Keynote Lecture Series

Overcoming prosthesis-patient mismatch with transcatheter aortic valve replacement

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For decades, surgeons have recognized the risk of prosthesis-patient mismatch (PPM) when treating aortic stenosis (AS) with surgical aortic valve replacement (SAVR). The concept of PPM—or placing a valve that is too small for the cardiac output requirements of the patient—has been associated with worse patient outcomes, including increased risk of death. Transcatheter aortic valve replacement (TAVR) has become the standard treatment for most patients with severe symptomatic AS and is associated with improved hemodynamics and lower risks of PPM. Larger surgical valves, stentless, and sutureless technology, and surgical aortic annulus enlargement (AAE) have been employed to avoid severe PPM. However, especially in the small aortic annulus (SAA), TAVR may provide a benefit. Understanding who is at risk for PPM requires preplanning, and cardiac-gated computed tomography (CT) imaging is the standard of care when considering TAVR. It should be standard for all patients with AS. Once SAA is identified, the risk of PPM can be calculated, and an informed decision made on whether to proceed with SAVR or TAVR. In the current TAVR era, younger patients are treated with TAVR driven by patient preference, but with little long-term data to support the practice. Selecting the best valve for the patient is a multifactorial decision often nuanced by anatomical considerations, hemodynamic and durability expectations, and decisions regarding lifetime management that may include placing a second valve. Although PPM may be only one of the factors to consider, the association with elevated mean gradients and worse outcomes certainly makes TAVR a good solution for many patients.

Keywords: Aortic valve replacement; aortic valve stenosis; transcatheter aortic valve replacement (TAVR); heart valve diseases; cardiovascular surgical procedures

Submitted Apr 12, 2024. Accepted for publication Apr 22, 2024. Published online May 15, 2024.
doi: 10.21037/acs-2024-aae-27
View this article at: https://dx.doi.org/10.21037/acs-2024-aae-27

Introduction

The management of severe aortic stenosis (AS) has evolved. Now, most patients undergo transcatheter aortic valve replacement (TAVR) (1-4). For younger patients with longer life expectancy, surgery is still the first-line therapy. Surgical aortic valve replacement (SAVR) is associated with excellent long-term outcomes when the implanted valve relieves the mechanical obstruction of the left ventricle, facilitating mass regression (5-7). However, prosthesis-patient mismatch (PPM) has been a known risk since first reported in 1978, whereby the valve effective orifice area (EOA) is physiologically too small in relation to the body size to meet the cardiac output needs of the patient (8). When the mismatch is severe, and even in moderate PPM in some series, the patient is at greater risk of mortality in both the short- and long-term (7,9-14). PPM has also been

associated with heart failure hospitalization, valve durability, and reduced functional recovery. Based on preoperative annular measurements, the anticipated valve size can be assessed, and the risk of PPM is predictable. Surgical strategies to avoid PPM are described in detail in this special issue series, but an alternative approach is to utilize TAVR. TAVR has been consistently associated with lower rates of PPM (15-18). Herein, we review the preoperative prediction of PPM, discuss the management of patients with small aortic annulus (SAA), review TAVR valve selection and PPM risk, and finally propose an algorithm where TAVR may be an appropriate first-choice therapy for the treatment of patients with severe, symptomatic AS.

Defining and avoiding PPM

It is no surprise that placing too small of a valve would fail to relieve the outflow obstruction of severe AS and leave the patient with a residual gradient. In this scenario, the valve exhibits dysfunction even though the leaflets are normal, which is termed non-structural valve dysfunction (NSVD). Rahimtoola described this well: "*All prostheses (mechanical and bioprosthesis) have an in vitro effective orifice area that is smaller than that of the normal human valve. … all valve replacements can be considered to be 'stenotic', even if they are 'normal'*" (8). With this in mind, we can appreciate the impact of a small EOA in a larger human, or as Pibarot and Dumesnil noted, PPM is like inserting "*a mouse's valve in an elephant's aorta*" (5). In essence, we have removed the diseased valve but left the patient with a residual stenosis. The patient's body surface area (BSA) is a surrogate for cardiac output. The calculation for PPM factors in the indexed EOA (iEOA) to the patient's BSA. To avoid a significant transvalvular gradient, the iEOA should be >0.85 cm^2/m^2 (5,19,20). The severity of the mismatch and the size/weight of the patient are thus important in assessing PPM. Valve Academic Research Consortium 3 (VARC-3) (20) defines PPM differently based on the body mass index (BMI) of the patient: for non-obese patients (BMI <30 kg/m^2), moderate 0.85–0.66 cm^2/m^2 and severe ≤0.65 cm^2/m^2; for obese patients (BMI ≥30 kg/m^2), moderate 0.70–0.56 cm^2/m^2 and severe ≤0.55 cm^2/m^2.

The diagnosis of severe AS is typically by transthoracic echocardiography. With careful attention to the diameter of the aortic valve annulus, one can estimate the anticipated valve to be implanted. For those in whom a valve <23 mm is expected, additional preoperative imaging can further confirm the valve size and complete preoperative planning (21). Initially, 3-dimensional transesophageal echocardiography was utilized to assess valve size for TAVR planning but has been replaced by computed tomography (CT).

The potential for PPM can be assessed preoperatively based on multimodality imaging. Specifically, cardiac-gated multidetector computed tomography (MDCT) is used to evaluate candidacy for TAVR to determine the aortic annular area and perimeter for valve sizing. Unlike SAVR, where the predicted EOA of the surgical valve is fixed, the final size of the TAVR prosthesis is determined by the native annular size. Additional anatomical considerations, such as coronary heights and sinus of Valsalva diameters, further confirm the appropriateness of the valve choice. After the valve model and size are selected, tables of normal valve EOAs published by Hahn *et al.* (22) can be referenced. By dividing the normal EOA by the patient's BSA, an estimate of the risk of PPM for the specific patient can be calculated. With the iEOA estimated and the risk of PPM evaluated, valve choice can be confirmed, and alternative TAVR choices or surgical strategies can be assessed. Specifically, a valve likely to provide a larger EOA can be selected to avoid PPM and provide better hemodynamics.

Given the ability to predict and further prevent PPM, MDCT is becoming standard practice in preoperative evaluation for all patients with severe AS, especially when a multidisciplinary team evaluates the patient at a Structural Heart Center. Routine preoperative MDCT allows for a better assessment of aortic calcification and is used to size the annulus and predict the surgical or TAVR valve to be implanted to prevent PPM. Many believe this preoperative evaluation should be the standard of care. Indeed, additional assessment is warranted for those with aortic valve diameter measurements on transthoracic echocardiogram that suggest a small implant, specifically patients who would likely receive a <23 mm bioprosthetic valve.

Addressing the SAA and PPM after TAVR

As data accrues on the various valve platforms, it has become clear that TAVR does not have a class effect. The performance of each brand of valve will be unique to that specific platform. In general, self-expanding valves (SEVs) have been associated with lower gradients, larger EOAs, and less PPM, particularly supra-annular valves (17,21,23-26).

In the Placement of Aortic Transcatheter Valve (PARTNER) 3 trial comparing outcomes after TAVR and SAVR in low-risk patients, surgical valves had lower mean gradients and larger EOAs for the first time in a randomized

controlled trial. There was no reported difference in risk of paravalvular leak (PVL) between balloon-expandable valves (BEVs) (Sapien 3, Edwards Lifesciences, Irvine, California, USA) and SAVR at one year, at 0.6% versus 0.5% (23). However, in the supplement materials available at NEJM.org, at 30 days, PPM is reported as moderate in 29.8% BEV and 23.3% SAVR, and severe in 4.3% BEV and 6.3% SAVR. The results from the Evolut Low-Risk Trial (Medtronic, Minneapolis, Minnesota, USA) assessing TAVR versus SAVR in a similar low-risk patient population show the supra-annular SEVs had lower mean gradients, larger EOAs, and less moderate (5.0% versus 15.7%) and severe (1.8% versus 8.2%) PPM at one year compared to surgery (17).

These findings are consistent with early TAVR trials in which BEV had a lower incidence of severe PPM (19.7% versus 28.1%) (27) but only significant in small annuli, compared to surgery (19.7% versus 37.5%; P=0.03) with the original first-generation BEV in the PARTNER randomized high-risk cohorts (28). The authors proposed a hemodynamic advantage with TAVR, especially in small annuli. In the CoreValve US High Risk Pivotal Trial (Medtronic), severe PPM was significantly lower at one year with SEVs, 6.2% versus 25.7%, P<0.0001 (16). Further, an association was identified between one-year all-cause mortality and severe PPM (TAVR + SAVR) compared to no PPM (20.6% versus 12.0%, P=0.0145). Here, the authors propose TAVR with a supra-annular SEV to prevent PPM.

Outside of the randomized controlled trials comparing TAVR to surgery, an extensive observational analysis of data from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry assessed PPM in 62,125 TAVR recipients [2014–2017] with commercially approved devices and linked outcomes to Medicare claims data (29). The incidence of PPM based on the site-reported discharge echocardiograms was 12.1% severe and 24.6% moderate, with higher mortality (17.2%) and heart failure hospitalization (14.7%) in patients with severe PPM at one year. In this large registry analysis, predictors of PPM included small valves ≤23 mm, valve-in-valve (ViV) procedures, larger BSA, female sex, younger age, non-White/Hispanic race, lower ejection fraction, atrial fibrillation, and severe mitral or tricuspid valve regurgitation (29). Larger patients and those receiving smaller valves had the highest odds of post-TAVR PPM. Notably, the authors conclude that efforts should be made to identify and minimize the risk of PPM. Although the distribution of valve models was not reported, it is assumed that most valves were BEVs due to commercial practice in the United States during that period (1). Tang *et al.* performed a similar analysis using the TVT Registry but narrowed the focus to only supra-annular SEVs (Evolut R/Pro/Pro+, Medtronic), including TAVR in native AS and failed surgical valves (30). From 2015 to 2020, 63,885 supra-annular SEVs were implanted, 5.3% developed severe PPM in the native AS cohort, and 13.9% had moderate. In the failed SAVR group, 27.0% had severe PPM, and 27.7% had moderate, likely related to the small internal diameter of the initial valve and baseline PPM. Despite higher mean gradients in patients with severe PPM, there was no significant difference in one-year mortality or valve-related readmission. Small annular size <20 mm was a predictor of severe PPM. Longer follow-up is needed to understand the impact on durability fully.

Studies directly comparing TAVR platforms help delineate the differences in valve performance and outcomes. The CHOICE (Comparison of Transcatheter Heart Valves in High Risk Patients with Severe Aortic Stenosis) randomized trial and CHOICE-Extend registry attempted to answer the question with older valve platforms and specifically investigated differences based on aortic valve mean diameter (large >23 mm versus small) (31). Compared to BEVs in CHOICE-Extend, supra-annular SEVs (Evolut) had lower mean gradients and significantly larger EOAs for both large and small annuli. In small annuli, TAVR with Evolut was significantly associated with lower PPM rates than Sapien 3 (0% versus 27%; P=0.011).

Focusing only on patients with small annuli, the TAVI-SMALL registry (International Multicenter Registry to Evaluate the Performance of Self-Expandable Valves in Small Aortic Annuli) retrospectively assessed outcomes in patients with annular perimeter <72 mm or area <400 mm^2 by MDCT (32). Valve platforms included Evolut R/Pro, ACURATE (Boston Scientific, Marlborough, Massachusetts, USA), and Portico (Abbott Vascular, Santa Clara, California, USA). They found severe PPM in 9.4% of patients with no significant difference between valve types, and 19.6% had moderate PPM. In a subsequent analysis (25) of only the 129 patients with moderate or severe PPM, 90% were women. Those with severe PPM were, on average, younger, with higher BSA and weight. Of the SEV platforms, intra-annular SEVs (Portico) were associated with more frequent severe PPM compared to supra-annular valves. Severe PPM in the study was also associated with a higher risk of all-cause mortality. Thus, although the overall risk of severe PPM was low with

all SEVs, intra-annular valves did not perform as well as supra-annular valves despite large EOAs. TAVI-SMALL 2 extended the analysis through the year 2020 and included BEVs (26). The study again demonstrated an association between intra-annular valves (Sapien and Portico) and increased rates of severe PPM, which predicted all-cause mortality (18.9%) at a median of 380 days. Unique to the analysis, they found that among patients with severe PPM, the iEOA did not differ significantly between groups but was smaller for intra-annular valves compared to supra-annular valves and for BEV compared to SEV. Treatment of severe AS with supra-annular SEVs was protective from severe PPM, with Evolut R/Pro the most common valve (52.4%) in the group with less than moderate PPM.

The OCEAN-TAVI (Optimised transCathEter vAlvular iNtervention-TAVI) registry (33) directly compared different generations of BEV (Sapien XT and Sapien 3) in a high surgical risk Japanese population with SAA. PPM was more frequent after Sapien 3 implantation than XT both in the total cohort (14.6% versus 8.8%, P<0.0001) and in matched patients (14.9% versus 8.1%, P<0.0001), but there was no difference in the frequency of severe PPM. Interestingly, more 20 mm Sapien 3 valves were implanted due to lower over-sizing requirements with the third-generation valve and external sealing skirt. PPM was identified in 36.0% of patients who received 20 mm Sapien 3 valves. In this high-risk Asian population, there was no signal for increased mortality in those patients with PPM at a median of 721 days.

The most recent trial to address these questions, and the study that will ultimately answer the question of which TAVR is better for patients with severe AS and a SAA at risk for PPM, is the Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus (SMART) trial (24). SAA was defined as an area of 430 mm^2, and 716 patients were randomized to TAVR with a BEV (Sapien 3/Ultra) or supra-annular SEV (Evolut R/Pro/Pro+) and followed for 12 months. In a population comprising primarily women (87%), at one year, there was no difference in clinic outcomes (death, stroke, or heart failure hospitalization) but superior hemodynamic performance of the SEV with significantly larger EOA (1.99 versus 1.5 cm^2) and lower mean gradients (7.7 versus 15.7 mmHg). Moderate or severe PPM at 30 days was also significantly lower in the SEV cohort (10.3% versus 35.1%, P<0.001) and severe also lower (1.8% versus 7.1%). The percentage of patients with bioprosthetic valve dysfunction was 9.4% for the SEVs and 41.6% for BEVs [–32.2%; 95% confidence interval (CI): –38.7% to –25.6%; P<0.001]. Notably, the TAVR sizes differed for the same size annulus; SEV 68.9% received 26 mm and 28.9% 29 mm; BEV 7.9% size 20 mm and 90.1% 23 mm valves.

While the SMART trial provides valuable insights into which TAVR platform would be best for patients with SAA, it does not answer whether TAVR would be better than SAVR in this scenario. The recently published VIVA trial (34) (Transcatheter Aortic Valve Replacement Versus Surgical Aortic Valve Replacement for Treating Elderly Patients With Severe Aortic Stenosis and Small Aortic Annuli) randomized 151 patients with SAA. All patients underwent a preoperative MDCT for valve planning, and those with mean aortic annular diameter <23 mm and a minimal diameter of ≤21.5 mm were included. Patients were randomized to TAVR with a range of devices (Sapien 3/Ultra (40.8%), SEV (59.2%) Evolut R/Pro/Pro+/Fx, and ACURATE neo/neo2) versus SAVR (including 7.0% AAR and 21.1% sutureless valves). The patient population was similar to the low-risk TAVR trials, with a mean age of 75.5±5.1 years and a predicted risk of surgical mortality of 2.50%, but notably, 93% were women. There was numerically lower severe PPM after TAVR 5.6% versus SAVR 10.3%, but this did not reach statistical significance. There was no moderate or severe aortic regurgitation in either group. At a median follow-up of two years, there were no differences in mortality, stroke, or cardiac hospitalization. The results should be interpreted with caution because of the underpowered sample size. Nonetheless, the results are hypothesis-generating and support MDCT preplanning for TAVR and SAVR for treating patients with severe AS and SAA. Valve choice matters. Selecting the best valve for the specific patient will likely provide excellent results.

The totality of evidence supports individualizing the patient's treatment. Further, there is no TAVR class effect. The individual valves have differing performance based on design, the deployment mechanism (self-expanding versus balloon-expandable), and the sizing matrix per the published manufacturer's instructions for use. Treatment selection should be individualized according to baseline characteristics, additional anatomical risk factors, and patient preference.

Paving the way for ViV-TAVR without PPM: the role of aortic annulus enlargement (AAE)

ViV-TAVR (i.e., placing a TAVR in a failed surgical valve), is a valuable option with lower incidence of postoperative

complications and better early survival than redo SAVR (35). However, ViV-TAVR is associated with higher rates of severe PPM, which may lead to higher mortality over time (14,35). Previous studies showed that ViV-TAVR is associated with lower survival than redo SAVR at five (36) and eight years (37). Interestingly, these studies also found a correlation between PPM and poor survival (36) and small valves and higher mortality (37) in the context of ViV-TAVR versus redo SAVR, thus highlighting the impact of the first valve implanted at the index SAVR on the outcomes of ViV-TAVR.

To place an adequate-sized valve for patients with SAA, AAE has a significant role in lifetime management, demonstrating a decreased overall risk of PPM and higher iEOA (38). The benefit of reduced PPM must be balanced against a possibly higher risk of perioperative mortality, above all, in patients requiring concomitant procedures (such as coronary bypass, mitral valve surgery, and aortic surgery) (38). Unfortunately, the adoption of SAVR with AAE remains very weak, as evidenced by the Society of Thoracic Surgeons Adult Cardiac Surgery Database (39), which showed that among 189,268 patients who underwent SAVR in the United States since 2008, only 2.9% of patients underwent AAE. Although the survival analysis demonstrated a higher mortality risk with AAE during the first three years, the survival curves cross after this timepoint, favoring AAE.

In the era of pre-TAVR MDCT, surgical valves remain primarily chosen intraoperatively using sizers, which may result in variation among operators and risk of PPM. We should ask ourselves: is there any benefit with pre-SAVR MDCT? Okada *et al.* evaluated the usefulness of preoperative CT annulus measurement for SAVR valve sizing. Implantation of smaller size valves than the CT-predicted size and severe PPM were significantly decreased by CT sizing than with conventional sizing [12% versus 31% (P=0.001) and 0% versus 6% (P=0.039), respectively] (40). Interoperator variability was associated with an implanted size smaller than CT predicted with conventional sizing but was nonsignificant with CT sizing. The authors concluded that applying CT sizing to SAVR improved valve size selection, decreased PPM, and decreased interoperator variability. CT sizing for SAVR could also predict PPM before SAVR and identify patients who need AAE. Considering the study by Okada *et al.* (40), pre-SAVR MDCT should be stimulated (if not standard) when treating patients with AS.

Choosing the right first valve

There is growing evidence that the impact of PPM may be more significant in SAVR than TAVR and in BEVs than SEVs (24,31,41) In patients with small annuli, particularly women, deciding the best treatment option for severe AS is nuanced. Preoperative imaging and anticipating the implant valve size based on the diameter of the transthoracic echocardiogram is the initial step. With the evidence available, a small surgical valve that will leave the patient with severe PPM should be avoided. Predicting the right first valve is best done with a complete analysis of the aortic valve and root. MDCT is essential for TAVR planning and is quickly becoming the standard of care for the preoperative assessment of all patients with severe AS.

Deciding which treatment strategy, TAVR or SAVR, is best for patients with AS goes beyond the anatomic assessment. Factors such as patient preference, surgical risk, candidacy for transfemoral TAVR, and life expectancy must also be considered (3,4). The ability to place a surgical valve of adequate size to avoid PPM and provide a large enough platform for future TAVR if and when the first valve fails is an advantage when a root enlargement is performed. The decision around placing a first TAVR is similar in younger patients; a large valve with an adequate EOA to avoid PPM and provide a platform for future re-valving is ideal.

Algorithms have been proposed to simplify the treatment of severe AS and reduce the risk of PPM (42,43). Based on the available data, we propose a routine stepwise assessment.

(I) Confirm the diagnosis of severe AS by transthoracic echo and assess the patient's symptoms.
(II) Engage in a shared decision-making discussion to ascertain patient preferences and estimate life expectancy.
(III) Obtain an MDCT to measure the aortic valve and root anatomy and determine candidacy for transfemoral access.
(IV) Assess the aortic annulus and root for valve options based on labeled prosthesis normal EOA per anticipated size.
(V) Calculate predicted iEOA: valve EOA/BSA.
(VI) If ≤ 0.85 cm^2/m^2 (or ≤ 0.70 cm^2/m^2 in a patient with BMI ≥ 30 kg/m^2), there is a risk of moderate PPM. Assess for factors with increased risk of severe PPM: female sex, younger age, low left ventricular ejection fraction, low gradient AS, and concomitant mitral or tricuspid valve disease.

(i) If none of the factors, proceed with the initial valve choice.
(ii) If any of the factors, consider a strategy to prevent PPM.

(VII) If ≤0.65 cm^2/m^2 (or ≤0.55 cm^2/m^2 in a patient with BMI ≥30 kg/m^2), there is a severe risk of PPM.

(VIII) Proceed with the strategy to prevent PPM: implant a valve with superior hemodynamics and a larger EOA (likely supra-annular SEV), perform TAVR instead of SAVR or plan for AAE to place a larger valve if performing SAVR.

Defining the best treatment strategy is challenging with the current data, with a need for long-term durability data. The longest-term TAVR data is for SEVs in the NOTION trial; at 10 years, there was no significant difference in clinical outcomes between patients randomized to SAVR or the first-generation SEV CoreValve (44). Despite higher PPM in the surgical cohort, the rates of bioprosthetic valve failure were also similar. Until the low-risk trials complete 10-year follow-up and head-to-head trials like SMART conclude, we will define best practices based on available results. For the patient at risk of severe PPM, a supra-annular SEV is likely better than an intra-annular or BEV TAVR, which is better than a small surgical valve.

Conclusions

The treatment strategy for severe AS is evolving and beyond just surgical risk assessment. With younger and lower-risk patients now receiving TAVR as the initial treatment, we must consider optimizing the first valve platform to avoid PPM and provide a foundation for future re-valving. There may not be one "best" treatment based on the literature, but there is consistent data associating PPM with increased mortality. Preventing PPM should be a priority, and TAVR can be a solution in patients with a small annulus.

Acknowledgments

Funding: None.

Footnote

Conflicts of Interest: K.J.G. reports consulting fees from Medtronic, Abbott, Boston Scientific, Ancora Heart, 4C Medical, and OpSens; institutional support from Edwards Lifesciences. I.S. receives institutional research support from Abbott, Artivion, Boston Scientific, Edwards, Medtronic, and Terumo Aortic. The other authors have no conflicts of interest to declare.

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Cite this article as: Grubb KJ, Tom SK, Sultan I, Sá MP. Overcoming prosthesis-patient mismatch with transcatheter aortic valve replacement. Ann Cardiothorac Surg 2024;13(3):236-243. doi: 10.21037/acs-2024-aae-27

