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Branch Pulmonary Artery Valve Implantation Reduces Pulmonary Regurgitation and Improves Right Ventricular Size/Function in Patients With Large Right Ventricular Outflow Tracts

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ABSTRACT

OBJECTIVES The authors sought to assess the intermediate-term effects of percutaneous placed valves in the branch pulmonary artery (PA) position.

BACKGROUND Most patients with large right ventricular outflow tracts (RVOTs) are excluded from available percutaneous pulmonary valve options. In some of these patients, percutaneous branch PA valve implantation may be feasible. The longer-term effects of valves in the branch PA position is unknown.

METHODS Retrospective data were collected on patients with significant pulmonary regurgitation who had a percutaneous branch PA valve attempted.

RESULTS Percutaneous branch PA valve implantation was attempted in 34 patients (18 bilateral and 16 unilateral). One-half of the patients were in New York Heart Association (NHYA) functional class III or IV pre-implantation. There were 2 failed attempts and 6 procedural complications. At follow-up, only 1 patient had more than mild valvar regurgitation. The right ventricular end-diastolic volume index decreased from 147 (range: 103 to 478) ml/m^2 to 101 (range: 76 to 429) ml/m^2, $p < 0.01$ ($n = 16$), and the right ventricular end-systolic volume index decreased from 88.5 (range: 41 to 387) ml/m^2 to 55.5 (range: 40.2 to 347) ml/m^2, $p < 0.01$ ($n = 13$). There were 5 late deaths. At a median follow-up of 2 years, all other patients were in NYHA functional class I or II.

CONCLUSIONS Percutaneous branch PA valve implantation results in a reduction in right ventricular volume with clinical benefit in the intermediate term. Until percutaneous valve technology for large RVOTs is refined and more widely available, branch PA valve implantation remains an option for select patients. (J Am Coll Cardiol Intv 2018;11:541–50)

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ABBREVIATIONS AND ACRONYMS

LV = left ventricle/ventricular

MRI = magnetic resonance imaging

NYHA = New York Heart Association

PA = pulmonary artery

PR = pulmonary regurgitation

RV = right ventricle/ventricular

RVEDVIx = right ventricular end-diastolic volume index

RVESVIx = right ventricular end-systolic volume index

RVOT = right ventricular outflow tract

The advent of percutaneous pulmonary valve technology using the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, Minnesota) and the Edwards Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, California) has changed the therapeutic landscape for many patients with dysfunctional right ventricular outflow tracts (RVOT). Subsequent to early studies (1), the Melody valve was Food and Drug Administration approved (2–4) for implantation in dysfunctional right ventricle (RV) to pulmonary artery (PA) conduits and stented bioprosthetic valves on delivery systems that provide an outer diameter up to ~24 mm. The Edwards Sapien transcatheter heart valve, initially designed for transcatheter aortic valve replacement, can be implanted in the pulmonary position using valve sizes of 23, 26, and 29 mm (5).

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Unfortunately, these indications exclude the vast majority of post-operative patients with a dysfunctional RVOT, particularly those with a "native" or patch-augmented RVOT anatomy (6). In the absence of an RV-PA conduit or bioprosthetic valve, pulmonary regurgitation (PR) tends to be the predominant lesion, and chronic PR results in dilation and distortion of the RVOT. In most patients with this anatomy, the RVOT is too large to allow for implantation of existing balloon-expandable devices (Melody and Sapien) in the orthotopic position. Self-expanding devices such as the Harmony Valve (Medtronic) and the Venus-P valve (Venus Medtech, Hangzhou, China), which are designed to anchor within the dilated RVOT, though promising, are still in early development (7–11). In the absence of a device specifically intended for implantation into the dilated RVOT/main PA, several investigators have reported off-label implantation of commercially available balloon-expandable valves into the branch PAs as a nonsurgical alternative in high-risk patients (12–16). This technique has been shown to reduce PR in the short term (13–16), but the longer-term physiological consequences of this unique circulation have not been reported. Specifically, in the presence of a "nonvalved" RVOT/main PA segment (proximal to the branch PA valves), the effect on RV size and function in the longer term remains unknown.

The purpose of this multicenter study was to assess the technical feasibility of percutaneous branch PA valve implantation, the intermediate term function of these valves, and their impact on RV remodeling and functional status of these patients.

METHODS

PATIENTS AND PROCEDURAL TECHNIQUE. Patients who underwent attempted percutaneous implantation of a Melody or Sapien valve into a branch PA from January 2007 to May 2016 were solicited from 13 centers (10 in the United States and 3 in Europe). Institutional review board approval was obtained according to requirements at each center. Patients were included if an attempt was made to place a transcatheter valve into a branch PA unilaterally or bilaterally due to an RVOT that was deemed too large for percutaneous implantation. Patients undergoing unilateral valve implantation attempts were only included if there was no blood flow to the contralateral lung. Patients with a functionally single-lung circulation who had a percutaneous valve intended to be implanted in the RVOT were excluded, because the aim was to assess the physiological and clinical implications of a valve specifically implanted into a branch PA. Procedural implantation techniques were variable, but in general, they were similar to methods for implanting a Melody or Sapien valve in a RV-PA conduit in the cardiac catheterization laboratory. Pre-stenting of the branch PAs and choice of valve to be implanted was at the operators' discretion.

BASELINE AND FOLLOW-UP DATA. Patient demographics, New York Heart Association (NYHA) functional class, anatomic diagnosis, comorbidities,

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and indication for implantation of a valve in a branch PA were obtained. Noninvasive data were obtained from echocardiograms and cardiac magnetic resonance imaging (MRI) scans before the procedure and at the time of the most recent follow-up evaluation. Post-implantation RV volumes were measured in the same fashion as when measured following transcatheter or surgical pulmonary valve replacement in the usual position (i.e., the nonvalved RVOT/main PA segment was not included in measurements). Follow-up clinical data, development of stent fractures, and any catheter-based or surgical reinterventions were noted.

STATISTICAL ANALYSIS. Continuous variables were presented as mean ± SD or median (minimum to maximum). Differences between pre- and post-implantation measures were compared using paired Student *t* test or Wilcoxon signed-rank test. SAS version 9.4 (SAS Institute, Cary, North Carolina) was used for all statistical analyses.

RESULTS

BASELINE AND PROCEDURAL CHARACTERISTICS. A total of 34 patients who underwent attempted percutaneous branch PA valve implantation were ascertained, as detailed in Table 1. Eighteen of these patients underwent attempted bilateral branch PA valve implantation (Figure 1) and 16 underwent attempted unilateral PA implantation (Figure 2). Patients with unilateral implantations had no flow to the contralateral PA as a result of an acquired atresia/absent proximal PA (n = 13), pulmonary vein occlusion (n = 2), and a single lung (n = 1). All but 1 of the patients who received bilateral valves had the same type of valve in each branch PA. One patient received a Melody valve and a Sapien valve due to differential PA size. The median age at catheterization was 26 (12.6 to 58.0) years, and the median weight was 74 (26 to 147) kg. Almost all patients (94%) had an underlying diagnosis of tetralogy of Fallot with pulmonary stenosis or atresia. One-half of the patients were in NYHA functional class III or IV (Table 1) before the procedure. The indication for the procedure was significant PR with significant RV dilation and/or clinical symptoms in all patients. Twenty-one (62%) patients were deemed to be more than standard risk surgical candidates for pulmonary valve replacement at the respective institutions where the implantations occurred based on comorbidities (Table 2). Baseline noninvasive imaging and catheterization are summarized in Table 1.

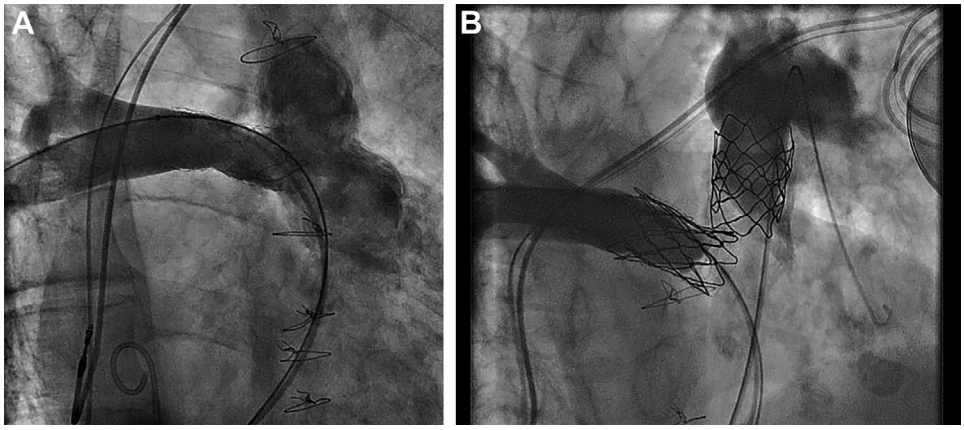
TABLE 1 Demographic, Baseline Testing, and Procedural Data (N = 34)

	(n)	Median (Min, Max)
Age, yrs	34	26.2 (12.6, 58.0)
Weight, kg	33	74.0 (26.0, 147)
Branch PA valve attempt (pts)		
Bilateral branch PA	18 (53)	
Unilateral branch PA	16 (47)	
Diagnosis		
ToF, PA/VSD	32 (94)	
Truncus arteriosus	1 (3)	
PA sarcoma (post-surgery)	1 (3)	
High-risk surgery candidate	21 (62)	
NYHA functional class	34	
I	1 (3)	
II	16 (47)	
III	9 (26)	
IV	8 (24)	
Echocardiography	34 (100)	
Severe PR	34 (100)	
RV size		
Severe dilation	23 (68)	
Moderate dilation	7 (21)	
Mild dilation	3 (9)	
Normal size	1 (3)	
Cardiac MRI		
RVEDVIx, ml/m^2	28	149 (103, 478)
RVESVIx, ml/m^2	22	90.5 (41, 387)
RVEF, %	26	41 (18, 63)
LVEF, %	25	54 (37, 65)
PR fraction, %	26	47 (25, 66)
Cardiac catheterization		
Cardiac index, (ml/min/m^2)	21	2.4 (1.5, 4.4)
RV pressure, mm Hg	34	50.5 (20, 110)
Ao pressure, mm Hg	34	98 (75, 127)
RVOT gradient, mm Hg	34	0 (0, 20)
PA stenosis (valve implantations, n = 52)	15 (29)	
Pre-stent (valve implantations, n = 52)	47 (90)	
Success (patients)	32 (94)	
Success (valve implantations, n = 52)	50 (96)	
Valve implantation diameter, n = 50		
18-mm Melody valve	6 (12)	
20-mm Melody valve	7 (14)	
22-mm Melody valve	21 (42)	
24-mm Melody valve	10 (20)	
26-mm Sapien valve	3 (6)	
29-mm Sapien valve	3 (6)	

Ao = aorta; LVEF = left ventricular ejection fraction; MRI = magnetic resonance imaging; NYHA = New York Heart Association; PA = pulmonary artery; PA/VSD = pulmonary atresia/ventricular septal defect; PR = pulmonary regurgitation; RV = right ventricle; RVEDVIx = right ventricular end-diastolic volume index; RVEF = right ventricular ejection fraction; RVESVIx = right ventricular end-systolic volume index; RVOT = right ventricular outflow tract; ToF = tetralogy of Fallot.

SHORT-TERM PROCEDURAL OUTCOMES. The procedure was successful in 32 (94%) patients, with 50 of 52 attempted valve implantations performed successfully. Stenosis was present in 15 (29%) of the branch PAs. Pre-stenting was performed before 47 (90%) valve implantation attempts, and the balloon

FIGURE 1 Bilateral Percutaneous Branch PA Implantation

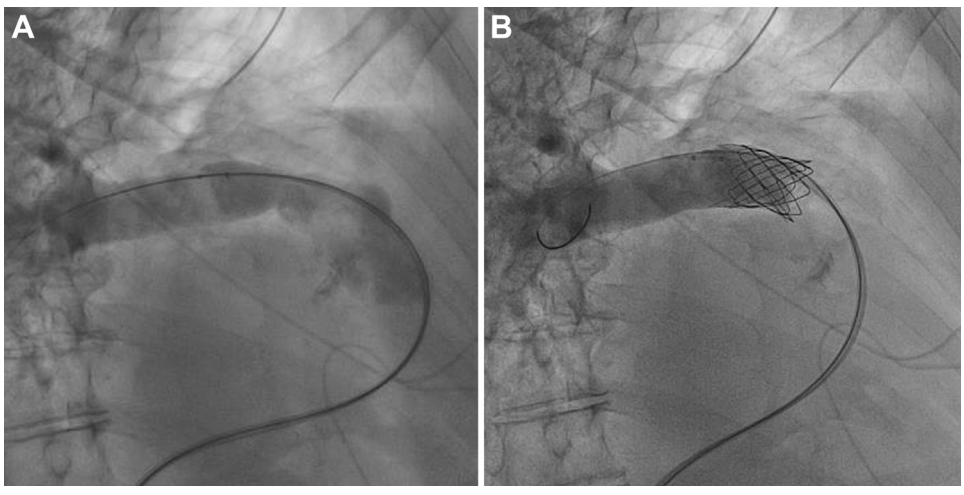


This 57-year-old patient with repaired tetralogy of Fallot had a history of ventricular tachycardia and was in New York Heart Association functional class III. **(A)** An angiogram in the right pulmonary artery (PA) showed severe PR and stenosis of the right PA. **(B)** After placement of a Melody valve in both branch PAs simultaneous angiograms demonstrated no significant regurgitation from either valve.

size for valve implantation ranged from 18 to 29 mm (Table 1). No patient had jailing of a lobar PA branch.

There were 2 unsuccessful implantation attempts. In 1 patient who underwent attempted bilateral Melody valve implantation through jugular venous access, the distal end of the delivery system could not be advanced sufficiently beyond a previously placed left PA stent. The valve was unsheathed and the inner balloon inflated in an effort to advance the delivery system far enough to allow deployment of the valve. These maneuvers were unsuccessful, and the delivery system and uncovered valve were withdrawn

FIGURE 2 Unilateral Percutaneous Branch PA Implantation



(A) This pulmonary artery (PA) angiogram in a right anterior oblique projection in a patient with repaired tetralogy of Fallot and left PA atresia demonstrates mild stenosis at the origin of the right PA with severe PR. **(B)** Following stent placement, a Melody valve was implanted in the proximal right PA. The follow-up angiogram demonstrates a competent valve.

TABLE 2 Reasons for Being Considered More Than Standard Risk for Surgical Pulmonary Valve Replacement

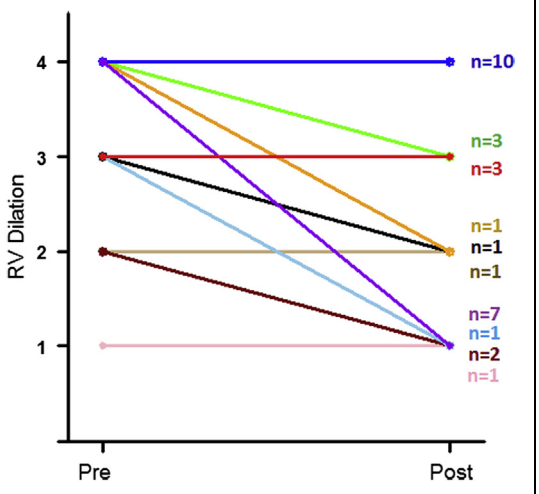
Comorbidities	(n = 21)
Scoliosis/morbid obesity	4
Pulmonary hypertension	3
Multiple prior complex cardiac operations	3
Renal failure	3
Severe left ventricular dysfunction	2
Renal/liver failure	1
Liver failure, obesity, restrictive lung disease	1
Portal hypertension	1
Intrathoracic radiation scar tissue	1
Diaphragm paralysis, restrictive lung disease	1
Pulmonary hypertension, bowel ischemia, tracheostomy	1

and implanted in the superior vena cava, then stented open with a bare-metal stent. The patient developed severe tricuspid regurgitation with evidence of new leaflet prolapse on transthoracic echocardiography, likely due to injury during withdrawal of a partially expanded valve. In another patient with chronic left pulmonary vein atresia and no blood flow to the left lung, a Sapien valve was placed in the right PA. During withdrawal of the delivery system, the valve migrated back to the main PA. Although the main PA was initially felt to be too large for safe deployment of a percutaneous valve, it was successfully secured in the main PA by overinflating the balloon. Both of these unsuccessful implantations were excluded from follow-up analysis.

There were a total of 6 (18% of patients) acute adverse events: catheter-related tricuspid valve injury and regurgitation (n = 1, described in the preceding text), wire-related lung perforation that required no treatment (n = 1), pulmonary embolism that resolved with anticoagulation (n = 1), dislodgement of an implantable cardioverter defibrillator lead that was subsequently replaced (n = 1), PA stent dislodgement that was stabilized with another stent (n = 1), and atrial flutter requiring cardioversion (n =1). There were no procedural deaths.

FOLLOW-UP. Two patients were lost to follow-up, and the 2 technically unsuccessful cases were excluded from follow-up analysis. In the remaining 30 patients, the median follow-up duration was 2 years (0.1 to 7.6 years). On the most recent follow-up echocardiogram, all but 1 patient had mild or less regurgitation through the implanted valves by echocardiography; 1 patient had moderate regurgitation through the valve (26-mm Sapien valve implantation) that was seen soon after the procedure and persisted for unclear reasons. The RV size decreased by echocardiography in 15 (50%) of the patients. Before the

FIGURE 3 RV Size by Transthoracic Echocardiography Pre- and Post-Percutaneous Branch PA Implantation

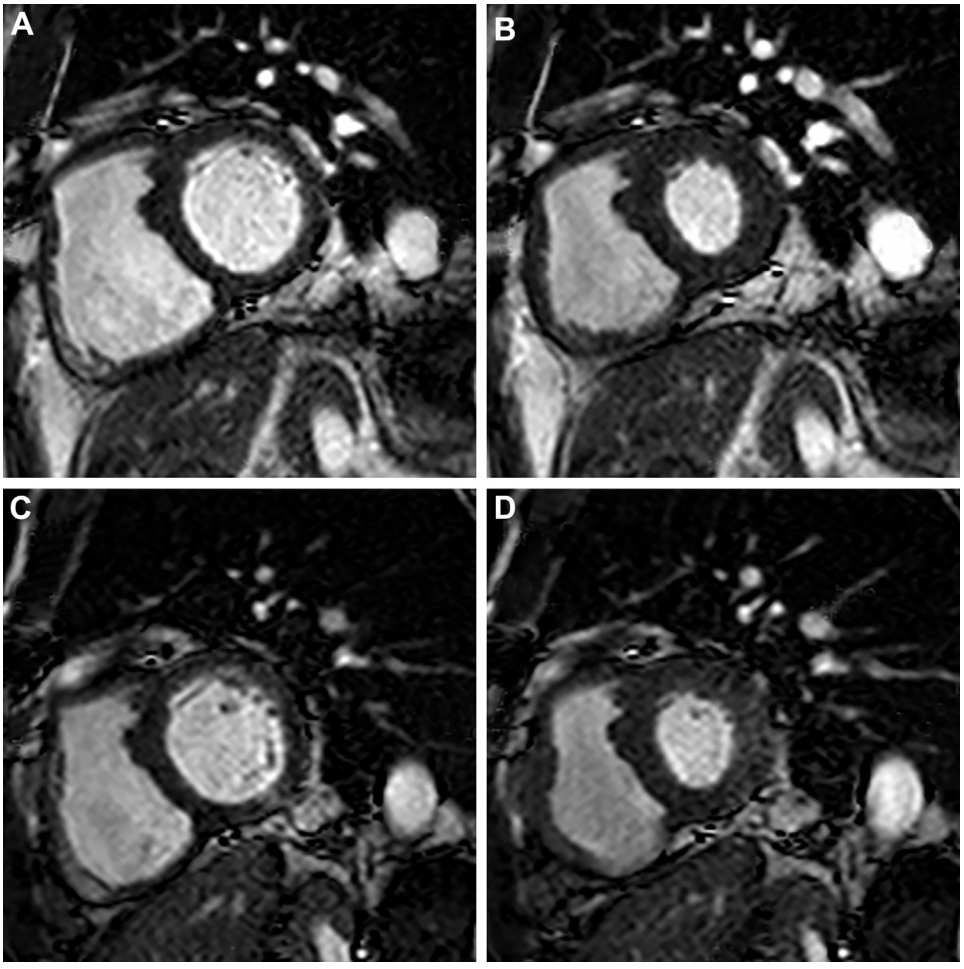


1 = normal size, 2 = mild dilation, 3 = moderate dilation, and 4 = severe dilation. PA = pulmonary artery; RV = right ventricle.

procedure, 21 patients had severe RV dilation by echocardiography, and after the procedure, 10 patients had severe RV dilation. Only 1 patient had a normal-sized RV before the procedure, and 11 patients had normal-sized RVs after the procedure (Figure 3). Excluding the 5 patients who died (described later in the text), all patients were in NYHA functional class I or II at most recent follow-up (9 in class I and 16 in class II). There were no reinterventions and no stent fractures noted on chest radiographs. One valve (unilateral 22-mm Melody valve implantation) was surgically explanted secondary to endocarditis 6 years after implantation.

Five patients died as a consequence of their severe comorbid conditions, at a median of 2 years (21 days to 2 years) after the procedure. These 5 patients were all in NYHA functional class III or IV before the procedure with 3 undergoing unilateral and 2 undergoing bilateral branch PA valve implantation. A 17-year-old with pulmonary hypertension and scoliosis experienced a ventricular fibrillation arrest. The patient developed bowel ischemia and underwent a tracheostomy, ultimately dying 21 days after valve implantation as a result of sepsis. A 41-year-old with severe biventricular diastolic dysfunction, atrial and ventricular tachycardia, liver cirrhosis, renal insufficiency, and ascites died from constrictive pericarditis and fungal sepsis 50 days after valve implantation. A 33-year-old with morbid obesity, severe restrictive lung disease, obstructive sleep apnea, liver cirrhosis, and

FIGURE 4 RV Remodeling After Unilateral Percutaneous Branch PA Implantation

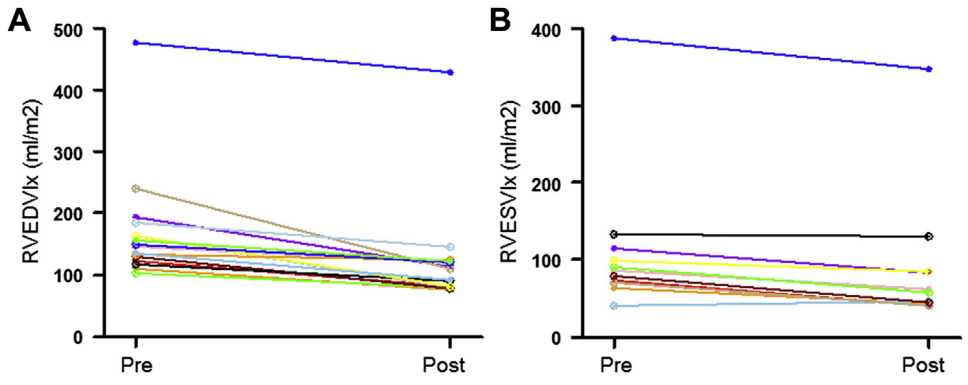


Cardiac MRI in a 58-year-old man with right PA occlusion (after surgical right PA reconstruction and RVOT augmentation) due to sarcoma shows an RVEDVIx of 110 ml/m^2 **(A)** and RVESVIx of 63 ml/m^2 **(B)**. His symptoms immediately improved after percutaneous branch PA valve implantation and a cardiac MRI 3 years later showed a decrease in the RVEDVIx and RVESVIx to 76 ml/m^2 **(C)** and 43 ml/m^2 **(D)**, respectively (Online Videos 1 and 2). RVEDVIx = RV end-diastolic volume index; RVESVIx = RV end-systolic volume index; RVOT = right ventricular outflow tract; other abbreviations as in **Figure 3**.

thrombocytopenia died 2 years after valve implantation from end-stage left ventricular (LV) heart failure. A 56-year-old with atrial arrhythmias, morbid obesity, obstructive sleep apnea, renal insufficiency, hypothyroidism, and type 2 diabetes died 2 years after valve implantation as a result of these comorbidities. Finally, a 55-year-old who had end-stage LV failure who was not a suitable candidate for heart transplantation died 2 years after valve implantation.

MRI DATA. Paired MRI data (**Figure 4**, Online Videos 1 and 2) were available for RV end-diastolic volume index (RVEDVIx) in 16 patients (unilateral implantation 10, bilateral implantation 6) and for RV end-systolic volume index (RVESVIx) in 13 (unilateral 8, bilateral 5) patients at a median of 12.6 (4.0 to 91.1) months post-implantation. Both RV end-diastolic and end-systolic volume indices decreased significantly, and were lower after implantation than before in all patients (RVEDVIx decreasing from 147 [range: 103 to 478] ml/m^2 to 101 [range: 76 to 429] ml/m^2, [$p < 0.001$]; and RVESVIx decreasing from 88.5 [range: 41 to 387] ml/m^2 to 55.5 [range: 40.2 to 347] ml/m^2, [$p < 0.001$]) (**Figure 5**). RV and LV ejection fractions increased (paired data available in 12 and 11 patients, respectively), though not significantly.

FIGURE 5 Change in RVEDVIx and RVESVIx



(A) Change in RVEDVIx from pre and post-percutaneous branch PA implantation (n = 16). **(B)** Change in RVESVIx from pre- and post-percutaneous branch PA implantation (n = 13). Abbreviations as in Figures 1 and 4.

DISCUSSION

This multicenter cohort of high-risk patients who underwent percutaneous branch PA valve implantation provides important insights into the clinical and physiological outcomes of this procedure. We found that, not only did the valves function well in the intermediate term, but the procedure resulted in clinical improvement and positive remodeling of the RV in most patients, similar to what one would expect to see had valves been implanted within the RVOT. There were few major procedural adverse events, and the vast majority of cases resulted in successful implantations of percutaneous branch PA valves.

It is noteworthy that most of the patients in this series were very ill, with one-half of them in NYHA functional class III or IV before the procedure. This is in sharp contrast to patients who underwent percutaneous valve implantation in the orthotopic position in most published large series, where the majority of patients were in NYHA functional class I or II before valve implantation (2,4). In our cohort, individual operators favored the technique of percutaneous implantation of a branch PA valve over surgical pulmonary valve placement in the majority of patients, due to the higher than usual risks surgical pulmonary valve replacement would have entailed in these patients. Despite technical success, 5 patients ultimately died due to their significant comorbidities.

Although it may be intuitive that implantation of percutaneous branch PA valves will lead to remodeling of the RV, this procedure results in unique anatomic and physiological implications that are of unclear significance. Robb et al. (15) previously reported early outcome data in a sheep study. They found that there was a net regurgitant fraction of only 4% at the main PA in the valve group, and significant improvement in RV function and volumes, as well as left ventricular ejection fraction. Although important physiological findings were noted in that study, the follow-up interval was short (6 weeks), and thus longer-term effects of the "nonvalved," or ventricularized RVOT and main PA segment could not be assessed.

In our cohort, no lobar branches were covered by any valve, and we were able to assess the downstream physiological consequences of the nonvalved RVOT/main PA. Although we showed positive remodeling of the RV by echocardiographic and MRI parameters, it is not clear whether the same degree and same rate of RV remodeling would have occurred had a valve been placed in the RVOT instead. In addition, we were not able to assess the ability of this nonvalved segment to remodel. Nevertheless, there seems to be positive remodeling of the RV in these patients, to a similar degree and over similar time frames, to what has been reported when percutaneous valves have been implanted in the RVOT (2,17), suggesting that in the intermediate term at least, the contribution from this nonvalved segment to the PR fraction seems inconsequential. One may consider the nonvalved RVOT/main PA segment as a capacitor that stores blood and charges during systole, then discharges back into the RV during diastole. It is unlikely that this segment would simply dilate over time because the RV pressure stays low and is reduced if PA stenosis is treated. Longer-term studies on this same cohort of patients and other patients

may be able to address whether some mild degree of RV volume load continues to exist and whether RV remodeling is substantially different from patients who had valves implanted in the RVOT (due to an ongoing trivial amount of regurgitation from the nonvalved RVOT/main PA). It is also noteworthy that the lack of significant improvement in RVEF was similar to findings in most surgical and transcatheter valve studies in patients with predominant PR (2,17–21).

There are certain technical considerations for percutaneous branch PA valve implantation that merit discussion. Two patients had unsuccessful attempts at branch PA implantation. In 1 patient, the delivery system could not be advanced to the intended area of implantation due to angulation in the left PA. Difficulties in advancing delivery systems are not an uncommon aspect of percutaneous pulmonary valve implantation. However, typically, the delivery system only has to be advanced far enough to allow implantation in the RVOT and only a small segment, if any, of the delivery system must be negotiated across the potential difficult angles in the branch PAs. In the other patient (without branch PA narrowing), a 26-mm Sapien valve was implanted in the right PA, but migrated back during withdrawal of the sheath. The potential risk of malposition in this setting is important to consider, because in the absence of stenosis, stent or valve migration can occur due to the elastic and highly variable sizes of the branch PAs in the cardiac cycle, particularly in the presence of significant PR. Negotiating withdrawal of the delivery system through the curvature from the RVOT to the right PA may have also played a role. Branch PA diameters were favorable to implantation percutaneous valves in our cohort, including stenosis in some cases, but in other patients with significant PR, the branch PAs may be too large to facilitate this technique.

Pre-stenting was performed in almost all patients in this cohort, and there were no cases of stent fracture or valve reintervention. Data from the US IDE Melody valve experience (3,22) showed that valves implanted after pre-stenting are less susceptible to fractures and thus valve dysfunction. PA stents in situ are also known to fracture in response to fatigue, dynamic forces across the cardiac cycle, proximity to the aorta, and kinking/flexion of the PA branches (23,24). In addition to decreasing the risk of fracture of the valve platform and consequent valve dysfunction, pre-stenting treats an area of stenosis that may be present and provides a safe "landing zone" and angiographic marker for percutaneous branch PA valve implantation. Moreover, the operator can, in effect, test the feasibility of percutaneous valve implantation—if the pre-stent cannot be delivered easily, the same is likely to hold for the valve. Although all valves in this series were implanted at the same procedure, if stability of the stent (and thus valve to be implanted) is in question, an option with unproven benefit is to stage the procedure, implanting the valve several months after the pre-stent, allowing for stent endothelialization and presumably stabilization. Whether stent placement before percutaneous branch PA valve implantation imparts protection against stent factures and helps preserve valve function, as it does with percutaneous pulmonary valve placement into the RVOT, will be determined with further longitudinal follow-up.

Percutaneous pulmonary valve placement can be performed in the native RVOT using existing valve technology if the dimensions of the RVOT are favorable (25–27). In addition, a number of alternative strategies have been reported to implantation percutaneous pulmonary valves in patients with a large RVOT, including PA jailing techniques and hybrid procedures, which have their own inherent drawbacks (28–32). Self-expanding valve systems designed for the large native or patched RVOT, such as the Harmony valve and the Venus P-valve (7–11), are in clinical trials, but require strict criteria for implantation with regard to RVOT morphology and size (still have size constraints), and it is likely that a number of patients will not be ideal candidates. It will also require time before such native RVOT valves are more widely available, and it is also unknown how they will behave in terms of aortic root distortion, paravalvular leaks, and coronary artery compression. For these various reasons, percutaneous branch PA valve implantation may continue to be an option for select patients in the future.

STUDY LIMITATIONS. Due to the retrospective design, some data were missing, follow-up was not uniform, and cardiac MRI data were not available in all patients. There was insufficient information to comment on the remodeling of the main PA and RVOT segment. Some data obtained were subjective, for example, some echocardiographic data and reporting of stent fractures by chest radiographs. Objective markers of clinical status, for example, brain natriuretic peptide levels or 6-min walk test data, were not available. We did not aim to compare this procedure with alternative percutaneous techniques or surgery, because our primary goal was to assess technical feasibility and clinical and physiological implications of the procedure. Finally, this report does not aim to recommend this technique as an alternative to other

percutaneous techniques that can be performed to replace a pulmonary valve or to surgical pulmonary valve replacement. We recommend that this technique be considered in selected high-risk patients in whom alternative treatments to replace the pulmonary valve either via a percutaneous technique or surgically are felt to incur higher than usual risks due to clinical status or comorbidities.

CONCLUSIONS

Percutaneous branch PA valve implantation can be achieved with acute success in most patients, and positive RV remodeling and clinical improvement in the intermediate term. The long-term effects of this technique with regard to valve function and persistent RV remodeling need to be determined from longitudinal studies. Until percutaneous valve technology for the large RVOT is refined and becomes more widely available, percutaneous branch PA valve implantation is an acceptable treatment for selected patients.

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PERSPECTIVES

WHAT IS KNOWN? In many patients with repaired tetralogy of Fallot and severe PR, the RVOT is not suitable for existing percutaneous valves. Case reports have described percutaneous implantation of branch PA valves as an alternative to surgery in patients with a large RVOT. There is minimal published information about longer-term outcomes after this procedure.

WHAT IS NEW? Bilateral branch PA valve implantation leads to favorable remodeling of the RV in the intermediate term and provides clinical benefit.

WHAT IS NEXT? It will be important to follow these patients and other patients who undergo this procedure to determine whether the long-term benefits of RV remodeling persist.

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APPENDIX For supplemental videos, please see the online version of this paper.