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ORIGINAL ARTICLE

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Comparison of valvar and right ventricular function following transcatheter and surgical pulmonary valve replacement

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Abstract

Objective: Trans-catheter (TC) pulmonary valve replacement (PVR) has become common practice for patients with right ventricular outflow tract obstruction (RVOTO) and/or pulmonic insufficiency (PI). Our aim was to compare PVR and right ventricular (RV) function of patients who received TC vs surgical PVR.

Design: Retrospective review of echocardiograms obtained at three time points: before, immediately after PVR, and most recent.

Patients: Sixty-two patients (median age 19 years, median follow-up 25 months) following TC (N = 32) or surgical (N = 30) PVR at Yale-New Haven Hospital were included.

Outcome Measures: Pulmonary valve and right ventricular function before, immediately after, and most recently after PVR.

Results: At baseline, the TC group had predominant RVOTO (74% vs 10%, $P < .001$), and moderate-severe PI was less common (61% vs 100%, $P < .001$). Immediate post-procedural PVR function was good throughout. At last follow-up, the TC group had preserved valve function, but the surgical group did not (moderate RVOTO: 6% vs 41%, $P < .001$; >mild PI: 0% vs 24%, $P = .003$). Patients younger than 17 years at surgical PVR had the highest risk of developing PVR dysfunction, while PVR function in follow-up was similar in adults. Looking at RV size and function, both groups had a decline in RV size following PVR. However, while RV function remained stable in the TC group, there was a transient postoperative decline in the surgical group.

Conclusions: TC PVR in patients age <17 years is associated with better PVR function in follow-up compared to surgical valves. There was a transient decline in RV function following surgical but not TC PVR. TC PVR should therefore be the first choice in children who are considered for PVR, whenever possible.

KEYWORDS
echocardiography, melody valve, pulmonary valve replacement, right ventricular function, surgical, transcatheter

Abbreviations: ANOVA, analysis of variance; CPB, cardiopulmonary bypass; EF, ejection fraction; MRI, magnetic resonance imaging; PI, pulmonic insufficiency; PS, pulmonary valve stenosis; PVR, pulmonary valve replacement; ROC, receiver operating characteristics; RVOTO, right ventricular outflow tract obstruction; S, surgical; TAPSE, tricuspid annular plane systolic excursion; TC, transcatheter; TDI, tissue Doppler imaging; TOF, tetralogy of Fallot.

1 | INTRODUCTION

Chronic pulmonary insufficiency (PI) and/or right ventricular outflow tract obstruction (RVOTO) are common among patients with congenital heart disease. They often lead to progressive right ventricular (RV) dilation and dysfunction, and sometimes associated left ventricular diastolic and systolic dysfunction. These are well-known risk factors for arrhythmias, sudden death, and heart failure.[1–4] Thus, adequate timing of pulmonary valve replacement (PVR) is critical to prevent such complications. Prior to approval of the first trans-catheter (TC) PVR Melody valve (Medtronic Inc., Minneapolis, Minnesota) by the United States Food and Drug Administration (FDA) in 2010, many of these patients required repeated surgical PVR throughout a lifetime, with an associated increasing risk of perioperative complications. Over the past 7 years, TC PVR has become common practice for patients with RVOTO and/or PI as a less invasive alternative to traditional surgical PVR. The Melody valve, as the first FDA approved TC PVR, has been studied most extensively. It has been shown to be safe and effective with excellent short- and intermediate-term outcomes.[5–8] Some cardiologists therefore advocate for an earlier PVR when using a TC valve compared to surgical PVR.[9]

To date, there is little data comparing outcomes in patients who receive TC vs surgical PVR. The aim of this study was to compare PVR and RV function of patients who received TC Melody valves to those who underwent surgical PVR before, shortly following PVR, and at the time of last follow-up.

2 | METHODS

This is a retrospective cohort study of congenital heart disease patients who underwent Melody valve (group TC) or surgical (group S) PVR at Yale New Haven Children's hospital between January 2011 and June 2014.

Exclusion criteria were lack of follow-up echocardiogram >180 days following PVR. We recorded patients' original cardiac anatomy, prior surgeries, and clinical characteristics such as age, age at valve replacement, and body surface area. Right ventricular outflow tract (RVOT) physiology prior to PVR was categorized as follows: (1) at least moderate RVOTO, at most mild PI, (2) moderate or severe PI, at most mild RVOTO, (3) at least moderate RVOTO and moderate or severe PI. Echocardiograms from three different time points (last study prior to PVR, first study after PVR, and last available follow-up) were analyzed (see 2.1).

PVR dysfunction as the primary outcome was defined as the presence of at least moderate graft PS and/or PI.

2.1 | Echocardiograms

Echocardiograms were performed by experienced pediatric echocardiographers according to the pediatric guidelines of the American Society of Echocardiography.[10] Philips iE33 (Philips Medical Systems, Andover, Massachusetts), and Siemens Sequoia SC2000 (Siemens Medical Solutions USA, Mountain View, California) were used, and probe frequency was selected according to patient size. Measurements were performed offline (Lumedx, Oakland, California) and averaged over three cardiac cycles. All measurements were performed by at least one of three investigators (WL, HP, CW).

RVOTO was graded according to the American Society of Echocardiography (ASE) guidelines for pulmonic stenosis (maximum instantaneous gradient <36 mm Hg for mild, 36–64 mm Hg for moderate, >64 mm Hg for severe stenosis).[11] Pulmonary insufficiency was graded as none/trivial, mild, moderate/severe. Severity of tricuspid regurgitation (TR), and estimated right ventricular systolic pressure based on TR jet velocity were documented as well.

Parameters characterizing right heart structure (right atrial major and minor dimensions, right atrial end-systolic area, right ventricular dimension at the base and mid-ventricular level, RV end-diastolic and end-systolic areas, RVOT dimensions proximal and distal, RV wall thickness) and function (tricuspid annular plane systolic excursion [TAPSE], pulse-wave tissue Doppler [TDI] derived peak systolic [S′], early [E′], and late [A′] diastolic velocities at the lateral tricuspid valve annulus, and fractional area change) were determined according to the American Society of Echocardiography (ASE) guidelines.[12]

2.2 | Statistics

Continuous variables are expressed as median (range), categorical ones as numbers (percent). Unadjusted between-group comparisons of continuous variables were done using analysis of variance (ANOVA) and Wilcoxon rank-sum test for normal and nonnormal distributions, respectively. Chi-square test or Fisher's exact test were used as appropriate to compare categorical variables between groups. Receiver operating characteristics (ROC) curves were created. Multiple logistic regression modeling was used to determine risk factors for developing PVR dysfunction. For analysis of right heart size and function, we used mixed effects linear regression approach to control for effects of preoperative RVOT physiology (PS, PI, or mixed PS/PI), age at procedure and BSA, as well as the subject effect (using a random intercept). The set significance level was $P < .05$. Statistical analysis was performed using Statistical Package for Social Sciences, version 21 (IBM SPSS, Chicago, Illinois).

3 | RESULTS

3.1 | Baseline clinical characteristics

We identified 76 patients who had undergone surgical or TC PVR between January 2011 and June 2014. Fourteen patients were excluded because the follow-up period was <180 days (4 surgical, 10 TC). The cohort had a median age of 19.2 (range 4.7–63.1) years and was divided into group TC (n = 32) and group S (surgical PVR; n = 30). There was no significant difference between groups in age, gender, body surface area, or length of follow-up (Table 1). In the TC group, the most frequent underlying cardiac diagnoses were tetralogy of Fallot (TOF) with or without pulmonary atresia (24/32 [75%]), and the most common prior interventions were bioprosthetic valve or homograft (23/32 [72%]) although 8 (25%) patients had a TC valve placed following a transannular patch. In the surgical group S, TOF spectrum (16/30 [53%]), valvar pulmonic stenosis or atresia (13/30 [43%]) were the

TABLE 1 Baseline characteristics for patients who underwent transcatheter (TC) Melody versus surgical pulmonary valve replacement (PVR)

	Transcatheter PVR (n = 32)	Surgical PVR (n = 30)	*P*
Age at PVR, years	22.1 (4.7–55.3)	16.5 (5.1–63.1)	.160
BSA (m2)	1.8 (0.7–2.1)	1.5 (0.7–2.2)	.173
Female (%)	14 (45%)	14 (48%)	1
Diagnosis			.001
TOF	15 (47%)	15 (50%)	
TOF/pulmonary atresia	9 (28%)	1 (3%)	
DORV, dTGA, TAC	3 (9%)	1 (3%)	
Aortic valve disease	4 (13%)	0 (0%)	
Pulmonary valve stenosis or atresia	0 (0%)	13 (43%)	
Prior RVOT surgeries			<.001
Homograft	11 (34%)	0 (0%)	
Bioprosthetic valve	12 (38%)	1 (3%)	
Transannular patch	8 (25%)	23 (77%)	
Rev or valvectomy	1 (3%)	5 (17%)	
Balloon angioplasty	0 (0%)	1 (3%)	
Indication for PVR			<.001
RVOTO	10 (31%)	0 (0%)	
PI	9 (28%)	27 (90%)	
Combined RVOTO/PI	13 (41%)	3 (10%)	
Time since PVR at last follow-up (days)	745 (212–1397)	697 (222–1482)	.618

Data are presented as median (range) or number (percent) as appropriate.
Abbreviations: DORV, double outlet right ventricle; dTGA, D-transposition of the great arteries; PI, pulmonary valve insufficiency; PVR, pulmonary valve replacement; RVOTO, right ventricular outflow tract obstruction; TAC, truncus arteriosus communis; TOF, tetralogy of Fallot.

most common underlying lesions, and transannular patch the most frequent prior surgery (23/30 [77%]).

The RVOT physiology at baseline differed between the two groups as well, in that the majority of group S had PI without significant RVOT obstruction, while the picture was rather mixed in group TC (Tables 1 and 2).

3.2 | Right ventricular outflow tract physiology

At the initial postprocedural echocardiogram group, TC had a slightly higher peak gradient across the RVOT, but there was no significant PI in either group (Table 2). At most recent follow-up, however, group TC had stable valve function without significant insufficiency or stenosis

TABLE 2 Echocardiographic characteristics of right ventricular outflow tract (RVOT) physiology and estimated right ventricular pressure at three different time points: (1) before transcatheter Melody or surgical pulmonary valve replacement (pre PVR), (2) at the time of the first postprocedural echocardiogram (post PVR), and at most recent follow-up (last follow-up)

	Transcatheter PVR (n = 32)				Surgical PVR (n = 30)			
	Pre PVR	Post PVR	Last follow-up	*P* (time)	Pre PVR	Post PVR	Last follow-up	*P* (time)
Moderate-severe RVOT obstruction [n(%)]	23 (74%)**	7 (22%)	2 (6%)**	<.001	3 (10%)	3 (10%)	12 (41%)	<.001
Max. gradient [mmHg]	52 (26)	27 (12)*	22 (9)**	<.001	20 (17)	22 (8)	33 (11)	<.001
Moderate-severe pulmonary insufficiency [n(%)]	22 (69%)**	0 (0%)	0 (0%)**	<.001	30 (100%)	0 (0%)	7 (24%)	<.001
Moderate-severe RVOT obstruction and/or pulmonary insufficiency	32 (100%)	7 (22%)	3 (9%)**	<.001	30 (100%)	3 (10%)	16 (53%)	<.001
RVOT antegrade diastolic flow [n(%)]	13 (42%)	3 (10%)	0 (0%)*	<.001	15 (52%)	0 (0%)	4 (14%)	<.001
TR degree > mild [n(%)]	6 (21%)	4 (13%)	0 (0%)	.031	5 (17%)	3 (10%)	2 (7%)	.444
TRJG [mmHg]	49 (25)**	39 (19)	31 (9)	.004	30 (14)	31 (12)	35 (10)	.364

Data are presented as mean (standard deviation) or number (%) as appropriate. Comparisons between groups: $^{*}P < .05$, $^{**}P < .01$. *P* (time): within group time effect.
Abbreviations: PVR, pulmonary valve replacement; TR, tricuspid regurgitation; TRJG, TR jet gradient.

TABLE 3 Function of the transcatheter Melody vs surgical pulmonary valve by age (A: <17 years, B: ≥17 years of age at time of PVR)

A: Age <17 years			
	Transcatheter PVR (n = 10)	Surgical PVR (n = 17)	*P*
Follow-up (days)	755 (391)	956 (360)	.187
At least moderate PS	1 (10%)	11 (65%)	.007
At least moderate PI	0 (0%)	8 (47%)	.011
PVR dysfunction (PS and/or PI)	1 (10%)	14 (82%)	<.001
B: Age ≥17 years			
	Transcatheter PVR (n = 22)	Surgical PVR (n = 13)	*P*
Follow-up (days)	836 (343)	570 (235)	.011
At least moderate PS	2 (9%)	2 (15%)	.478
At least moderate PI	0 (0%)	0 (0%)	N/A
PVR dysfunction (PS and/or PI)	2 (9%)	2 (15%)	.478

Abbreviations: PI, pulmonary valve insufficiency; PS, pulmonary valve stenosis; PVR, pulmonary valve replacement. Data are presented as mean (standard deviation) or number (%) as appropriate.

(2/32 [6%] with moderate stenosis). By contrast, patients in group S commonly had significant RVOT obstruction (12/30 [41%]) and/or PI (7/30 [24%]; Table 2). Three patients in group S received subsequent TC PVR between 18.2 and 46.4 months following surgical PVR. All of those patients were < 17 years old at the time of PVR.

3.3 | Effect of age at PVR on surgical PVR dysfunction

There was a strong effect of age at surgical PVR on the occurrence of significant PVR dysfunction (area under the curve (AUC) 0.86 [95% confidence interval 0.72-0.99, $P = .001$]). Age <17 years had an 81% sensitivity and 79% specificity for having valve dysfunction in follow-up. In a multiple logistic regression model, only age at intervention <17 years ($P = .02$; adjusted OR 14.8, 95% CI 1.6–139), but not length of follow-up ($P = .79$) or type of surgical valve placed ($P = .60$) were associated with surgical PVR dysfunction.

3.4 | Groups TC vs S - age effect on PVR function

For patients <17 years of age at the time of PVR, the TC group had significantly better valve function in follow-up compared to group S (Table 3). For patients age 17 or more, there was no significant difference between groups TC and S. In a multiple logistic regression model, length of follow-up was not significantly associated with higher risk for valve dysfunction in either group.

3.5 | Right heart structure and function

Lastly, we evaluated the effect of TC vs S PVR on right heart size and function (Table 4). Both groups had a significant decrease in right atrial and RV size following PVR, whereas RVOT dimensions and RV free wall thickness showed no significant change. RV systolic function assessed by quantitative echocardiographic measures remained stable following TC PVR. However, in group S there was a significant decline in RV function immediately following PVR (Table 4) that only partially recovered at the time of last follow-up.

4 | DISCUSSION

This is the first published study on patients with TC vs surgical PVR that compares both PVR and right heart function in follow-up. We demonstrate strikingly better valve function of TC Melody valves vs bioprosthetic surgical valves in children and adolescents <17 years of age at the time of intervention. Patients age 17 years or older had comparable valve function in follow-up. Further, the transient decline in RV function after surgical PVR is not seen following TC PVR.

4.1 | Indications for PVR

Timing of PVR in pediatric patients continues to be controversial given the associated added risk of additional cardiac surgical procedures in a life time. Prior studies have suggested that an aggressive approach to PVR (end diastolic volume <150 ml/m^2) leads to normalization of RV volumes, and improvement in biventricular function, and submaximal exercise capacity.[13] The authors showed that normalization of ventilatory response to carbon dioxide production, a parameter that has been shown to predict outcome in TOF, is most likely to occur when surgery is performed below age <17.5 years.[13,14]

4.2 | Data on surgical PVR

Data on surgical PVR durability, however, varies widely from 50% to 96% at 10 years.[15–17] A large study of 505 patients pediatric and young adult patients has shown that homografts may be superior to xenografts with a mean time to reoperation of 16 compared to 10.3 years.[18] The effect of age on PVR longevity has also been analyzed by several groups, suggesting that younger age at PVR predicts shorter graft longevity.[19–22] Earlier PVR dysfunction appears particularly noticeable in children <13–18 years of age.[17,20,21] These reports are

TABLE 4 Echocardiographic characteristics of right heart size and function in the transcatheter vs surgical PVR groups at three different time points: (1) before transcatheter Melody or surgical pulmonary valve replacement, (2) at the time of the first postprocedural echocardiogram, and at most recent follow-up

	Transcatheter PVR (n = 32)				Surgical PVR (n = 30)			
Time point:	Pre PVR	Post PVR	Last follow-up	*P* (time)	Pre PVR	Post PVR	Last follow-up	*P* (time)
Right atrial structure								
Major dimension (cm)	4.7 (0.1)	5.3 (0.7)	4.4 (0.2)	13**	5.1 (0.2)	5.1 (1.3)	4.8 (0.2)	13**
Minor dimension (cm)	4.3 (0.1)	4.1 (0.2)	3.9 (0.1)	12* 13**	4.6 (0.2)	4.5 (0.2)	4.3 (0.2)	13**
Area in end-systole (cm²)	18.4 (1)*	17.5 (1)	15.9 (1)	13* 23*	22.4 (1.4)*	18.9 (1.4)	10 (1.4)	12** 13**
Right ventricular structure								
Basal dimension (cm)	4.4 (0.2)**	4.2 (0.2)	4.2 (0.2)	NS	5.2 (0.2)**	4.4 (0.2)	4.2 (0.2)	12** 13**
Mid-ventricular dimension (cm)	3.7 (0.1)*	3.3 (0.1)	3.2 (0.1)	12** 13**	4.3 (0.2)*	3.3 (0.2)	3.2 (0.2)	12** 13**
End-diastolic area (cm²)	30.1 (1.6)*	26.1 (1.6)	26.6 (1.4)	12** 13**	37 (2.3)*	26.4 (2.3)	24.7 (2.1)	12** 13**
End-systolic area (cm²)	16.7 (1.1)	14.8 (1)	14.9 (1.0)	NS	19.6 (1.4)	16.5 (1.4)	14.2 (1.4)	12** 23* 13**
RVOT proximal (cm)	2.4 (0.1)	2.3 (0.1)	2.2 (0.1)*	NS	2.6 (0.2)	2.5 (0.1)	2.7 (0.1)	NS
RVOT distal (cm)	2.1 (0.1)*	2.2 (0.1)	2.1 (0.1)	NS	2.4 (0.1)*	2.3 (0.1)	2.3 (0.1)	NS
Free wall thickness (mm)	5.5 (0.2)	5.5 (0.2)	5.1 (0.2)	23*	5.5 (0.3)	5.6 (0.3)	5.4 (0.3)	NS
Right ventricular function								
RV fractional area change (%)	43.6 (2.2)	42 (1.9)	44.5 (2.3)	NS	48.4 (2.9)	39.3 (2.7)	44.2 (3)	12** 23*
TAPSE (cm)	1.5 (0.1)	1.5 (0.1)*	1.5 (0.1)	NS	1.7 (0.1)	1.2 (0.1)*	1.4 (0.1)	12** 23* 13**
TDI RV S' (cm/s)	7.4 (0.5)**	8 (0.4)	7.1 (0.3)	23*	9.3 (0.6)**	7.4 (0.6)	7.1 (0.5)	12** 13**

Data are derived from a mixed linear model correcting for PVR indication (PS, PI, or PS/PI), BSA, and age at intervention. Data are presented as estimate (standard error). Comparisons between groups: $^{*}P < .05$, $^{**}P < .01$. *P* (time): within group time effect between time points 1, 2, and 3. Abbreviations: PVR, pulmonary valve replacement; TAPSE, tricuspid annular plane systolic excursion; TDI, RV S'; velocity of the tricuspid annular systolic motion; RVOT, right ventricular outflow tract.

consistent with our data on surgical PVR showing that children <17 years of age at the time of PVR were at high risk for early valve dysfunction. Due to the rapid valve degeneration in some of our young patients with surgical PVR, we believe that somatic growth alone cannot explain this phenomenon. We speculate that other, for example, immunologic factors may play a role.[23,24] Whatever the cause of early valve degeneration in children and adolescents is, we have to acknowledge that there is a fine balance between preserving RV function and limiting the number of surgeries in a lifetime.

4.3 | Data on TC PVR

Over the last decade TC PVR has been used increasingly. It has been shown in a single center study of 51 patients (including 26 younger than 16 years of age) that younger age at the time of TC PVR is associated with incremental improvements in RV size, function and maximum oxygen consumption.[9] Procedural and mid-term results with up to seven years follow-up have been excellent.[8,9,25] As experience with TC PVR is growing, some centers—including ours—have been successfully been placing TC PVR in native outflow tracts as well.[26] TC TPV replacement can also be performed in children <30 kg with good procedural and early hemodynamic results in the majority of patients.[27] In small children (≤15 kg) who are not suitable for a TC approach, the Melody valve has been placed via the perventricular route with good mid-term results (personal experience).

Given the previously published positive effect of younger age at the time of TC PVR on RV size, function and maximum oxygen consumption[9] and our data showing that TC PVR longevity is excellent and comparable to adult patients, we suggest that TC PVR should in fact be considered first choice in children and adolescents, including select patients with at "native" RVOT or a transannular patch.

4.4 | Right heart remodeling following PVR

Right atrial and right ventricular size decreased in both groups following PVR. However, there was a differential effect on quantitative parameters of RV systolic function—while function was preserved in group TC, there was a transient decline in group S that only partially recovered in follow-up. This effect is likely related to cardiopulmonary bypass (CPB) as a decline in longitudinal right ventricular function has been described previously.[28] While our findings should be validated in a larger cohort and validated by MRI, they are further evidence supporting TC PVR when feasible.

4.5 | Limitations

This study's main limitation is that it is a retrospective observational echocardiography based study without concomitant MRI imaging. As the duration of follow-up is limited, we plan to revisit the data in a few years to assess long-term results.

4.6 | Conclusion

We conclude that TC Melody valve placement in patients <17 years of age is associated with better pulmonary valve function in mid-term follow-up when compared to surgical PVR. In adult patients, however, there was a low incidence of PVR dysfunction in both groups. The transient decline in RV function seen following surgical PVR was not observed following TC PVR. We propose that TC Melody PVR should therefore be the first choice for children and adolescents who are considered for PVR. This should include patients who have undergone a transannular patch or who have a "native" outflow if their RVOT is considered favorable on a preprocedural MRI.

CONFLICT OF INTEREST

WE Hellenbrand is proctor for Medtronic. IRB approval at Yale University: #1207010587; date of first approval 7/27/2012.

AUTHOR CONTRIBUTIONS

Concept/Design: Weismann
Data collection: Li, Pollard, Weismann
Data analysis/interpretation: Weismann, Northrup, Li, Pollard
Drafting article: Weismann, Li
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