Limitations in the Assessment of Prosthesis-Patient Mismatch

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Abstract

Background Prosthesis-patient mismatch (PPM) after aortic valve replacement (AVR) may affect survival but data are conflicting. It is assessed by relating effective orifice area (EOA) to body surface area (EOAi). EOA is patient-specific as the result of flow-velocity times area at the individual patient's outflow tract levels ($LVOT_A$) divided by trans-prosthetic flow velocity. However, some studies use projected EOAs (i.e., valve size associated EOAs from other patient populations) to assess how PPM affects outcome.

Methods We analyzed 76 studies addressing hemodynamic outcome and/or mortality after bioprosthetic AVR.

Results In 48 studies, projected or measured EOA for calculation of EOAi and PPM assessment was used (of which 25 demonstrated an effect on survival). We identified 28 additional studies providing measured EOA values and the corresponding Bernoulli's pressure gradients after AVR. Despite EOA being a patient-specific parameter, 77% of studies assessing a PPM impact on survival used projected EOAs. The 28 studies are providing measured EOA values and the corresponding Bernoulli's pressure gradients in patients after AVR showed a highly significant, linear relationship between EOA and Bernoulli's gradient. Considering this relationship, it is surprising that relating EOA to body surface area (BSA) (EOAi) is standard but relating pressure gradients to BSA is not.

Conclusion We conclude that the majority of studies assessing PPM have used false assumptions because EOA is a patient-specific parameter and cannot be transferred to other patients. In addition, the use of EOAi to assess PPM may not be appropriate and could explain the inconsistent relation between PPM and survival in previous studies.

Keywords
- aortic valve replacement
- cardiac surgery
- hemodynamic evaluation
- echocardiography
- flow velocity
- pressure gradient

Introduction

Aortic valve replacement (AVR) is the therapy of choice for aortic valve stenosis. Surgical success depends on a significant reduction of transvalvular gradients. Valve gradients are assessed most commonly with echocardiographic measurement of flow velocity and use of the modified Bernoulli's equation to derive the pressure gradient. Another way to assess the hemodynamic performance of a valve is deriving the effective orifice area (EOA), representing the smallest cross-sectional area of the transprosthetic jet flow. EOA is measured by Doppler's echocardiography using flow velocity and the area of the left ventricular outflow tract (LVOT; ►**Fig. 1**). Both

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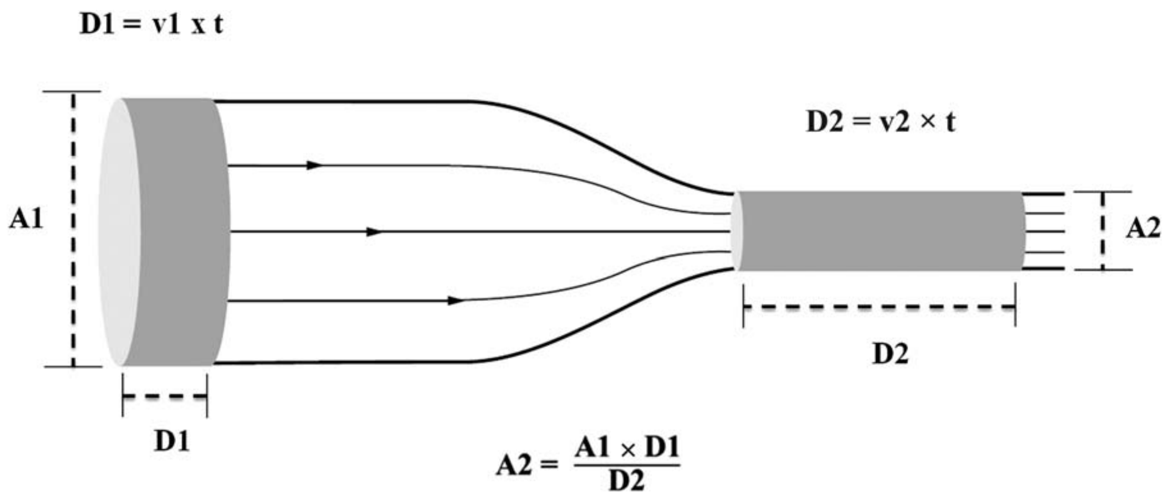

Fig. 1 Principle of echocardiographic determination of the effective orifice area (EOA) through the continuity equation. A1 is the area of flow at the left ventricular outflow tract, A2 is the area of flow at the vena contracta (EOA). D is the distance the fluid advances during a given time (t). V is the velocity of the fluid. The advance in fluid volume ($A \times D$) is the same at the two different points, therefore $A1 \times D1 = A2 \times D2$. A2 is the EOA. EOA, effective orifice area.

pressure gradient and EOA are standards for determining hemodynamic outcome after AVR. If gradients are too high or the EOA is too low, a mismatch between prosthesis and patient may occur.[1] Prosthesis-patient mismatch (PPM) has been the subject of interest and controversy for over 35 years and has regained interest with the advent of transcatheter aortic valve replacement,[2] specifically in the context of patients with the option of valve-in-valve procedures.[3]

By definition, PPM is present when the opening of the inserted prosthetic valve is smaller than that of the patient's normal, native valve.[1] Its main hemodynamic consequence is the development of elevated pressure gradients through an otherwise normally functioning prosthetic valve. If significant, PPM may be detrimental and dampen the benefits of AVR and possibly lead to an unfavorable clinical outcome. To date, the indexed EOA (EOAi), that is, the EOA divided by the patient's body surface area, is used frequently to quantify PPM.[4,5] Most studies comply with the classification that an EOAi ≤ 0.65 cm^2/m^2 represents severe, 0.65 to 0.85 cm^2/m^2 moderate, and > 0.85 cm^2/m^2 reflects insignificant PPM.[5–16] Unfortunately, this classification has not achieved a consensus among published studies addressing the impact of PPM on postoperative survival, resulting in ongoing controversy regarding the clinical importance of PPM. We have reviewed the literature on this topic and have identified potential shortcomings in the assessment of PPM that may shed some light on the inconsistent relationship between PPM and survival.

Methods

Search Strategy

The PubMed database was systematically searched in June 2016 to identify published full-length English studies reporting outcome of patients after AVR, stratified by the presence of PPM and/or measurements of EOA and pressure gradients. No year of publication exclusion was implied. Studies were identified by a search using the following key words in all fields: "mismatch OR PPM," "AVR OR aortic valve replacement" and "Aortic valve hemodynamics."

Study Inclusion

The title and abstract of studies identified by the search were independently screened using the following four criteria: (1) the publication was an original full-article contribution in a peer-reviewed journal; (2) patients were adults; (3) patients had undergone AVR with a bioprosthetic valve; and (4) either PPM was assessed or EOA and pressure gradients were measured. For studies those met all these criteria, or in case of uncertainty, the full texts were further evaluated. Studies were separated between those that measured EOA as well as pressure gradients and those that addressed the impact of PPM on outcome.

Methodology for EOA, EOAi and Pressure Gradient Determination

In the selected studies, we assessed which tools were used to assess PPM, EOA, EOAi, and pressure gradients. The determination for PPM cut-off values was not uniform and is described elsewhere in the text. All studies addressing PPM used EAO related to body surface area (EOAi). We used the following terminology for reporting EOAs. Measured EOA: assessment of the effective opening area (i.e., the vena contracta area) by continuity equation using velocity time integrals of the preprosthetic flow determined in the left ventricular outflow tract (LVOT) and of the transprosthetic flow. The measured EOA is a patient-specific parameter which considers the geometry of LVOT as well as of the prosthesis itself.

Projected EOA: EOA-value for a given valve size published by another study or an industry-generated EAO chart. All presented pressure gradients were obtained in the studies based on the modified Bernoulli's equation (see specifically ►**Supplementary Table S1**, available in online version only).

Statistical Analysis

For the statistical evaluation of the relation between pressure gradients and Effective orifice area, we applied random-effects meta-regression to account for heterogeneity between the studies and investigated the association of mean pressure gradients and EOA by considering a linear, quadratic, cubic, inverse, as well as logarithmic relationship between EOA and pressure gradients, using SAS 9.4 for Windows, Cary, NC, USA. Here, metaregression is similar in essence to simple regression, in which the mean pressure gradient as the dependent variable is modeled by EOA as the only covariate. The difference to simple regression is that the dependent variable is an effect estimate in the studies included for the analysis rather than individual observations and that the covariate information are characteristics of the studies. Thus, to account for different study sizes and since larger studies have more influence on the considered relationship than smaller studies, studies are weighted by the precision of their respective effect estimate in applying metaregression. Incorporating a so called random effect in the metaregression model, we allow that the true effect estimates may vary between different studies which is not explained by the covariate (residual heterogeneity).

Table 1 Studies assessing the relevance of PPM on mortality using measured or projected EOA

PPM relevant	EOA	PPM not relevant	EOA
Rao et al 2000	Projected	Pibarot et al 1996	Projected
Pibarot et al 2001	Measured	Moon et al 2006[a]	Projected
Blais et al 2003	Measured	Flameng et al 2006	Measured
Ennker et al 2005	Projected	Monin et al 2007	Projected
Walther et al 2006	Projected	Ryomoto et al 2008	Projected
Tasca et al 2006	Projected	Florath et al 2008	Projected
Moon et al 2006[a]	Projected	Mascherbauer et al 2008	Projected
Ruel et al 2006	Projected	Moon et al 2009[a]	Projected
Kulik et al 2006	Projected	Mohty et al 2009[b]	Projected
Yap et al 2007	Projected	Nozohoor et al 2008	Measured
Kato et al 2007	Projected	Vicchio et al 2008	Measured
Fuster et al 2007	Projected	Kato et al 2008	Projected
Kohsaka et al 2008	Projected	Urso et al 2009	Projected
Moon et al 2009[a]	Projected	Price et al 2009	Projected
Mohty et al 2009[b]	Projected	Jamieson et al 2010	Projected
Bleiziffer et al 2010	Measured	Cotoni et al 2011	Projected
Head et al 2012[c]	Measured	Jeong et al 2013	Measured
Hong et al 2012	Projected	Concistrè et al 2013	Projected
Hernández-Vaquero et al 2012	Projected	Kitamura et al 2013	Projected
Hong et al 2013	Measured	Koene et al 2013	Projected
Urso et al 2014	Projected	Dayan et al 2015[d]	Projected
Pibarot et al 2014	Measured	Sportelli et al 2016	Measured
Iosifescu et al 2014	Projected	Joshi et al 2016	Projected
Shahzeb et al 2014	Projected		
Une et al 2015	Projected		

Abbreviations: EOA, effective orifice area; LV, left ventricle; PPM, prosthesis-patient mismatch.

[a]Authors reported impact of PPM was age dependent.

[b]Authors reported impact of PPM only on decreased LV-function.

[c]Largest systematic review and meta-analysis.

[d]PPM was not found to be associated with adverse outcome, after adjusting for confounders.

Results

Of the 76 analyzed studies, 48 assessed the association between PPM and mortality. All of them are listed in ►**Table 1**. Reports were highly discrepant. Of the 48 studies, 25 demonstrated an impact on survival (in three reports, presence of PPM was associated with age or LV function). Regarding the source of the data in these publications, only 11 studies determined patient-specific values for EOA (six studies with and five without a relevant association between PPM and survival), whereas the vast majority (approximately 77%) used a projected EOA (i.e., an EOA value for a given valve size published by another study or an industry-generated EOA chart). ►**Fig. 2** schematically illustrates the influence of the LVOT dimension on the EOA for a given tissue valve. If a given valve is implanted into a patient with larger anatomic dimensions (panel A), the EOA becomes smaller than the actual opening of the tissue valve (i.e., the geometric opening area [GOA]). This effect is related to flow convergence and reflects a principle of fluid dynamics.[17,18] If the same valve is implanted into a patient with smaller LVOT dimensions (Panel B), EOA and GOA become similar to each other and possibly even converge. Thus, the same valve may result in different EOAs depending on the size of the annulus/

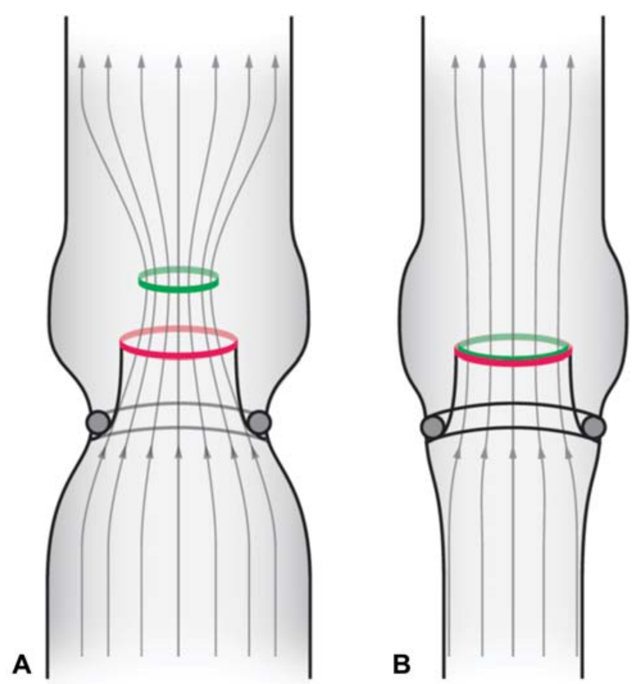

Fig. 2 Schematic illustration of two identical bioprosthetic valves implanted into two anatomically different aortic roots.
Note that the effective orifice area (EOA; red circle) is smaller than the geometric opening area (GOA, green circle) in panel (A) and equal to the GOA in panel (B). Thus, two identical valves deliver two different hemodynamic outcomes depending on the patients' anatomic dimensions.

LVOT dimensions. This recognition also means that using a projected EOA cannot take interindividual differences into account for assessing the impact of PPM on outcome in actual patients.

We therefore searched for additional studies that measured EOA as well as pressure gradients after AVR. Based on the study-specific summary data about pressure gradients and EOA, we performed a metaregression to gain insight into the association of measured gradients and EOAs. In total, 28 studies,[11,13,19–44] (►**Supplementary Table 1**; supplementary table is available in online version only) were found with information about mean EOA and mean pressure gradients. The results are presented in ►**Fig. 3** together with I^2 as a measure between study heterogeneity, that is, heterogeneity not explained by the covariates in the regression. The numbers represent the size label of the prosthesis while the size of the circle corresponds with the size of the sample. Note that, all measured values report EOAs greater than 1 cm^2 which is considerably different from most values obtained for the assessment of aortic valves stenosis (severe $< 1\ cm^2$). As a result, the relationship of EOA to pressure gradients may not immediately appear logarithmic as expected. In contrast, all five statistical approaches considered in the analysis showed a highly significant association between pressure gradients and EOA with high I^2 for each ($p < 0.0001$). In other words, the relationship between pressure gradients and EAO after biological valve replacement may also be considered linear (it is important to again emphasize, that this consideration can only be made for the EOA range above 1 cm^2). Based on this finding, it is interesting to note that many studies relate EOA to body surface area (BSA) but none relates pressure gradients to BSA.

Discussion

We demonstrate in this study that the majority of studies assessing PPM have used false assumptions because EOA is a patient-specific parameter and cannot be transferred to other patients. In addition, the use of EOAi to assess PPM may not be appropriate and could explain the inconsistent relation between PPM and survival in previous studies.

There has been much controversy in the published literature about the impact of PPM on postoperative outcomes. Differences in the classification of PPM have been pointed out as a possible explanation for these conflicting findings regarding its impact on survival.[10,45] However, the divergence persists even when evaluating studies using the same classification as suggested by Blais et al in 2003.[5] Another explanation for the different opinions regarding PPM and survival may rely on the fact that indexing EOA for body surface area can be misleading. The rationale for using this parameter is that pressure gradients are essentially determined by the valve opening area and transvalvular flow which in turn are largely related to cardiac output requirements which may alter according to individual body size. Although the use of EOAi is believed to account for these differences in physical constitution, it relates a measure of flow velocity to individual parameters twice (i.e., LVOT area

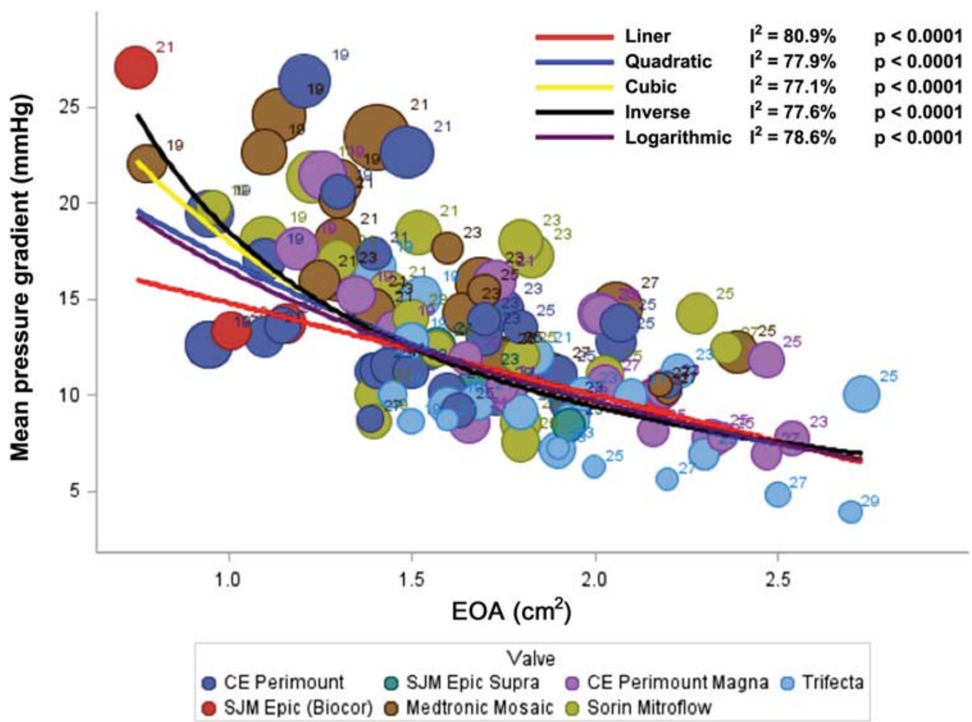

Fig. 3 Postoperative mean pressure gradients as a function of the effective orifice area (EOA) after bioprothetic aortic valve replacement taken from publications reporting both values for the same patients (Epic,[30] Epic Supra,[33,41] Mosaic,[24,27,28,31,38,39,44] Perimount,[19–21,23,25,28,30,35,39,42] Magna,[20,23,24,27,41] Sorin Mitroflow,[23,29,43,48,49] and Trifecta[22,26,27,32,34,37,40,43]). The numbers represent the size label of the prosthesis and the size of the circle corresponds with the size of the sample. The lines represent the fitting of the values to different mathematical functions (quadratic, cubic, inverse, as well as linear and logarithmic). Note that almost all published EOA values are larger than 1 cm^2 and that all mathematical functions obtain a highly significant regression coefficient ($p < 0.0001$). See text for further details.

and BSA), since both may vary according to body size. While EOAi may appropriately account for different cardiac output requirements in "normal" patients (based on the rationale that a mouse needs less valve opening than an elephant), this assumption may be flawed in humans with obesity or those who are tall and thin. As illustrated in ►**Fig. 3**, a linear relationship can be found between the EOA values and mean pressure gradients in patients after AVR. In addition to this finding, there is a high variability of MPG among the studies for similar EOAs (►**Fig. 3**). Therefore, despite speculation that the indexation of EOA may account for differences in patient size and values move in a linear manner. Considering this "linearity" of the direct EOA measurements and pressure gradients, the relation of EOA to body surface area and hence the need to index EOA is questionable. Based on our findings, it is conceivable that using EOAi to assess the presence and severity of PPM may not be appropriate and its use could explain the contradictory outcomes of previous studies. The figure also demonstrates that assessing the EOA does not increase our ability to evaluate hemodynamic outcome compared with using the echocardiographic pressure gradients directly. In theory, EOA assessment would be superior to pressure gradients if examinations were made under stressed conditions with elevation of flow. However, most evalulations, including all quoted in this text, evaluated hemodynamics only at rest.

The most striking finding of our analysis is that the majority of studies of this topic were based on projected EOA data rather than actually measured EOA values, despite previous reports that the use of projected EOAs results in inaccurate comparison with measured EOA values.[13,45,46] The EOA of a valve is a calculated value. It first estimates the area of the LVOT, multiplying it by the velocity time integral (VTI) at the same point; assuming that this product (area $\times$ VTI) is the same before and after the valve (►**Fig. 1**). The VTI at or after the valve is measured at the point of highest flow compression, the so called vena contracta, which (depending on how much the flow is compressed) is smaller than the actual opening area of the prosthesis (►**Fig. 2A**). Therefore, the same prosthesis could present different EOAs depending on how much the flow is compressed by passing through the valve and thus by the individual patient's LVOT area. As is apparent in ►**Fig. 2**, it would not be appropriate to conclude that valve A is hemodynamically inferior to valve B (although it would be appropriate to conclude that hemodynamics in setting A are inferior to setting B). Using the same reasoning, it would be equally incorrect to use the EOA from patient A to assess PPM on patient B. EOA is a patient-specific measure of hemodynamic performance and not a valve-specific value (as suggested by the globally available EOA charts) and by definition cannot be transferred from one person to another. Nonetheless, this inappropriate inference has been used extensively in the literature as the "projected" EOA when addressing PPM. Some studies have even used values from in vitro measurements. The reason for this common mistake may be the assumption that the EOA represents the actual opening area of the valve. As noted above, this is only true on some occasions.[47] Hence, the reliability of studies using projected EOA to assess the relation between PPM and survival is highly questionable. Until this conundrum has been replaced with a more reliable way of quantifying PPM in daily practice, pressure gradients similarly to their use in the determination of the severity of primary aortic valve stenosis may suffice for decision-making.

Conclusion

Our study demonstrates severe limitations and inconsistencies in the literature regarding the role of PPM for clinical practice. First, EOA is a patient-specific measure of hemodynamic performance and cannot be reliably transferred to other patients; therefore the majority of studies that have used projected EOA data may have reported inaccurate data. Second, indexing the EOA for body surface area may not be appropriate for assessing PPM and use of EOAi could explain the contradictory reports of previous studies regarding the association of PPM and postoperative survival. We believe that PPM is relevant and in some patients does have important clinical impact on symptoms and survival. However, the way that we measure it is an issue that has led to considerable discordance and controversy. It seems that (in the absence of structural cusp degeneration) currently no echocardiographic analysis exceeds the value of the Bernoulli's pressure gradients for assessing hemodynamic relevance of a bioprosthesis.

Perspectives

Competencies

In daily practice, PPM is defined by relating the EOA to body surface area (EOAi). For values below 0.85 cm^2/m^2 and 0.65 cm^2/m^2 moderate and severe PPM has been defined, definitions which are used for clinical decision making, for instance for the decision to treat a stenosed prosthetic valve.

The EOA reflects the area of the point of maximal flow compression over the prosthetic valve (vena contracta) which is a function of the outflow tract area based on the continuity equation (i.e., it is patient-specific). However, in four out of five studies addressing PPM, EOAs were not measured but projected from other studies which originally measured the EOA for their patient population. Thus, the majority of studies assumed that the EOA is prostheses-specific.

Hence, EOA data in the majority of studies may be inherently inaccurate.

Translational Outlook

Since EOA is patient-specific based on its relation to the individual patient's outflow tract area, relating the EOA to body surface area is questionable since the same echocardiographic flow measurement is then related to two different patient-specific parameters. In addition, based on a series of studies having measured Bernoulli's pressure gradients and patient-specific EOAs, we identified a significant correlation of transprosthetic pressure gradients to EOA. Thus, in clinical practice, the use of the questionable EOAi may be redundant and the use of transvalvular pressure gradients appears sufficient. In the future, hemodynamic assessment of prosthetic aortic valves requires thorough re-evaluation. In the meantime, the use of pressure gradients, as assessed by the modified Bernoulli's equation, may make daily life in the echolab easier.

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None disclosed.

Note
The papers were cited to exemplify relevant issues on publications addressing PPM as outlined in the manuscript. It is not our intention to criticize any particular publication.

Conflict of Interest
Author T.D. received occasional honoraria from St. Jude Medical, Inc. for lectures on aortic valve topics. All other authors have nothing to disclose.

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