preoperative lifelong anticoagulation indication (e.g. AF, PVD, hypercoagulable state)</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Reoperations for valve thrombosis because of compliance failure or inadequate INR regulation</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>High bleeding risk</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Contra-indication for anticoagulation treatment</td>
<td>✗</td>
<td></td>
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<tr>
<td>End-stage renal failure on dialysis</td>
<td>✗</td>
<td></td>
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<tr>
<td>Metabolic syndrome</td>
<td>✗</td>
<td></td>
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<tr>
<td>Hyperparathyroidism</td>
<td>✗</td>
<td></td>
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<tr>
<td>Small aortic annulus</td>
<td>✗</td>
<td></td>
</tr>
</tbody>
</table>

These factors should be weighted and could potentially lean towards performing mechanical or bioprosthetic valve implantation. Presence of any of these factors does not exclude the opportunity to perform valve replacement with another type of valve.

AF, atrial fibrillation; INR, international normalized ratio; PVD, peripheral vascular disease.
Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database

James M. Brown, MD, a Sean M. O’Brien, PhD, b Changfu Wu, PhD, c Jo Ann H. Sikora, CRNP, d Bartley P. Griffith, MD, e and James S. Gammie, MD f

<table>
<thead>
<tr>
<th>Outcomes of Middle Aged Patients 15 Years Post Implant: Mechanical vs Bioprosthetic Valves</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
<td>1.10</td>
<td>0.99-1.36</td>
</tr>
<tr>
<td>Freedom From Stroke</td>
<td>1.14</td>
<td>0.77-1.71</td>
</tr>
<tr>
<td>Freedom From Endocarditis</td>
<td>1.51</td>
<td>0.63-3.63</td>
</tr>
<tr>
<td>Freedom From Reoperation</td>
<td>1.05</td>
<td>1.16-3.30</td>
</tr>
<tr>
<td>Freedom From Thromboembolic Events</td>
<td>0.61</td>
<td>0.44-0.86</td>
</tr>
<tr>
<td>Freedom From Major Bleeding</td>
<td>0.40</td>
<td>0.19-0.84</td>
</tr>
</tbody>
</table>
Conclusions

• There continues to be a dramatic shift towards bioprosthetic valve implantation.
• Younger patients must be given a very realistic expectation of the need for re-intervention and implications throughout their lifetime.
• Patients younger than 55 receive a mortality benefit from a mechanical Aortic valve.
• The future likely belongs to TAVR.
• However, still awaiting long term data.
• Paucity of data for Valve in Valve, and Valve in Valve in Valve etc.
• Mechanical valve should be strongly considered for patients < 55 yoa.