Impact of Patient Prosthesis Mismatch on the Outcome of Transcatheter Pulmonic Valve Implantation

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Patient prosthesis mismatch (PPM) is an important factor of the outcome in transcatheter aortic valve implantation. However, the impact of PPM in transcatheter pulmonic valve implantation (TPVI) has not been studied. Based on the narrowest valve stent diameters in two views of fluoroscopy, internal geometric orifice area (GOA) of the valve stent was calculated and indexed by body surface area (BSA), deriving iGOA. To define PPM in TPVI, receiver operating characteristics (ROC) curve analysis for iGOA for predicting significant residual right ventricular outflow tract (RVOT) gradient was used to derive the optimal cut-off value of iGOA. Our cohort were divided into 2 groups: PPM versus non-PPM. The clinical data were compared between 2 groups. TPVI was performed using Melody valve in 101 patients. Significant RVOT residual pressure gradient (≥ 15 mmHg) was observed in 31 patients (39.6%). Over a mean follow up periods of 6.9 ± 2.7 years, 22 patients (21.8%) required repeat interventions (16 transcatheter, 11 surgical, and both in 5 patients). Based on the ROC analysis, the best cut-off value of iGOA was 1.25 cm^2/m^2 (area under the curve 0.873, $p < 0.001$) to define PPM. PPM was present in 42 patients (42%). On the Kaplan-Meier survival analysis, PPM was associated with the need of repeat intervention ($p = 0.02$). In conclusion, in TPVI, PPM was a strong predictor for the need of re-intervention. Considering PPM, target diameter of valve stent would depend on the patient body size and should be taken into account for optimal outcome of TPVI. **(Am J Cardiol 2021;151:93−99)**

The patient-prosthetic mismatch (PPM) is the condition of when the effective orifice area of prosthetic valve is less than that of a normal human valve.[1] The reduced orifice area in prosthetic valve is known to affect the outcomes in the transcatheter aortic valve implantation.[2] In contrast, the PPM has not been studied for transcatheter pulmonic valve implantation (TPVI). Furthermore, the PPM in pulmonic position has not been defined. Certain clinical factors associated with the risk of TPVI re-intervention were reported to include compression of transcatheter pulmonic valve,[3] Melody valve Ensemble system size, and pre-stent technique.[4] Although these factors are related to the stent diameter of Melody valve, the effect of the valve orifice area of TPVI has not been evaluated. The geometric orifice area (GOA) is the anatomical area of the prosthetic valve orifice, which can be measured in the biplane fluoroscopic imaging after the TPVI. To account for the effect of body size, the indexed GOA (iGOA) is derived by indexing GOA by the body surface area (BSA). The objectives of this study were to define the PPM with the optimal cut-off value of iGOA and to evaluate the effect of PPM on the re-intervention in patients undergoing TPVI.

Methods

This was a single-center, retrospective study that was approved by the Wayne State University Institutional Review Board. Cardiac catheterization database was used to identify patients who underwent TPVI between 2010 and 2020. Inclusion criteria were patients who underwent TPVI using the Melody valve (Medtronic Inc, Minneapolis, MN, USA) for significant stenosis and/or insufficiency of right ventricular outflow tract (RVOT). The exclusion criteria were patients undergoing TPVI using the Sapien valve (Edwards Lifesciences, Irvine, CA, USA), those receiving the Melody valve at branch pulmonary arteries or left ventricle to pulmonary artery conduit and those having significant RVOT obstruction proximal to the Melody valve. The primary outcome was the need of re-interventions for the Melody valve at follow-up. Re-interventions included balloon angioplasty and/or stent placement on the Melody valve and surgical pulmonic valve replacement. Data on demographics, cardiac diagnosis, surgical history, echocardiography and cardiac catheterization were collected. Body surface area was calculated with the Mosteller formula.

Cardiac catheterization and TPVI were performed under general anesthesia. Hemodynamic data were collected before and after TPVI. Post-TPVI, the narrowest valve stent diameters were measured in both antero-posterior and lateral projections (Figure 1). The GOA was calculated with the ellipse formula based on the assumption that the measured narrowest diameters in two projections represent the major (1) and minor (1) axis of the orifice area: $GOA = \pi * (a/2) * (b/2)$. The GOA was indexed to the BSA, weight and height to derive iGOA (cm^2/m^2), iGOA (cm^2/kg), and iGOA (cm^2/m), respectively. The GOA was utilized to

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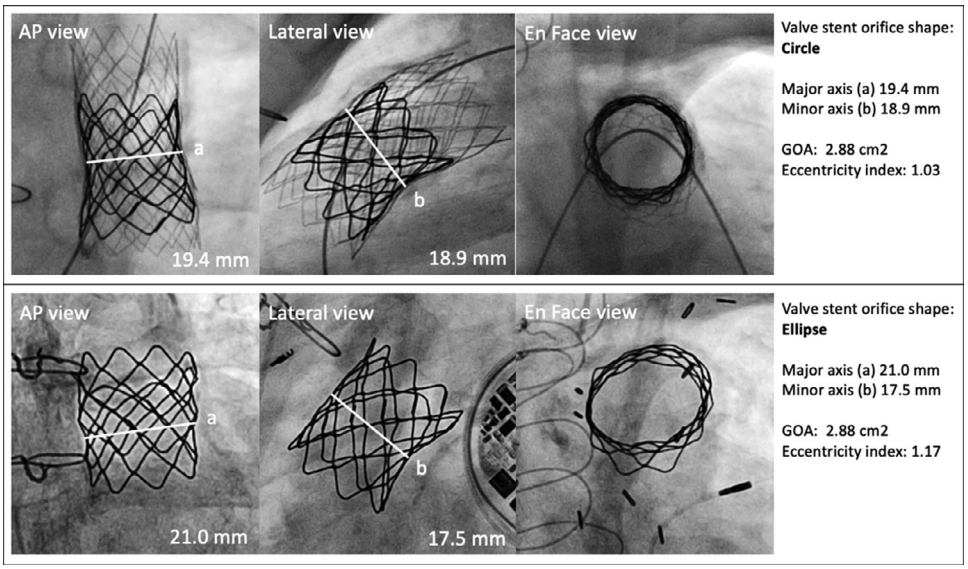

Figure 1. Measurement of geometric orifice area in the transcatheter pulmonary valve implantation. The narrowest valve stent diameter is measured in anteroposterior (AP) and lateral views.

define the PPM because there is no established method to measure the effective orifice area by Doppler echocardiography for the pulmonic valve prosthesis. Eccentricity index was defined as a ratio of a and b: eccentricity index = a/b [3]. When the valve stent orifice is complete circle, eccentricity index is 1. Abnormal eccentricity index > 1.1 indicates greater ellipse indicating the presence of compressed valve stent orifice.[3]

Statistical analysis was performed using SPSS version 27 (IBM SPSS Inc., Chicago, IL). Data were expressed as mean ± standard deviation or number and percent based on the types of variables. Pearson's correlation was used to measure the association between two continuous variables. In our cohort, the residual RVOT gradient ≥ 15 mmHg was considered significant at the time of TPVI.[5] Based on the assumption that patients having PPM would have significant residual RVOT gradient, the receiver operating characteristics (ROC) curve analysis was performed to identify the optimal cut-off value of iGOA to predict significant residual RVOT gradient. Our cohort was then divided into two groups (PPM vs. non-PPM) based on the cut-off value of iGOA (cm^2/m^2). Data were compared between two groups using the independent sample t-test or Chi-square test. The Kaplan-Meier survival analysis with a log-rank test was used to evaluate the factors associated with the need of re-intervention at follow up. Univariable and multivariable Cox proportional hazards regression along with backward model selection technique were used to arrive at the final predictive model to show factors associated with the need of re-intervention. The analysis was repeated in subset of patients who underwent TPVI at the age of 16 years or older, because there may be a potential effect of the somatic growth on the PPM in younger patients. This cut-off age was selected because the CDC growth charts shows no significant increase of height after 16 years of age for both men and females. Clinical guide reference table was created to show the minimum Melody valve stent diameter to avoid the PPM based on the cut-off value of iGOA, BSA and eccentricity index.

Results

Our cohort consisted of 101 patients, after excluding patients with Sapien valve (n = 24), bilateral Melody valve (n = 4), and Melody valve on the left ventricle to pulmonary artery conduit (n = 2). The mean age was 21.3 ± 10.2 years and there were 38 patients aged < 16 years. Primary cardiac diagnosis, RVOT type and primary indication for TPVI are shown in Table 1. The Melody valve was delivered through transfemoral approach (n = 99) and transjugular approach (n = 2). Pre-stenting was performed in 40 patients (40%). Among 61 patients without pre-stenting, the majority (n=36) was patients with failed bioprosthetic valve. Hemodynamic changes with TPVI, Ensemble system size and valve stent measurement are shown in Table 2. Significant RVOT residual gradient (≥ 15 mmHg) was observed in 31 patients (40%). The narrowest diameter in either AP or lateral views was 16.1 ± 2.4 mm. There were 30 patients (30%) having the eccentricity index >1.1 (Figure 2A). The measured GOA was 2.22 ± 0.67 cm^2 and iGOA was 1.42 ± 0.48 cm^2/m^2. There was significant negative correlation between the post-TPVI residual RVOT gradient and iGOA (cm^2/m^2) (Pearson correlation -0.620, $p < 0.001$, Figure 2B), although 23 patients (23%) had a discrepant relationship between these indices.

The ROC curve analysis was performed to identify the best iGOA measure to predict the significant residual RVOT gradient ≥ 15 mmHg. The iGOA indexed by the BSA had the best overall model quality (area under the curve 0.873, $p < 0.001$, Figure 3) and its optimal cut-off value of iGOA was 1.25 cm^2/m^2.

Based on the cut-off value of iGOA, our cohort was divided into two groups: PPM group (n = 42, iGOA < 1.25 cm^2/m^2) and non-PPM group (n = 59, iGOA ≥1.25 cm^2/m^2).

Table 1
Comparison of demographics in patients (n = 101) who underwent transcatheter pulmonic valve implantation (TPVI) using the melody valve between patient prosthesis mismatch (PPM) and non-PPM groups based on iGOA cutoff

Parameters	All patients (n = 101)	Patient prosthesis mismatch		p value
		Yes (n = 42)	No (n = 59)	
Male	66 (65.3%)	29 (69.0%)	37 (62.7%)	0.51
Age at catheterization (years)	21.3 ± 10.2	22.2 ± 9.6	20.7 ± 10.7	0.46
Height (cm)	159.1 ± 13.9	162.5 ± 11.0	156.8 ± 15.3	0.04
Weight (kg)	62.0 ± 23.5	68.4 ± 24.6	57.4 ± 21.8	0.02
Body surface area (m^2)	1.63 ± 0.36	1.74 ± 0.33	1.56 ± 0.37	0.02
Primary diagnosis				0.23
Tetralogy of Fallot	43 (42.6%)	14 (33.3%)	29 (49.2%)	
Pulmonary atresia	19 (18.8%)	6 (14.3%)	13 (22.0%)	
Truncus arteriosus	19 (18.8%)	12 (28.6%)	7 (11.9%)	
Aortic valve disease	10 (9.9%)	5 (11.9%)	5 (8.5%)	
Double outlet right ventricle	3 (3.0%)	2 (4.8%)	1 (1.7%)	
Others	7 (6.9%)	3 (7.1%)	4 (6.8%)	
Right ventricle outflow tract type				0.32
Native or patch-extended right ventricle outflow tract	6 (5.9%)	1 (2.4%)	5 (8.5%)	
Homograft	51 (50.5%)	23 (54.8%)	28 (47.5%)	
Stented bioprosthetic valve conduit	34 (33.7%)	15 (35.7%)	19 (32.2%)	
Stented bioprosthetic valve without conduit	9 (8.9%)	2 (4.8%)	7 (11.9%)	
Other	1(1.0%)	1 (2.4%)	0 (0.0%)	
Primary indication for TPVI				0.01
Stenosis	8 (7.9%)	3 (7.1%)	5 (8.5%)	
Regurgitation	48 (47.6%)	12 (28.6%)	36 (61.0%)	
Both	45 (44.6%)	27 (64.3%)	18 (30.5%)	

The PPM group was likely to have the significant residual RVOT gradient with the odds ratio 13.0 (95% confidence interval 4.6 − 36.9, $p < 0.001$). The comparison of demographics, hemodynamic data and valve stent measurement between groups is shown in Table 1 and Table 2. The PPM group had a higher post-TPVI residual RVOT gradient (17.4 ± 7.9 vs 8.1 ± 4.9 mmHg, $p < 0.001$), whereas pre-TPVI RVSP and RVOT gradient did not differ. The PPM group had a lower iGOA (1.04 ± 0.16 vs 1.70 ± 0.44 cm^2/m^2, $p < 0.001$).

Over the mean follow up period of 6.9 ± 2.7 years, 22 patients (22%) required re-interventions (16 transcatheter,

Table 2
Hemodynamic data and measurement of valve stent and indexed geometric orifice area (iGOA) at the transcatheter pulmonic valve implantation (TPVI)

Parameters	All patients (n = 101)	Patient prosthesis mismatch		p value
		Yes (n = 42)	No (n = 59)	
Pre-TPVI				
Right ventricle systolic pressure (mmHg)	56.1 ± 16.1	59.1 ± 15.1	54.0 ± 16.5	0.11
Right ventricle outflow tract gradient (mmHg)	26.0 ± 15.3	29.9 ± 16.6	23.3 ± 13.8	0.03
Post-TPVI				
Right ventricle systolic pressure (mmHg)	41.8 ± 13.3	46.6 ± 11.2	38.4 ± 13.7	< 0.01
Right ventricle outflow tract gradient (mmHg)	11.9 ± 7.8	17.4 ± 7.9	8.1 ± 4.9	< 0.01
Right ventricle outflow tract gradient ≥ 15 mmHg	31 (30.7%)	25 (59.5%)	6 (10.2%)	< 0.01
Ensemble system size (mm)				
18	9 (8.9%)	3 (7.1%)	6 (10.2%)	< 0.01
20	40 (39.6%)	25 (59.5%)	15 (25.4%)	
22	52 (51.5%)	14 (33.3%)	38 (64.4%)	
Valve stent measurement				
Narrowest diameter in anterior-posterior view (mm)	16.7 ± 2.7	14.7 ± 1.5	18.1 ± 2.5	< 0.01
Narrowest diameter in lateral view (mm)	16.8 ± 2.5	15.3 ± 1.8	17.9 ± 2.3	< 0.01
Narrowest diameter in either anterior-posterior or lateral views (mm)	16.1 ± 2.4	14.4 ± 1.4	17.3 ± 2.3	< 0.01
Eccentricity index	1.08 ± 0.06	1.08 ± 0.06	1.08 ± 0.06	0.89
Abnormal eccentricity index >1.1	30 (30%)	14 (33%)	16 (27%)	0.50
Geometric orifice area (cm^2)	2.22 ± 0.67	1.78 ± 0.34	2.57 ± 0.65	< 0.01
Indexed geometric orifice area (cm^2/m2)	1.42 ± 0.48	1.04 ± 0.16	1.70 ± 0.44	< 0.01

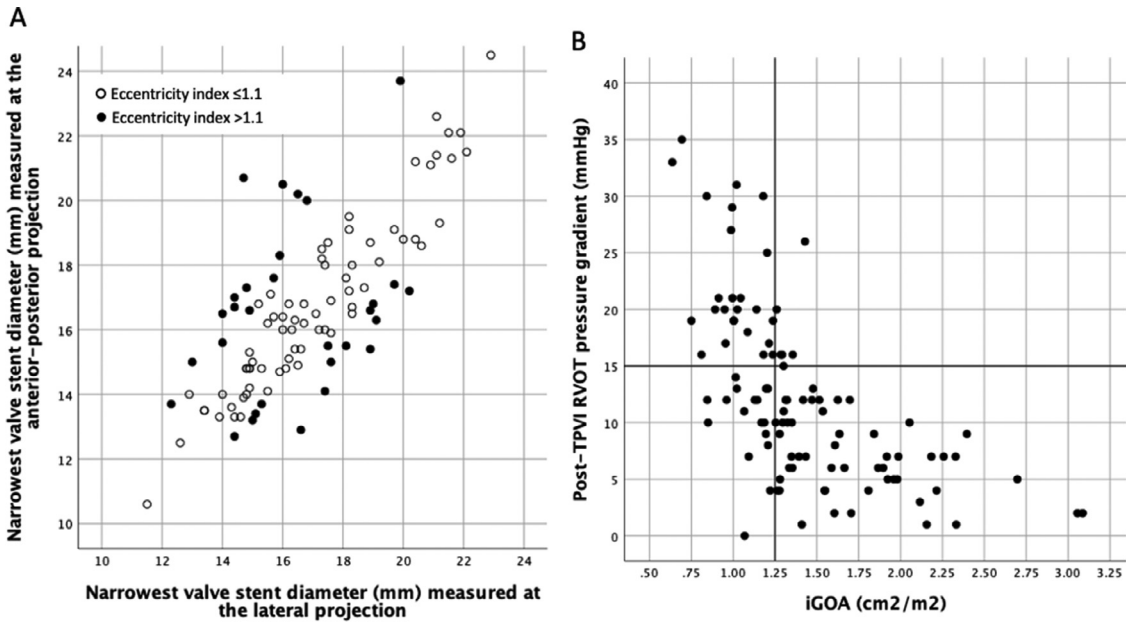

Figure 2. (A) Scatter-plots showing the relationship between the narrowest stent diameter measures at the anteroposterior and the lateral projections; (B) Scatter-plots showing the relationship between indexed geometric orifice area (iGOA) and post-transcatheter pulmonic valve implantation (TPVI) right ventricular outflow tract (RVOT) pressure gradient.

11 surgical, and both in 5 patients). On the Kaplan-Meier survival analysis, both PPM and significant residual RVOT gradient ≥ 15 mmHg were significantly associated with the need of re-intervention ($p < 0.05$, Figure 4). In the univariable Cox proportional regression analysis, three variables were identified as strong predictors on the need of re-intervention: the presence of PPM, significant residual RVOT gradient and the use of homograft (reference: other RVOT types). The final multivariable model showed that the significant predictors were PPM (hazard ratio 2.67, $p = 0.021$) and homograft (hazard ratio 2.85, $p = 0.022$, Table 3). The smaller size (18 mm) of the delivery Ensemble system was associated with significant residual RVOT gradient ($p = 0.021$), smaller iGOA ($p = 0.011$) and higher incidence of PPM ($p = 0.011$) as compared to the larger size (20 mm or 22 mm). Abnormal eccentricity index was not associated with the presence of PPM. Neither the Ensemble system size nor eccentricity index had no effect on the need of re-intervention at follow-up.

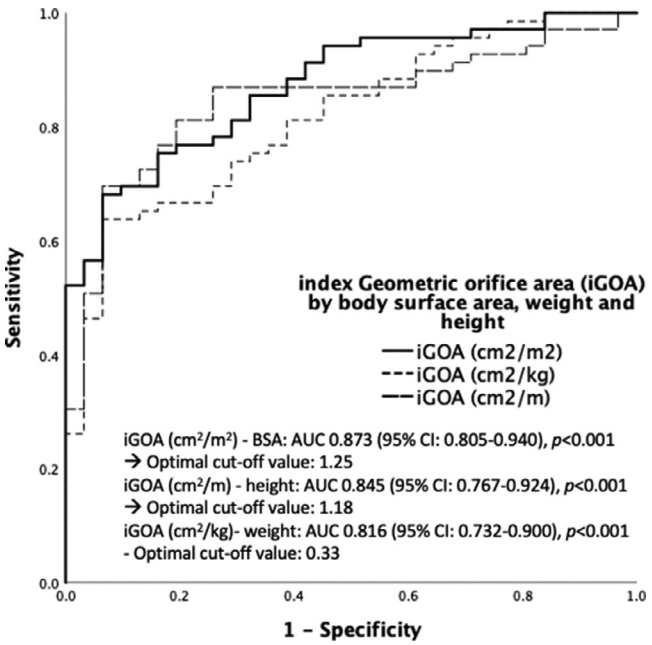

Figure 3. Receiver operator characteristic curve analysis to identify the optimal cut-off value of indexed geometric orifice area (iGOA) by body surface area, weight and height, to detect the significant RVOT residual gradient (≥ 15 mmHg) in transcatheter pulmonic valve implantation.

The analysis was repeated in the subset of patients ≥ 16 years (n = 63) aged: PPM (n = 32) and non-PPM (n = 31). On the Kaplan-Meier survival analysis, both PPM and significant residual RVOT gradient ≥ 15 mmHg remained significantly associated with the need of re-intervention ($p < 0.05$). The only significant predictor in the final multivariable analysis was the PPM (hazard ratio 6.39, $p = 0.017$, Table 3). Using the proposed cut-off value of iGOA 1.25 cm^2/m^2, the clinical guide (Table 4) is shown as reference values of the Melody stent valve diameters based on BSA and eccentricity index.

Discussion

This was the first study to attempt defining the PPM and evaluate the impact of PPM on the re-intervention in the TPVI using the Melody valve. Based on the ROC curve analysis, the optimal cut-off of iGOA was defined as 1.25 cm^2/m^2. Our data showed that PPM was a strong predictor for re-intervention and was a better predictor than the significant residual RVOT gradient in the final multivariable model.

To best of our knowledge, there have been no studies investigating the PPM for TPVI. In our study, the GOA was

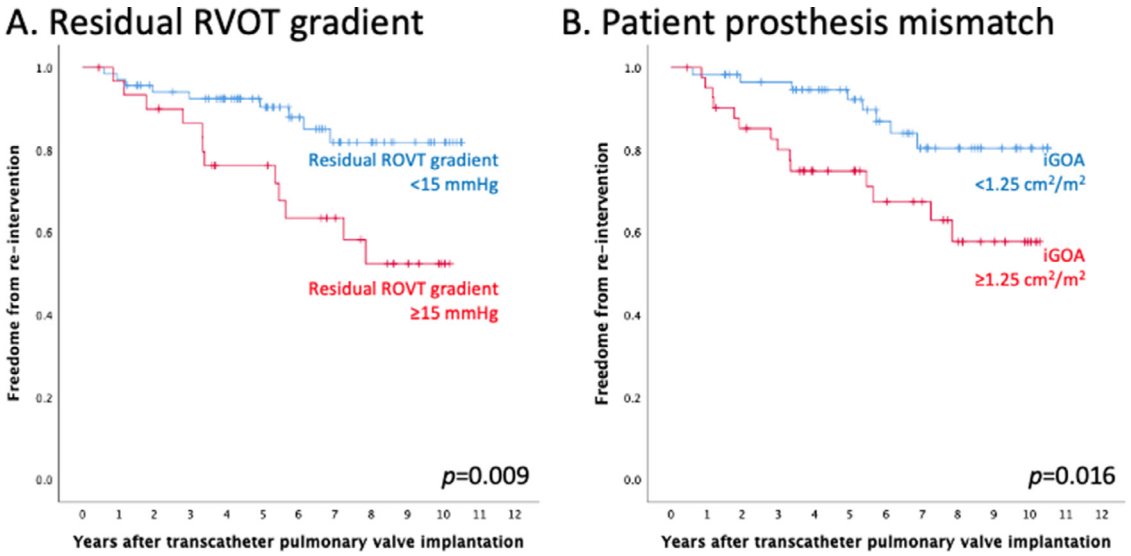

Figure 4. Kaplan-Meier survival curve showing the freedom from the re-intervention in 101 patients undergoing transcatheter pulmonic valve implantation using Melody valve, based on (A) residual right ventricular outflow tract (RVOT) gradient and (B) patient prosthesis mismatch.

utilized to define the PPM. The GOA can be calculated by measuring the major and minor axis of the valve stent diameter on the post-TPVI fluoroscopy. As shown in our data, a higher residual RVOT gradient was associated with a lower iGOA. To identify the best cut-off value of iGOA to define the PPM, the post-TPVI residual gradient ≥ 15 mmHg was used in the ROC curve analysis. This 15 mmHg of residual gradient was selected based on the previous studies of Melody valve outcomes.[3,4]

Our cohort had 22 patients (22%) requiring re-intervention on 6.9 years follow-up. Significant residual RVOT gradient was associated with the need of re-intervention. This was similar to the outcomes shown by others.[4,6,7] More importantly, the presence of PPM was associated with the need of re-intervention and was a better predictor than significant residual RVOT gradient in the final multivariable model. In our cohort, the size of the Melody Ensemble system and eccentricity index did not predict the need of re-intervention. We think that pre-Melody RVOT rehabilitation with angioplasty and/or pre-stenting would be more important to provide the satisfactory iGOA than the size selection of Ensemble system. Pre-Melody treated RVOT size would be a determining factor for the final Melody stent valve diameter in most cases, because the platinum iridium stent of the Melody valve does not have a strong radial force.

Why is the PPM important? Although iGOA and residual RVOT gradient correlate to each other, there is a fundamental difference between them. Post-TPVI residual RVOT gradient can be affected by multiple factors. This hemodynamic data is measured under general anesthesia and after the significant amount of contrast use at the TPVI. The RVOT gradient can be considerably different at the awake condition next day. Furthermore, dysfunctional right

Table 3
Univariable and Multivariable cox proportional hazard regression analysis to evaluate the predictors of the need of re-intervention in (A) all the cohort (A) and (B) the selected cohort aged ≥ 16 years. All the significant factors identified in the univariable analysis was included in the multivariable analysis

(A) All the cohort (n = 101)

	Univariable analysis		Multivariable analysis	
Predictors	Hazard ratio (95% CI)	p value	Hazard ratio (95% CI)	p value
patient-prosthesis mismatch	2.78 (1.17-6.64)	0.021	2.67 (1.17-6.4)	0.027
Significant residual right ventricle outflow tract gradient	2.70 (1.17-6.25)	0.020		
Age < 16 years	1.69 (0.73-3.92)	0.220		
Homograft	3.00 (1.21-7.40)	0.017	2.85 (1.12-7.15)	0.022
Pre-stenting	1.79 (0.77-4.18)	0.180		

(B) Selected Cohort aged ≥ 16 years (n = 63)

	Univariable analysis		Multivariable analysis	
Predictors	Hazard ratio (95% CI)	p value	Hazard ratio (95% CI)	p value
patient-prosthesis mismatch	6.39 (1.40-29.2)	0.017	6.39 (1.40-29.2)	0.017
Significant residual right ventricle outflow tract gradient	3.52 (1.01-11.7)	0.040		
Homograft	1.77 (0.57-5.53)	0.328		
Pre-stenting	1.34 (0.40-4.52)	0.642		

Table 4
Clinical guide for the Melody valve stent diameter to avoid the patient prosthesis mismatch based on the body surface area (BSA) and eccentricity index, using the cut-off value of the indexed geometric orifice area (GOA) of 1.25 cm^2/m^2

			Eccentricity index									
			1.0	1.05		1.1		1.15		1.20	
iGOA (cm^2/m^2)	BSA (m2)	GOA (cm^2)	Stent diameter a = b (mm)	Major axis a (mm)	Minor Axis b (mm)	Major Axis a (mm)	Minor axis b (mm)	Major Axis a (mm)	Minor axis b (mm)	Major Axis a (mm)	Minor axis b (mm)
1.25	0.8	1	11.3	11.6	11.0	11.8	10.8	12.1	10.5	12.4	10.3
	1.0	1.25	12.6	12.9	12.3	13.2	12.0	13.5	11.8	13.8	11.5
	1.2	1.5	13.8	14.2	13.5	14.5	13.2	14.8	12.9	15.1	12.6
	1.4	1.75	14.9	15.3	14.6	15.7	14.2	16.0	13.9	16.4	13.6
	1.6	2	16.0	16.4	15.6	16.7	15.2	17.1	14.9	17.5	14.6
	1.8	2.25	18.4	17.3	16.5	17.8	16.1	18.2	15.8	18.5	15.5
	2.0	2.5	18.9	18.3	17.4	18.7	17.0	19.1	16.6	19.5	16.3
	2.2	2.75	19.3	19.2	18.3	19.6	17.8	20.1	17.4	20.5	17.1
	2.4	3	19.6	20.0	19.1	20.5	18.6	21.0	18.2	21.4	17.8
	2.6	3.25	20.3	20.8	19.9	21.3	19.4	21.8	19.0	22.3	18.6
	2.8	3.5	21.1	21.6	20.6	22.1	20.1	22.6	19.7	23.1	19.3

The narrowest diameters of the Melody valve stent are measured in two projections and the major (A) and minor (B) axis of the orifice area is derived. The GOA was calculated with the ellipse formula: $GOA = \pi^*(a/2)^*(b/2)$. The GOA was indexed to the BSA to derive iGOA (cm2/m2). Eccentricity index was defined as a ratio of a and b: eccentricity index = a/b.

ventricle may not generate systolic force to increase a RVOT gradient immediately after the TPVI. These factors may lead to over- and under-estimation of residual RVOT gradient. In contrast, iGOA would not be affected by these factors at all. This measurement is simply dependent of the valve stent orifice area and body size. In our study, subgroup analysis was performed to eliminate the effect of somatic growth. The significance of PPM was the same in the selected cohort.

To optimize the outcomes of TPVI, pre-procedural patient selection is important to avoid the development of the PPM. Considering the body size, original RVOT size, and the degree of calcification and stenosis of RVOT on cross-sectional imaging, operators may think of achievable rehabilitated RVOT diameter, which can be referred to the clinical guide (Table 4). Our study was limited by a retrospective design and a sample size conducted at a single center. The valve stent shape is three dimensional and the narrowest stent valve diameter is possibly at different positions between antero-posterior and lateral projections. The better method to measure GOA would be the smallest area measurement of valve stent orifice on the CT scan. However, those data were not available in our cohort. The Sapien valve cases were not included in our cohort, because of its smaller patient volume, shorter follow up period, size difference between the Melody and Sapien valve delivery system and unknown difference in transvalvar hemodynamics.

In conclusion, patient prosthesis mismatch was a strong predictor for the need of re-intervention in the TPVI. Considering PPM, target diameter of valve stent would depend on the patient body size and should be taken into account for optimal outcome of TPVI.

Funding

None

Compliance with ethical standard

The authors declare that they have no conflict of interest. This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The Human Investigation Committee (IRB) of Wayne State University approved this study.

Authors' statement

Dr. Takajo, Dr. Forbes, and Dr. Kobayashi conceptualized and designed the study, designed the data collected instruments, collected data, drafted the initial manuscript, and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Disclosures

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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