Surgical versus transcatheter aortic valve replacement: Will gradients be a factor as we move into low risk?

John A. Goncalves, M.D., F.A.C.S., F.A.C.C
Director, Cardiac Surgery
Surgical Director, Transcatheter Valve Program
Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic Severe Aortic Stenosis


ABSTRACT

BACKGROUND Transcatheter aortic valve replacement (TAVR) is now the standard of care for patients with symptomatic severe aortic stenosis who are extreme, high, or intermediate risk for surgical aortic valve replacement (SAVR).

OBJECTIVES The authors sought to evaluate TAVR in a prospective multicenter trial involving low-risk patients.

METHODS The Low Risk TAVR (Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic, Severe Aortic Stenosis) trial was the first U.S. Food and Drug Administration-approved investigational Device Exemption trial to enroll in the United States. This investigator-led trial was a prospective, multicenter, unblinded, comparison to historical controls from the Society of Thoracic Surgeons (STS) database. The primary endpoint was all-cause mortality at 30 days.

RESULTS The authors enrolled 200 low-risk patients with symptomatic severe aortic stenosis at 11 centers to undergo TAVR. The authors compared outcomes with an inverse probability weighting-adjusted control cohort of 719 patients who underwent SAVR at the same institutions using the STS database. At 30 days, there was zero all-cause mortality in the TAVR group versus 1.74% mortality in the SAVR group. There was zero in-hospital stroke rate in the TAVR group versus 0.6% stroke in the SAVR group. Permanent pacemaker implantation rates were similar between TAVR and SAVR (5.0% vs. 4.5%). The rates of new-onset atrial fibrillation (3.0%) and length of stay (2.0 ± 1.1 days) were low in the TAVR group. One patient (0.5%) in the TAVR group had > mild paravalvular leak at 30 days. Fourteen percent of TAVR patients had evidence of subclinical leaflet thrombosis at 30 days.

CONCLUSIONS TAVR is safe in low-risk patients with symptomatic severe aortic stenosis, with low procedural complication rates, short hospital length of stay, zero mortality, and zero disabling stroke at 30 days. Subclinical leaflet thrombosis was observed in a minority of TAVR patients at 30 days. (Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic, Severe Aortic Stenosis [Low Risk TAVR; NCT02628899] (J Am Coll Cardiol 2018;11:1-12) © 2018 Published by Elsevier on behalf of the American College of Cardiology Foundation.
LRT trial design

Prospective TAVR cohort

Patients evaluated by Heart Team
n=290

Excluded (n=90)
• Not low risk (n=29)
• Refused/Preference for SAVR (n=13)
• AS not severe (n=10)
• Ineligible for TF access (n=8)
• Other (n=30)

Low-risk TAVR enrolled
n=200

30-day follow up
n=200

Historical SAVR cohort

Isolated SAVR in STS database
n=2959

Excluded (n=2240)
• STS score >3% (n=663)
• AS not severe (n=559)
• Bicuspid AS (n=439)
• Concomitant procedure (n=289)
• Other (n=290)

Low-risk isolated SAVR
n=719

30-day follow up
n=686

Inverse probability weighted adjustment
<table>
<thead>
<tr>
<th></th>
<th>TAVR (n=200)</th>
<th>SAVR (n=719)</th>
<th>p-value</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of stay post-procedure, days</td>
<td>2.0±1.1</td>
<td>6.4±3.9</td>
<td>&lt;0.001</td>
<td>-3.6 (-4.95 : -3.85)</td>
</tr>
<tr>
<td>VARC 2 life-threatening or major bleeding</td>
<td>5/200 (2.5)</td>
<td>74/719 (10.3)</td>
<td>&lt;0.001</td>
<td>-7.8 (-0.13 : - 0.02)</td>
</tr>
<tr>
<td>VARC 2 major vascular complications</td>
<td>5/200 (2.5)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>0/200 (0)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>All-cause death</td>
<td>0/200 (0)</td>
<td>5/719 (0.7)</td>
<td>0.591</td>
<td>-0.7 (-0.02 : 0.01)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0/200 (0)</td>
<td>4/719 (0.6)</td>
<td>0.582</td>
<td>-0.6 (-0.02 : 0.01)</td>
</tr>
<tr>
<td>MI</td>
<td>0/200 (0)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>0/200 (0)</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>New-onset atrial fibrillation</td>
<td>6/200 (3.0)</td>
<td>293/719 (40.8)</td>
<td>&lt;0.001</td>
<td>-37.8 (-0.46 : -0.30)</td>
</tr>
<tr>
<td>New PPM implantation</td>
<td>10/200 (5.0)</td>
<td>32/719 (4.5)</td>
<td>0.742</td>
<td>0.5 (-0.04 : 0.05)</td>
</tr>
<tr>
<td>Coronary artery obstruction</td>
<td>1/200 (0.5)</td>
<td>—</td>
<td>—</td>
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</table>

* Unadjusted
### Procedural details

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<th>TAVR (n=200)</th>
<th>% (n) or mean ± SD</th>
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</thead>
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<tr>
<td>General Anesthesia</td>
<td>24.5% (49)</td>
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<tr>
<td>Transfemoral Access</td>
<td>100% (200)</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>88.2 ± 40.4</td>
</tr>
<tr>
<td>Need for second valve</td>
<td>2.0% (4)</td>
</tr>
<tr>
<td>Balloon-expandable valve (S3)</td>
<td>88.2% (180)*</td>
</tr>
<tr>
<td>Self-expanding valve (Evolute R and Pro)</td>
<td>11.8 (24)*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAVR (n=200)</th>
<th>% (n)</th>
</tr>
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<tbody>
<tr>
<td><strong>TAVR valve size</strong>*</td>
<td><strong>(mean 25.8mm)</strong></td>
</tr>
<tr>
<td>20mm</td>
<td>4.9% (10)</td>
</tr>
<tr>
<td>23mm</td>
<td>22.5% (46)</td>
</tr>
<tr>
<td>26mm</td>
<td>49.0% (100)</td>
</tr>
<tr>
<td>29mm</td>
<td>20.6% (42)</td>
</tr>
<tr>
<td>31/34mm</td>
<td>2.9% (6)</td>
</tr>
</tbody>
</table>

* n=4 patients received two valves

<table>
<thead>
<tr>
<th>SAVR (n=719)</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SAVR valve size</strong></td>
<td><strong>(mean 22.6mm)</strong></td>
</tr>
<tr>
<td>19mm</td>
<td>10.6% (76)</td>
</tr>
<tr>
<td>21mm</td>
<td>30.0% (216)</td>
</tr>
<tr>
<td>23mm</td>
<td>36.3% (261)</td>
</tr>
<tr>
<td>25mm</td>
<td>17.1% (123)</td>
</tr>
<tr>
<td>27mm</td>
<td>5.1% (37)</td>
</tr>
<tr>
<td>29mm</td>
<td>0.8% (6)</td>
</tr>
</tbody>
</table>
AVOIDANCE OF PPM

CONSIDERATIONS FROM THE LITERATURE:

- Native valves have an area of 3-4 cm².¹⁻²
- Usually patients will not experience symptoms of AS until the area is reduced by more than half.¹
- As PPM is associated with poorer exercise capacity, a larger EOA may result in a quicker return to activity.³
- A Cleveland Clinic study of over 3,000 patients illustrated that younger patients were less tolerant of PPM as they were more likely to be active.²

Severity of PPM definition in the aortic Valve Position

<table>
<thead>
<tr>
<th></th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
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</thead>
<tbody>
<tr>
<td>Indexed EOA (cm²/m²)</td>
<td>0.65</td>
<td></td>
<td>0.85</td>
</tr>
<tr>
<td>EOA in obese (cm²/m²)</td>
<td>0.6</td>
<td>0.7</td>
<td></td>
</tr>
</tbody>
</table>

Indexed EOA versus Mean Gradient
Impact of PPM

Impact of Valve Prosthesis-Patient Mismatch on Left Ventricular Mass Regression Following Aortic Valve Replacement

Giordano Tasca, MD, Federico Brunelli, MD, Marco Cirillo, MD, Maigreta Dalla Torre, MD, Zen Mhagna, MD, Giovanni Troise, MD, and Eugenio Quaini, MD
Department of Cardiac Surgery, Policlinico Hospital, Brescia, Italy

Background. Valve prosthesis-patient mismatch is a frequent problem in patients undergoing aortic valve replacement and its main hemodynamic consequence is to generate high transvalvular gradients through normally functioning prosthetic valves. The persistence of high gradients may hinder or delay the regression of left ventricular hypertrophy after aortic valve replacement.

Methods. The aim of the study was to determine the impact of prosthesis-patient mismatch on the postoperative regression of left ventricular mass.

Left ventricular mass was measured by Doppler echocardiography in 109 patients undergoing aortic valve replacement with a single type of bioprosthesis (Carpentier-Edwards Perimount) for pure aortic stenosis. Prosthesis-patient mismatch was defined as a projected indexed effective orifice area less than 0.9 cm²/m². On this basis, 50 (46.2%) patients had prosthesis-patient mismatch.

Results. There was a good correlation (r = 0.53, p < 0.001) between the postoperative mean transprosthetic gradient and the projected indexed effective orifice area. The absolute and relative left ventricular mass regression was significantly (p = 0.002 and p = 0.01, respectively) lower in patients with prosthesis-patient mismatch (14 ± 7 g, 17% ± 16%) compared to those with no prosthesis-patient mismatch (27 ± 9 g, 24% ± 14%).

In a multivariate analysis, a higher projected indexed effective orifice area, female gender and a higher preoperative left ventricular mass are independent predictors of greater left ventricular mass regression.

Conclusions. This study shows that in patients with pure aortic stenosis, prosthesis-patient mismatch is associated with lesser regression of left ventricular hypertrophy after aortic valve replacement. These findings may have important clinical implications given that prosthesis-patient mismatch is frequent in these patients.

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Impact of PPM

- 53.2% incidence of PPM
- Patients wit PPM:
  - EOA 1.38cm²
  - Mean 19.8mmHg
  - Peak 33.2mmHg
- Significantly less LV mass regression
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. Mokhles¹, Ruben L.J. Osnabrugge¹,², Philippe Pibarot³, Michael J. Mack⁴, Johanna J.M. Takkenberg¹, Ad J.J.C. Bogers¹, and Arie Pieter Kappetein¹

Conclusion: Prosthesis–patient mismatch is associated with an increase in all-cause and cardiac-related mortality over long-term follow-up. We recommend that current efforts to prevent PPM should receive more emphasis and a widespread acceptance to improve long-term survival after AVR.
Predictors and Outcomes of Prosthesis-Patient Mismatch After Aortic Valve Replacement

Viete Elyyan, MD, PhD,1 Gustavo Viglino, MD,2 Gerardo Soca, MD,1 Juan Jose Paganini, MD,1 Daniël Brindel, MD,1 Philippe Tiberi, MD, PhD2

ABSTRACT

OBJECTIVE: This study sought to evaluate predictors of prosthesis-patient mismatch (PPM) and its association with the risk of perioperative and overall mortality.

BACKGROUND: PPM is associated with increased peri- and long-term mortality after surgical aortic valve replacement. Conflicting results have been reported with regard to its association with perioperative mortality.

METHODS: Databases were searched for studies published between 1965 and 2014. Main outcomes of interest were perioperative mortality and overall mortality.

RESULTS: The search yielded 382 studies for inclusion. Of these, 58 articles were analyzed and their data extracted. The total number of patients included was 40,381 (39,540 surgical aortic valve replacement and 81 transcatheter aortic valve replacement). Perioperative odds ratios 1.54 (95% confidence interval 1.29 to 1.86) and overall mortality (hazard ratio 1.28, 95% confidence interval 1.16 to 1.40) was increased in patients with PPM. The impact of PPM on mortality was higher in those studies in which the mean age of the patients was <70 years of age (odds ratio 1.28 with associated coronary artery bypass graft was included). Severe PPM was associated with increased risk of both perioperative and overall mortality, whereas moderate PPM was associated with increased risk of perioperative mortality but not of overall mortality. The impact of PPM was less pronounced in patients with larger body mass index (≥30 kg/m²) compared with those with lower values. Predictors of PPM were older age, female sex, hypertension, diabetes, renal failure, larger body surface area, larger body mass index, and the utilization of a bioprostheses.

CONCLUSIONS: PPM increases perioperative and overall mortality proportionally to its severity. The identification of predictors for PPM may be useful to identify patients at risk, with higher risk for PPM. The findings of this study support the implementation of strategies to prevent PPM, especially in patients >75 years of age and/or with concomitant coronary artery bypass graft.

40,381 patients

- PPM 43.8%
- Moderate PPM
  - 1.5 fold increase in 30 day mortality
- Severe PPM: 2.5 fold
- Less LV mass regression
- Impact worse for patients:
  - < 70 years of age
  - Concomitant CABG
Outstanding Questions:

• Hemodynamics of TAVR versus SAVR?
  • PPM rates

• Are hemodynamics related to durability?
5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

3-Year follow-up is now complete for the High Risk Study, which randomized TAVR with CoreValve to SAVR

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D.,
Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D.,
Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D.,
Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O.,
George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D.,
George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D.,
John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Muntaz, M.D.,
Sharla Chenoweth, M.S., and Jae K. Oh, M.D.,
for the U.S. CoreValve Clinical Investigators

CoreValve, N=390, STS 7.3%  vs. SAVR, N=357, STS 7.5%
Significantly better hemodynamics with TAVR vs. SAVR at all follow-ups (P<0.001)

Hemodynamic Data out to 5-YEARS

- Additional long-term data from the CoreValve Extreme Risk study was recently presented.
- The study showed that even in challenging patients at very high risk, the Evolut platform can achieve superb hemodynamics that are long-lasting.

1Sondergaard et al., presented at EuroPCR 2018; 2Petrossian et al., presented at ACC 2018
SURTAVI DATA demonstrates consistently large EOAs as well as very low gradients.

Hemodynamic Data: Intermediate RISK

CLINICAL DATA - EVOLUT PLATFORM

- The Evolut R FORWARD trial is a post-market approval study including over 1000 Evolut R patients with a mean STS of 5.5
- The SURTAVI CAS study is a non-randomized continued access study of SURTAVI. Unlike SURTAVI which included a high percentage of CoreValve, SURTAVI CAS used mostly second generation Evolut R
- Both studies continued to show the success of the Evolut platform, including excellent hemodynamic outcomes. Importantly, FORWARD demonstrated these hemodynamic results were maintained post-procedure to 1 year

1Williams et al., presented at ACC 2018; 2Grube, et al., presented at EuroPCR 2018
Hemodynamic Data

CLINICAL DATA - EVOLUT PLATFORM

- The NOTION six year results were also presented. NOTION is a prospective, multi-center, non-blinded trial that was the first to randomize lower risk patients to either TAVR with CoreValve or SAVR.

- NOTION found that the excellent hemodynamic outcomes with the Evolut Platform lasted out to >5 years.

- Additionally, the NOTION trial demonstrated that TAVR with CoreValve had significantly better hemodynamic outcomes than SAVR out to 6 years.

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1Sondergaard et al., presented at EuroPCR 2018; 2Petrossian et al., presented at ACC 2018
Prosthesis–patient mismatch in high-risk patients with severe aortic stenosis: A randomized trial of a self-expanding prosthesis

George L. Zorn III, MD, Stephen H. Little, MD, Peter Tadros, MD, G. Michael Deeb, MD, Thomas G. Gleason, MD, John Heiser, MD, Neal S. Kleiman, MD, Jae K. Oh, MD, Jeffrey J. Popma, MD, David Adams, MD, Jian Huang, MD, and Michael J. Reardon, MD

ABSTRACT

Objectives: We compared the incidence of prosthesis–patient mismatch (PPM) between transcatheter aortic valve replacement (TAVR) using a self-expanding bioprosthesis and surgical aortic valve replacement (SAVR) in the CoreValve US High Risk Pivotal Trial. We sought to determine the influence of PPM on clinical outcomes.

Methods: Patients with severe aortic stenosis and at increased risk for surgery were randomized 1:1 to TAVR or SAVR. Postoperative PPM was defined by the effective orifice area index (EOA) as severe PPM (EOA ≤ 0.85 cm²/m²) and no severe PPM (EOA > 0.65 cm²/m²); clinical outcomes were analyzed in the TAVR arm (n = 389) and SAVR arm (n = 353). Left ventricular mass index and regression were analyzed at baseline and 1 year.

Results: The incidence of severe PPM in the SAVR group at 1 year was 25.7% versus 6.2% in the TAVR group (P < .0001). Left ventricular mass index regression at 1 year was 6.8% for TAVR and 15.1% for SAVR in patients with severe PPM. At 1 year the rate of all-cause mortality and acute kidney injury were significantly greater in all patients (TAVR + SAVR) with severe PPM compared with no severe PPM (20.6% vs 12.0% [P = .0145] for death and 19.2% vs 8.5% [P = .0008] for acute kidney injury).

Perspective: Severe prosthesis–patient mismatch (PPM) is significantly more common after transcatheter aortic valve replacement than after surgical aortic valve replacement in patients at high risk with symptomatic severe aortic stenosis. Patients with severe PPM are at a greater risk for death and acute kidney injury than patients without severe PPM. (J Thorac Cardiovasc Surg 2016;151:1014-23)

All-Cause Mortality: TAVR+SAVR

CoreValve US Clinical Trials

Log-rank P=0.01

All-Cause Mortality %

0% 5% 10% 15% 20% 25% 30% 35% 40%

All-Cause Mortality %

0 1 2 3 4 5 6 7 8 9 10 11 12

No at Risk

PPM (EOA ≤ 0.85 cm²/m²)

99 84

602 593

602

PPM (EOA > 0.85 cm²/m²)

95 75

594

No PPM

553

516

516

Prosthesis-Patient Mismatch

Severe PPM at 1 year

- Severe PPM occurs significantly more after SAVR than TAVR
  - At 1 month rates are 7.0% for TAVR and 20.7% for SAVR (P<0.001)
- Moderate PPM occurred in 20.8% of TAVR and 30.6% of SAVR patients at 1 year
Impact of Annular Size on Outcomes After Surgical or Transcatheter Aortic Valve Replacement

G. Michael Deeb, MD, Stanley J. Chetcuti, MD, Steven J. Yakubov, MD, Himanshu J. Patel, MD, P. Michael Grossman, MD, Neal S. Kleiman, MD, John Heiser, MD, William Merhi, DO, George L. Zorn, III, MD, Peter N. Tadros, MD, George Petrossian, MD, Newell Robinson, MD, Mubashir Mumtaz, MD, Thomas G. Gleason, MD, Jian Huang, MD, John V. Conte, MD, Jeffrey J. Popma, MD, and Michael J. Reardon, MD

Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; Department of Internal Medicine, Division of Cardiology, University of Michigan, Ann Arbor, Michigan; Department of Cardiology, Riverside Methodist Hospital, Columbus, Ohio; Departments of Cardiology and Cardiothoracic Surgery, Houston Methodist DeBakey Heart and Vascular Center, Houston, Texas; Departments of Cardiothoracic Surgery and Cardiology, Spectrum Health Hospitals, Grand Rapids, Michigan; Departments of Cardiothoracic Surgery and Cardiology, University of Kansas Hospital, Kansas City, Kansas; Departments of Cardiology and Cardiothoracic and Vascular Surgery, St. Francis Hospital, Roslyn, New York; Department of Cardiovascular and Thoracic Surgery, Pinnacle Health, Harrisburg, Pennsylvania; Division of Cardiac Surgery, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania; Coronary and Structural Heart Clinical Department, Medtronic, Mounds View, Minnesota; Division of Cardiac Surgery, The Johns Hopkins Hospital, Baltimore, Maryland; and Department of Internal Medicine, Cardiovascular Division, Beth Israel Deaconess Medical Center, Boston, Massachusetts
30-Day PPM by Annular Size for TAVR and SAVR

Any PPM defined as EOAi ≤ 0.85cm²
Severe PPM defined as EOAi ≤ 0.65cm²
Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, Edward G. Soltesz, MD, Nakul Vakil, MD, Jeevanantham Rajeswaran, PhD, Eric E. Roselli, MD, Joseph F. Sabik III, MD, Nicholas G. Smedira, MD Lars G. Svensson, MD, PhD, Bruce W. Lytle, MD, and Eugene H. Blackstone, MD
Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio

Fig 4.
Structural valve deterioration (SVD) at 20 years and prosthesis–patient mismatch, represented by the number of standard deviations the geometric size of the aortic prosthesis deviates from normal. Nomogram is based on preoperative variables alone.
Valvular Heart Disease

Prosthesis-Patient Mismatch Predicts Structural Valve Degeneration in Bioprosthetic Heart Valves

Willem Flameng, MD, PhD; Marie-Christine Herregods, MD, PhD; Monique Vercalsteren; Paul Herijgers, MD, PhD; Kris Bogaerts, PhD; Bart Meuris, MD, PhD

Background—Prosthesis-patient mismatch (P-PtM) after aortic valve replacement results in disturbed valve performance associated with increased pressure gradients. However, it is unknown whether this can be related to future structural valve deterioration (SVD) of the bioprosthesis.

Methods and Results—In 564 patients (mean age, 74±5 years) receiving an aortic valve bioprosthesis, clinical follow-up (median, 6.1 years; maximum, 16.4 years) was analyzed including echocardiography. SVD was diagnosed in 40 patients (7%) as substantially increased stenosis (n=24) or regurgitation (n=16) of the operated valve over time. When patients with P-PtM (effective orifice area index <0.85 cm²/m²; n=285) developed SVD, it was preferentially of the stenosis type, whereas when patients without P-PtM (n=279) developed SVD, the majority was of the incompetence type (P<0.05). Multivariable analysis including patient- and valve-related variables revealed that P-PtM and label size ≤21 were independent predictors of SVD (P=0.04 and P=0.02, respectively). A nonparametric Turnbull estimate analysis showed that SVD is virtually nonexistent for up to 9 years in patients without P-PtM. Thereafter, SVD starts to occur and is mainly of the incompetence-type SVD (79% of cases). In patients with P-PtM, SVD starts to occur after 2 to 3 years after implantation and is mainly of the stenosis-type SVD (81% of cases).

Conclusions—These data suggest that stenosis-type SVD is an early, P-PtM-related, and thus preventable phenomenon. Incompetence-type SVD is a time-dependent, nonspecific wear damage to bioprosthetic valves, which is not related to P-PtM. (Circulation. 2010;121:2123-2129.)
564 consecutive bioprosthetic AVR’s
  • 50% moderate/severe PPM
    • Stentless: 22%
    • Stented: 65%

Independent Predictors of SVD
  • PPM
    • With PPM SVD starts early (2-to-3 years)
    • Virtually free of SVD in the first decade without PPM
  • Valve ≤ 21mm

Type of SVD
  • With PPM: primarily stenosis
  • Without PPM: primarily incompetence type
Avoiding PPM

Projected Indexed EOA ≥ 0.85 cm²/m²

BSA = 1.90 m²

Reference EOA = 1.98 cm² ± 0.56

Projected EO Ai = 1.04 cm²/m²

No PPM with a 29 mm Evolut R

CT Annular perimeter – derived diameter = 24 mm

<table>
<thead>
<tr>
<th>Quintiles</th>
<th>≤ 22.3 mm</th>
<th>&gt; 22.3 to ≤ 23.2 mm</th>
<th>&gt; 23.2 to ≤ 24.7 mm</th>
<th>&gt; 24.7 to ≤ 26.2 mm</th>
<th>&gt; 26.2 to ≤ 30.2 mm</th>
<th>p Value for Trend</th>
</tr>
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<tbody>
<tr>
<td><strong>Evolut R</strong></td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>EOA, cm²</td>
<td>1.66 ± 0.42 (53)</td>
<td>1.82 ± 0.43 (38)</td>
<td><strong>1.98 ± 0.56 (62)</strong></td>
<td>1.98 ± 0.59 (49)</td>
<td>2.56 ± 0.77 (53)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>EO Ai, cm²/m²</td>
<td>0.99 ± 0.27 (53)</td>
<td>1.09 ± 0.26 (38)</td>
<td><strong>1.10 ± 0.32 (62)</strong></td>
<td>1.06 ± 0.34 (49)</td>
<td>1.29 ± 0.37 (53)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean gradient, mm</td>
<td>7.94 ± 3.10 (58)</td>
<td>6.91 ± 2.58 (43)</td>
<td>7.66 ± 2.94 (63)</td>
<td>8.53 ± 3.49 (56)</td>
<td>6.40 ± 3.34 (57)</td>
<td>0.21</td>
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<tr>
<td>DVI</td>
<td>0.61 ± 0.11 (57)</td>
<td>0.61 ± 0.14 (41)</td>
<td>0.61 ± 0.15 (63)</td>
<td>0.56 ± 0.14 (51)</td>
<td>0.58 ± 0.15 (55)</td>
<td>0.07</td>
</tr>
</tbody>
</table>

Values are mean ± SD (n). Trend test p value from generalized linear modeling with quintiles as independent ordinal variable. Abbreviations as in Tables 1 and 3.