How to Avoid Prosthesis-Patient Mismatch

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Canada Research Chair in Valvular Heart Diseases
PPM occurs when the EOA of the prosthesis is too small in relation to patient’s body size / cardiac output requirements.
Severity and Prevalence of PPM in the Aortic Position

- **SEVERE**: Indexed EOA (cm²/m²) 0.65 (0.6-0.7), Prevalence 5-25%
- **MODERATE**: Indexed EOA (cm²/m²) 0.85 (0.8-0.9), Prevalence 20-70%
- **MILD/NONE (non significant)**: Indexed EOA (cm²/m²) 0.65 (0.6-0.7), Prevalence 5-25%
Impact of PPM on Clinical Outcomes

- Less regression of LVH
- Less recovery of coronary flow reserve
- Less regression of mitral regurgitation
- Less improvement in functional class / exercise capacity
- Increased incidence of late cardiac events
- Increased incidence of bioprosthesis SVD
- Negative impact on short- and long-term survival particularly if LV dysfunction

Pibarot & Dumesnil, 92:1022-9, 2006
Pibarot & Dumesnil, JACC 2000; 36: 1131-1141
The impact of prosthesis–patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years

Stuart J. Head¹*, Mostafa M. Molkhes¹, Ruben L.J. Osnabrugge¹,², Philippe Pibarot³, Michael J. Mack⁴, Johanna J.M. Takkenberg¹, Ad J.J.C. Bogers¹, and Arie Pieter Kappetein¹
Impact of PPM on All-Cause Mortality

Head et al Eur Heart J. 33:1518-29;2012
Impact of PPM on Cardiac Mortality

Head et al Eur Heart J. 33:1518-29;2012
Conclusions

Although the adverse effect of PPM on long-term survival has been denied in some studies, this meta-analysis of 34 studies with 27,186 patients demonstrates a significant increase in all-cause and cardiac-related mortality over long-term follow-up after AVR. Current efforts to prevent PPM should therefore receive more emphasis and widespread acceptance to improve long-term survival.
Prevention of PPM
Recommendations for the Prevention of PPM

➢ Avoid **severe** PPM (EOAI<0.65) in every patient undergoing AVR

➢ Avoid **moderate** PPM (EOAI<0.85) in:
  ➢ Patients with **LV dysfunction a/o severe LVH**
  ➢ Patients with **concomitant MR**
  ➢ **Young** (< 65-70 yr) patients
  ➢ **Athlete** patients
Calculate the Projected Indexed EOA to Predict Risk of PPM

Hypothetical Prosthesis Model

<table>
<thead>
<tr>
<th>Prosthesis size (mm)</th>
<th>19</th>
<th>21</th>
<th>23</th>
<th>25</th>
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<td>0.52</td>
<td>0.60</td>
<td>0.72</td>
<td>0.92</td>
<td>1.08</td>
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Table 1. Normal Reference Values of EOA for the Aortic Prostheses

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<tr>
<th>Prosthesis</th>
<th>Value 22</th>
<th>Value 23</th>
<th>Value 25</th>
<th>Value 27</th>
<th>Value 29</th>
<th>Reference</th>
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<td>Medtronic</td>
<td>1.2±0.2</td>
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<td>Hancock II</td>
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<tr>
<td>Carpentier-Edwards Perimount</td>
<td>1.2±0.2</td>
<td>1.3±0.3</td>
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<tr>
<td>Carpentier-Edwards Magna</td>
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<td>Bioflow (D)</td>
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<td>2.0±0.4</td>
</tr>
</tbody>
</table>

EOA is expressed as mean values ± standard deviation. *Note: These results are based on a limited number of patients and should be interpreted with caution.*

Pibarot & Dumesnil, 92:1022-9, 2006
Options to Prevent PPM

1- Use better performing prosthesis
   - Newer generation supra-annular bioprosthesis
   - Newer generation mechanical prosthesis
   - Stentless bioprosthesis
   - Sutureless bioprosthesis

2- Aortic root enlargement

3- Transcatheter aortic valve implantation
Option #1: Use of prosthesis with better hemodynamic performance and thus better “EOAbility”
**Prospective Randomized Study: Mosaic vs. CEP standard**

100 patients: intra-operative randomization to Mosaic or CEP standard

*Index of Effective Area (cm$^2$/m$^2$)*

PPM in New Generations of Bioprosthetic Valves

Results of the St Jude Medical Trifecta Multicenter Clinical trial

Mild to Moderate PPM: 22%
Severe PPM: 2%

Bavaria et al. JTCS 147:590-7; 2014
RCT of Minimally Invasive Rapid Deployment Versus Conventional Full Sternotomy AVR

XCL Bypass Time: 41 min 54 min  p<0.001
Severe PPM at 3 months: 0% 15%  p=0.04

Option #2: Aortic root enlargement
Prospective Strategy to Avoid PPM

657 consecutive patients
age: 73±12 years, 61 % women, BSA: 1.80 ±0.23 m²

Projected indexed EOA

≤ 0.85 cm²/m²

Enlargement of aortic root
+ AVR: 114 pts (17%)

> 0.85 cm²/m²

Standard AVR:
543 pts (83%)

Prevalence of mismatch:
2.6 %

Operative mortality:
0.9 %

2.4 %

4.1 %

Option #3: Transcatheter Aortic Valve Replacement
Severe Prosthesis-Patient Mismatch in Transcatheter vs. Surgical Valves

Clavel et al., JACC, 53;1883-1891, 2009
Prosthesis-Patient Mismatch in PARTNER-IA: TAVR vs. SAVR

Whole Cohorts

Subsets with Small Aortic Annulus (<20 mm)

TAVR has less PPM but more PVL than SAVR
Survival According to Annulus Size and Treatment: TAVR vs. SAVR

All-cause mortality (PARTNER-I Cohort A - RCT)

Small Annulus Tertile

Medium Annulus Tertile

Large Annulus Tertile

Rodés-Cabau et al. Circ Intervention 2014
All-Cause Mortality

- Transcatheter
- Surgical

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Transcatheter</th>
<th>Surgical</th>
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</thead>
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<tr>
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<td>359</td>
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<td>6</td>
<td>378</td>
<td>343</td>
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<td>12</td>
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<td>18</td>
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<td>282</td>
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<td>24</td>
<td>219</td>
<td>191</td>
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</tbody>
</table>

- Months Post-Procedure
- All-Cause Mortality
- Log-rank P=0.04

Δ = 6.5
Δ = 4.8
22.2%
28.6%
14.1%
18.9%
Paravalvular Regurgitation (Paired)

There was significantly lower PVL with SAVR over TAVR at each time point ($P<0.001$)
Echocardiographic Findings

TAVR had significantly better valve performance over SAVR at all follow-up visits ($P<0.001$)
Prevention of PPM: Conclusions

- Severe PPM has a significant impact on mortality & morbidity, whereas moderate PPM may have a significant effect in vulnerable subsets of patients.

- There are now several options to prevent PPM: newer generations of prostheses including sutureless valves, aortic root enlargement, TAVR.

- Preventive strategy should be individualized according to the anticipated severity of PPM and the patient’s baseline risk profile.
In the Field of Heart Valves, Size Matters!