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ORIGINAL STUDIES

Implantation of the Melody transcatheter pulmonary valve PB1016 in patients with dysfunctional right ventricular outflow tract conduits

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Abstract

Objectives: This study describes procedural and 1-year outcomes of the 16 mm Melody PB1016 valve in patients with dysfunctional RVOT conduits.

Background: The Melody PB1016 is a standard Melody valve produced from a 16 mm bovine jugular vein and is intended for deployment up to 20 mm.

Methods: This is a prospective, non-randomized, multicenter study of the procedural and short-term outcomes of Melody PB1016 TPV replacement within dysfunctional RVOT conduits. Data from eight centers were included in the analysis.

Results: During the study period, 39 patients underwent attempted Melody TPVR. Of the 39 patients, 30 underwent successful Melody TPVR. The majority of patients underwent placement of one or more stents prior to TPVR. There was a significant reduction in peak conduit pressure gradient following TPVR (38 mmHg vs. 11 mmHg, $P < 0.001$). There were three cases of confined conduit tears successfully treated with covered stents or the valve itself. Repeat catheterization was performed in one patient for early re-obstruction that was successfully treated with balloon valvuloplasty. At recent follow-up, there were no cases of more than mild valve regurgitation and the mean pulmonary valve gradient by echocardiogram remained reduced relative to pre-TPVR implant measurements (33.5 mmHg vs. 15.2 mmHg). There were no cases of valve stent fracture or endocarditis reported at the 1-year follow-up.

Conclusions: Our analysis of TPVR with the PB1016 valve in RVOT conduits showed it to be safe and effective and can be performed in a wide range of conduit sizes with preserved valve function.

ClinicalTrials.gov Identifier: NCT02347189.

KEYWORDS

adult congenital heart disease, congenital heart disease, transcatheter pulmonary valve

1 | INTRODUCTION

In patients with congenital anomalies of the right ventricular outflow tract (RVOT) such as tetralogy of Fallot or truncus arteriosus, surgical reconstruction of the RVOT with bioprosthetic conduits or valves is frequently necessary. Over time, the deterioration of these bioprosthetic valves results in RVOT obstruction and regurgitation. The long-term effects of these hemodynamic derangements on RV dilation, function, risk for arrhythmias and sudden death have been well documented.[1–3] Traditionally, multiple surgical revisions were required to replace failing valves.[4] The first transcatheter pulmonary valve replacement (TPVR) was reported by Bonhoeffer et al.[5] Based on that experience, the Melody transcatheter pulmonary valve (Medtronic, Minneapolis, MN) received the CE Mark in 2006 and was

approved by the U.S. Food and Drug Administration (FDA) in 2010 for patients with obstructed or regurgitant RVOT conduits. Follow-up data from the U.S. IDE trial and numerous other trials since that time have demonstrated substantial improvements in RVOT gradient, conduit regurgitation, and RV pressure following valve implantation.[6–10]

The original Melody TPV is constructed from an 18 mm bovine jugular vein and is approved for expansion up to 22 mm. To complement the original valve design, an additional Melody TPV was developed utilizing a 16 mm bovine jugular vein (number PB1016) mounted within a platinum-iridium stent and is approved for expansion up to 20 mm using the available Ensemble delivery system (Medtronic, Minneapolis, MN). The nominal length of the PB1016 valve is slightly longer than that of the PB1018 valve (30 mm vs. 28 mm). The Melody PB1016 valve was approved for use by the FDA in 2014 with the same indications as the original Melody TPV. This study evaluated the safety and effectiveness of the PB1016 valve platform.

2 | MATERIALS AND METHODS

2.1 | Patient selection

This is a prospective, non-randomized, multicenter study of the safety and effectiveness of the Melody PB1016 valve in dysfunctional RVOT conduits conducted across eight centers in the United States, Canada and Europe (Supporting Information Table 1). Patients were eligible for inclusion in the study if they met the indications for use (IFU) for the Melody PB1016 valve at the time of enrollment and provided written, informed consent for participation in the study and completion of follow-up requirements. The IFU for the Melody PB1016 are the same as those for the original Melody valve. Use of the PB1016 valve was determined prior to the catheterization based on nominal conduit size and measured conduit size on preprocedural imaging. There were no specific conduit size recommendations in the inclusion criteria beyond what are contained in the original IFU. At the discretion of the operator during the case, the larger PB1018 valve was used if it were felt to be the appropriate size based on the angiographic assessment and balloon sizing of the conduit. Exclusion criteria included: valve implantation intended for other positions outside of the pulmonary position, venous anatomy unable to accommodate a 22-Fr introducer sheath, signs of active infection including active endocarditis, a history of intravenous substance abuse or participation in an investigational drug or device study that would impede the ability of the patient to fulfill the study requirements.

2.2 | Catheterization and valve implantation

The technique for Melody TPVR has been described.[7] Patients who met criteria for TPVR underwent catheterization with hemodynamic and angiographic evaluation of the RVOT conduit and coronary compression assessment. Prestenting of the conduit prior to valve implantation was performed at the discretion of the operator. The risk for coronary artery compression was routinely assessed either with aortic root angiography or with dynamic coronary compression testing as described.[11]

2.3 | Outcome measures

Procedural success was defined as valve implantation in the desired location, peak to peak RVOT gradient following TPVR of <35 mmHg, no more than trace angiographic TPV regurgitation and freedom from valve explant at 24 hr postimplant. The primary outcome measure was acceptable valve function at 6-month follow-up, defined as: mean RVOT gradient ≤30 mmHg, less than moderate TPV regurgitation, and freedom from RVOT conduit reoperation or catheter re-intervention. Secondary outcome measures include acceptable hemodynamic function at 1 and 2 years, serious procedure-related and device-related adverse events, the development of TPV stent fractures or valve associated endocarditis, the need for catheter-based re-intervention or surgical TPV explant and all-cause mortality. The implanting physician characterized each adverse event as device or procedure related. Sponsor assessment of adverse event relationships was also done, with final determination left to the physician. While the study did not specifically define conduit disruption or injury, cases identified align with that defined in a previous report as confined (contrast extravasation >3 mm beyond the lumen but with no extension into the pericardial or pleural space) or unconfined (contrast extravasation into the pericardial or pleural space).[12] Stent fractures were characterized according to protocol definitions based on published guidelines: type 1, stent fracture with no loss of stent integrity; type 2, stent fracture with loss of stent integrity; type 3, stent fracture associated with embolization of stent fragments.[13] Results data described in this series include up to 1-year follow-up.

2.4 | Follow-up evaluation

Clinical assessments and transthoracic echocardiography were conducted at preimplant, discharge, 6-month and 1-year follow up. Chest radiography was conducted at discharge, at 6 months if the patient was symptomatic or had an increased mean RVOT gradient, and at 1 year follow-up.

2.5 | Statistical analysis

All patients taken to the catheterization laboratory to implant a Melody TPV in an RVOT conduit were included in the analysis. Continuous variables were expressed as median (minimum–maximum) or mean ± standard deviation and categorical variables were expressed as frequency (%). Pre- and post-intervention comparisons were performed using the paired *t*-test. Comparisons of categorical variables were performed using Fisher's exact test. A P value <0.05 was considered statistically significant. Statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, North Carolina). The study was approved by the Institutional Review Board at each participating center.

3 | RESULTS

3.1 | Patients

From 2014 to 2016, 39 patients were enrolled and underwent catheterization at a median age of 14 years (6–32 years) and weight of 53 kg (16.8–110 kg). Baseline demographics are depicted in Table 1. The most common diagnoses were tetralogy of Fallot and truncus arteriosus. Conduit stenosis and mixed stenosis and regurgitation were the most common indications for TPVR (43.6% and 46.2%, respectively). Homograft and biological valved conduits made up 95% (37/39 patients) of the cohort. A single patient underwent TPVR within a failed surgical bioprosthetic valve. This was recorded as a protocol deviation and the patient was followed and included in the final analysis. The median conduit diameter at the time of original surgical implantation was 18 mm (12–27 mm). Three patients had nominal conduit diameters less than 16 mm. Preprocedural echocardiographic data were available for all patients. The mean RVOT gradient was 32 mmHg and 62% of patients had moderate to severe conduit regurgitation (Table 2).

TABLE 1 Baseline demographics

	Enrolled patients (N = 39)
Age (years)	15.2 ± 6.3
	14.0 (6.0–32.0)
Male	25 (64.1%)
Weight (kg)	51.1 ± 20.7
	53.0 (16.8–110.0)
Original cardiac diagnosis	
Tetralogy of Fallot	16 (41.0%)
Truncus arteriosus	8 (20.5%)
Transposition of the great arteries	4 (10.3%)
Pulmonary atresia, intact ventricular septum	4 (10.3%)
Aortic valve disease (Ross)	3 (7.7%)
Double outlet right ventricle	3 (7.7%)
Other	1 (2.5%)
Original conduit size (mm)	18.0 (12.0–27.0)
RVOT conduit type	
Homograft	18 (46.2%)
Biological valved conduit	19 (48.7%)
Non-valved synthetic conduit	1 (2.6%)
Bioprosthesis[a]	1 (2.6%)
Duration of conduit placement (years)	9.9 ± 4.2
Previously placed conduit stent	
No	31 (79.5%)
Single stent	5 (12.8%)
Multiple stents	3 (7.7%)
Primary indication	
Stenosis	17 (43.6%)
Regurgitant	4 (10.3%)
Mixed	18 (46.2%)

Data are presented as mean ± SD, median (min–max) or frequency, n (%).
[a] There was one patient with a failed bioprosthesis in which a Melody PB1016 was implanted in the study. This was not per the on-label indications at the time and thus was reported as a protocol deviation of the eligibility criteria.

3.2 | Procedural details

TPVR was successful in 30 of the 39 (77%) patients enrolled in the study (Figure 1). Coronary artery compression (n = 3), unfavorable conduit dimensions (n = 2) and lack of hemodynamic indication (n = 2) were all reasons for not implanting a valve. At the discretion of the implanting physician, two additional patients underwent TPVR with the original 18 mm Melody TPV. In both patients, the operators felt the diameter of the landing zone for the valve was too large based on the initial angiographic assessment and elected to use the larger valve. There were no significant differences in baseline demographics, hemodynamics, or echocardiographic measurements between the patients who received a Melody PB1016 valve (n = 30) and those who did not (n = 9). The minimum angiographic conduit diameter at the time of catheterization was 11.6 ± 3 mm. Most patients demonstrated significant contraction of the conduit with an average minimum angiographic diameter:nominal conduit diameter ratio of 0.6 (0.3–1.2). Prestenting with single or multiple stents at the time of TPVR was performed in 73% (22/30) of cases (Table 3). Multiple stents were placed in 14 patients (47%) with four patients receiving three stents and two patients receiving four or more stents. Covered Cheatham Platinum stents (NuMed, Inc, Hopkinton, NY) were placed in four patients: two cases in response to an observed conduit tear following conduit angioplasty and in two cases with no evidence of conduit tear. Confined conduit tears were observed in three patients, two of which were sealed with covered stents (Figure 2). In the third case, the tear was covered with the valve itself. Of the eight patients who did not receive a prestent at the time of TPVR, three had undergone RVOT stenting at a prior procedure. Five patients did not undergo any stent implantation prior to TPVR. During conduit preparation for TPVR, most conduits were expanded to their original

TABLE 2 Preprocedural imaging data

	Enrolled patients (N = 39)
Echocardiography	
Mean RVOT gradient (mmHg)	32.4 ± 13.6
Maximum RVOT velocity (CW, m/s)	3.7 ± 0.9
Maximum TR velocity (CW, m/s)	3.7 ± 0.8
Pulmonary regurgitation by echocardiography	
None	5 (14.7%)
Trace	3 (8.8%)
Mild	5 (14.7%)
Moderate	6 (17.6%)
Severe	15 (44.1%)
Tricuspid regurgitation by echocardiography	
None	3 (7.9%)
Trace	15 (39.5%)
Mild	8 (21.1%)
Moderate	11 (28.9%)
Severe	1 (2.6%)

Data are presented as mean ± SD or frequency, n (%).

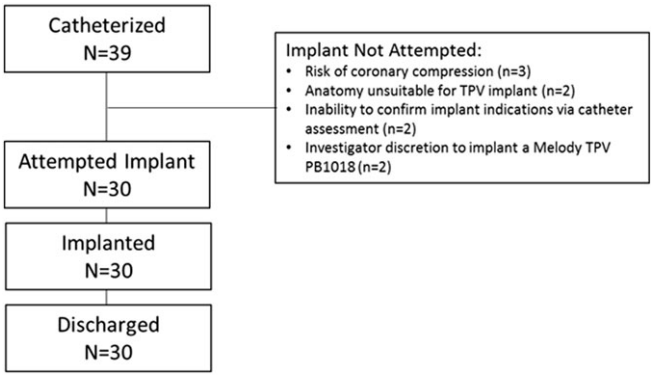

FIGURE 1 Flow diagram depicting the entire cohort. Valve implantation was not attempted as part of the study protocol in nine patients

diameter (predilation balloon diameter:nominal conduit diameter ratio: 0.9 [0.5–1.5]). However, all conduits were expanded beyond the initial angiographic diameter (predilation balloon diameter: angiographic diameter ratio: 1.4 [1.1–3.5]). The median size delivery system used was the 20 mm Ensemble delivery system. A 22 mm delivery system was used in one patient with a non-valved 18 mm Goretex conduit. At follow-up, no valve regurgitation was reported in this patient. Additional procedures were performed in 12 patients (40%), including branch pulmonary artery angioplasty and stent placement. Postdilation of the Melody valve following implant was performed in 20 patients (67%) with a median balloon diameter of 18 mm (14–20 mm).

3.3 | Acute outcomes

Appropriate valve position following deployment was confirmed in all 30 patients who underwent TPVR. There were no valve explants within 24 hr of implant. There was a significant reduction in peak conduit pressure gradient and RV to aortic pressure ratio acutely following TPVR (38 mmHg vs. 11 mmHg, $P < 0.001$; 0.75 vs. 0.47, $P < 0.001$, respectively, Table 4). A postimplant gradient >35 mmHg was reported in one patient and mild angiographic valve regurgitation was reported in three patients. At the discharge echocardiogram, no patient demonstrated more than trivial pulmonary valve insufficiency. The mean RVOT gradient by echocardiography was 17.7 ± 7.2 mmHg, down from 33.5 ± 11.7 mmHg prior to implant and the peak RVOT velocity was 2.8 ± 0.5 m/s, down from 3.8 ± 0.7 prior to implant. There was one patient with mild paravalvular leak that resolved spontaneously by the 6-month visit. Confirmed procedure-related adverse events were described in seven patients: confined conduit tears requiring placement of covered stent or valve (n = 3), early TPV obstruction requiring redilation 6 weeks following implant (n = 1), pulmonary edema requiring ICU admission (n = 1), access site bleeding (n = 1) and ventricular tachycardia requiring cardioversion (n = 1). Positive blood cultures were noted in one patient approximately 2 months following TPVR and were considered possibly related to the procedure. The patient was medically treated for the infection. Chest tube placement was required in one patient due to bleeding from a perventricular access site used during the case to perform serial pulmonary artery angioplasty. The patient received blood product replacement and the tube was removed the following day.

TABLE 3 Procedural data

	Implanted patients (N = 30)
Narrowest RVOT dimension by angiography (mm)	11.6 ± 3.0 12.0 (4.0–16.4)
Preimplantation stent placement[a]	22 (73.3%)
None	8 (26.7%)
Single	8 (26.7%)
Multiple	14 (46.7%)
Two stents	8 (26.7%)
Three stents	4 (13.3%)
Four or more stents	2 (6.7%)
Delivery system size	
18 mm	13 (43.3%)
20 mm	16 (53.3%)
22 mm	1 (3.3%)
Additional procedures performed[b]	12 (40.0%)
Balloon pulmonary artery angioplasty	3 (10.0%)
Pulmonary artery stent placement: peripheral	3 (10.0%)
Other	7 (23.3%)
Post-TPVR dilation performed	20 (66.7%)
Narrowest dimension (implant): original conduit size (baseline)	0.7 ± 0.2 0.6 (0.3–1.2)
Predilation balloon diameter used (implant): narrowest dimension (implant)	1.6 ± 0.5 1.4 (1.1–3.5)
Predilation balloon diameter used (implant): original conduit size (baseline)	0.9 ± 0.2 0.9 (0.5–1.5)
Postimplant dilation balloon diameter: narrowest dimension (implant)	1.7 ± 0.6, 1.5 (1.1–4.0)

Data are presented as mean ± SD, median (min–max), or frequency, n (%).
[a] Patients receiving a new prestent during the same catheterization as the Melody implant.
[b] A total of 13 concomitant procedures were performed in 12 patients. One patient had two concomitant procedures (branch PA balloon angioplasty and branch PA stent placement).

TPVR was attempted in three patients with nominal conduit diameters <16 mm. Implants were successful in all three cases. The median conduit size at time of surgical implant in those three patients was 12 mm (12–13 mm), compared with a median conduit size of 19 mm (16–24 mm) in the rest of the cohort. Although not statistically significant, the patients with nominal conduit diameters <16 mm were younger and smaller at the time of TPVR when compared to the rest of the cohort (9.7 ± 2.1 years vs. 15.7 ± 6.4 years, $P = 0.08$; 29.6 ± 8 kg vs. 53.8 ± 21.8 kg, $P = 0.071$). There were no significant differences in baseline demographics, hemodynamics, or echocardiographic measurements. All three patients with conduits <16 mm had undergone stent placement with one or more stents at a prior catheterization and two of the three patients underwent additional stent placement at the time of TPVR. The narrowest angiographic conduit diameter was similar to patients with larger conduits (11.4 ± 2.3

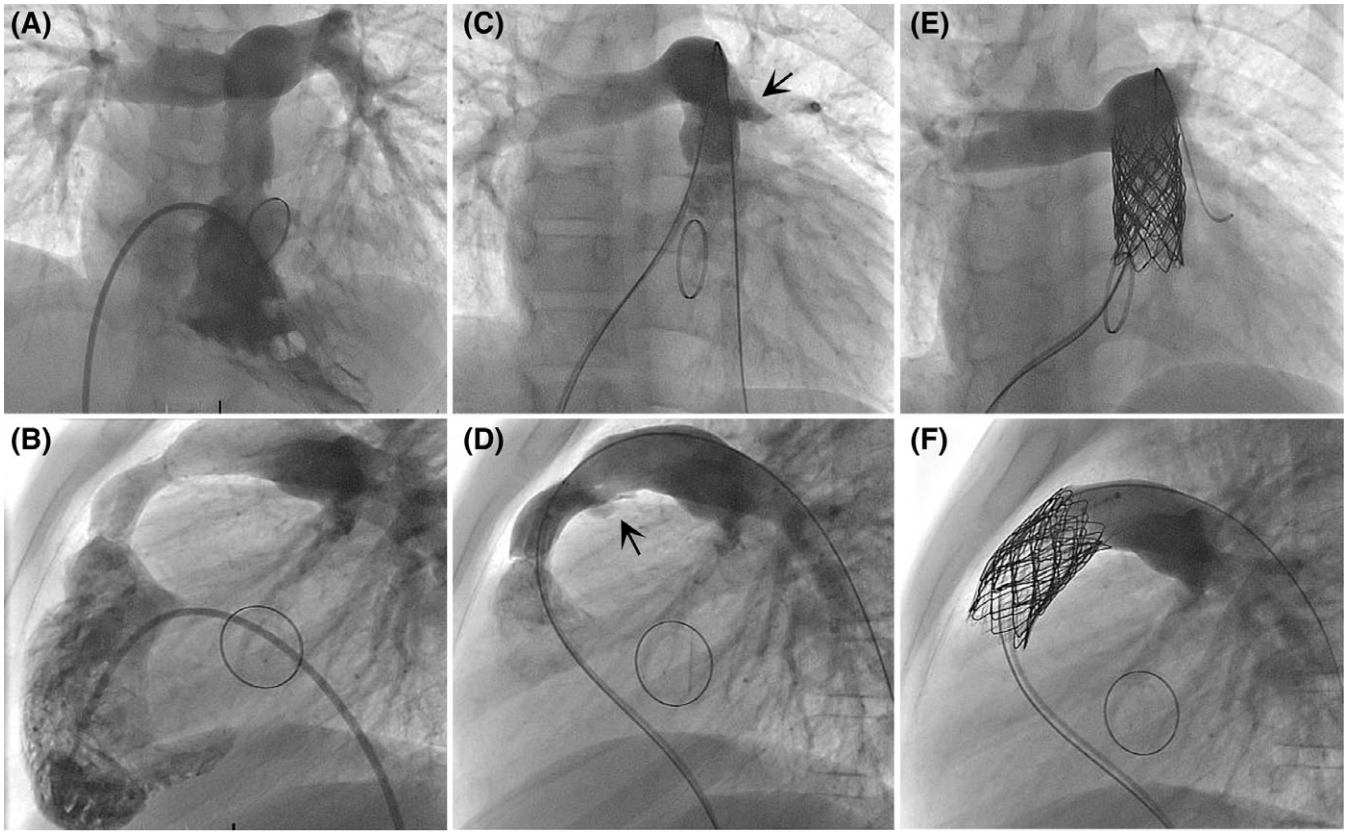

FIGURE 2 This is an 11-year-old boy who underwent Ross-Konno procedure in the setting of LV outflow tract obstruction following mechanical mitral valve replacement for severe mitral regurgitation. At that time, a 20 mm pulmonary homograft was placed in the RV to PA position. The peak RVOT gradient was 36 mmHg with an RV:Ao pressure ratio of 0.72. (A, B) initial AP and lateral projections demonstrate a minimum conduit diameter of 8.2 mm. (C, D) Following balloon angioplasty a confined conduit tear was observed (arrows). (E, F) The tear was contained with two covered Cheatham platinum stents and four additional P4010 bare metal stents. The stents were postdilated with an 18 mm atlas gold angioplasty balloon and the melody PB1016 valve was deployed on an 18 mm ensemble delivery system. The final conduit diameter was 17.6 mm with a peak RVOT gradient of 13 mmHg and an RV:Ao pressure ratio of 0.44

vs. 11.6 ± 3.1, $P = 0.772$). The predilation balloon diameter:nominal conduit diameter ratio was larger in the small conduit group (1.4 [1.2–1.5] vs. 0.9 [0.5–1.1], $P = 0.008$) suggesting more aggressive conduit preparation in the small conduits.

TABLE 4 Pre- and post-hemodynamics: implanted patients

	Pre-TPV(N = 30)	Post-TPV(N = 30)	*P* value
RV systolic pressure (mmHg): Apex or body	65.0 ± 23.7 (28)	40.4 ± 12.2 (28)	<0.001
RV systolic pressure (mmHg): sub-valvar	61.0 ± 18.8 (6)	36.0 ± 8.4 (6)	0.031
PA systolic pressure (mmHg)	28.3 ± 9.4 (28)	29.5 ± 9.0 (28)	0.175
Peak RVOT gradient (mmHg)	38.3 ± 22.6 (28)	11.4 ± 7.9 (28)	<0.001
Aortic pressure (mmHg): systolic	82.2 ± 10.2 (20)	90.0 ± 8.2 (20)	0.002
Aortic pressure (mmHg): diastolic	49.9 ± 9.7 (20)	52.8 ± 6.6 (20)	0.145
RV:AO pressure ratio	0.75 ± 0.14 (18)	0.47 ± 0.12 (18)	<0.001

Data are presented as mean ± SD (n). The Wilcoxon signed-rank test was used to evaluate the change in continuous paired data (preimplant to postimplant).

3.4 | Follow-up

Patients were seen at 6 and 12 months following TPVR. All patients were alive at follow-up. Complete data to evaluate valve function as prescribed by the study protocol were available for 25 patients. Of the 25 patients with complete data, 23 (92%) demonstrated adequate hemodynamic valve function based on the composite 1-year outcome measures. Of the two patients who did not meet the outcome criteria, one had undergone a repeat catheterization for valve dilation and one had a mean RVOT gradient >30 mmHg at the 1 year follow-up. The mean RVOT gradient and maximum RVOT velocity were significantly reduced compared to the precatheterization baseline measurements (15.2 ± 6.2 mmHg vs. 33.5 ± 11.7 mmHg, $P < 0.001$; 2.6 ± 0.5 m/s vs. 3.8 ± 0.7 m/s, $P < 0.001$, respectively). There were no patients with more than trivial pulmonary valve insufficiency and no evidence of paravalvular leak. There were no instances of stent fracture by fluoroscopy or chest X-ray and no reported cases of infective endocarditis.

4 | DISCUSSION

Outcomes for Melody TPV treatment of failing RVOT conduits or bioprosthetic valves have been well described.[6,8] The Melody PB1016

valve was developed as a complement to the original 18 mm valve and approved in 2014. This multicenter study was conducted to evaluate procedural success and short-term 1-year outcomes of the PB1016 valve in failing RVOT conduits.

TPVR success rates were similar to prior reports.[9,10,14] Stable valve position was achieved in all 30 patients who underwent attempted TPVR. There were significant reductions in RV pressure, RVOT gradient and RV to aortic pressure ratios. One patient had a persistently elevated RVOT gradient immediately following TPVR that improved on follow-up and required no further interventions. A second patient developed early exercise related symptoms and was found to have obstruction at the valve not related to infection or stent fracture and resolved with balloon valvuloplasty. Significant reductions in RVOT gradient by echocardiography were sustained through the 1 year follow-up period. No patient demonstrated more than trivial valve regurgitation and there were no cases of paravalvular leak.

There was significant contraction of the conduits as demonstrated by the minimum angiographic diameter:nominal conduit diameter ratio of 0.6 (0.3–1.2). This is similar to a recent cohort analysis of 313 Melody valve implants in which the angiographic diameter:nominal conduit diameter ratio was 0.63.[10] Despite this narrowing, most conduits were returned to their nominal size and, in some cases, expanded beyond their nominal size. Prestenting at the time of TPVR or at a prior procedure was performed in 25/30 patients (83%). In the original IDE study, only predilation with balloons <110%, the original conduit diameter was permitted.[7] In this study, the median ratio of predilation balloon diameter to original conduit diameter was 0.9 with some cases of expansion up to 150% of the original conduit diameter.

There are a growing number of studies of TPVR in smaller patients with smaller conduits and bioprosthetic valves. These studies have demonstrated the ability to expand small diameter conduits up to 18, 20 and even 22 mm with similar technical success rates and adverse event profiles to studies in larger patients.[15–17] In this current analysis, three patients with nominal conduit diameters <16 mm were successfully implanted and all were dilated to greater than 120% of the original conduit size and implanted with 18 mm or 20 mm delivery systems. If this practice continues to grow, it will be important to have a complementary valve option that functions well in smaller conduits and bioprosthetic valves. The use of the PB1016 or PB1018 valve will be at the discretion of the implanting physician but having the PB1016 valve offers an effective option for conduits or valves that cannot be safely expanded beyond 20 mm.

Confirmed procedural or device related adverse events occurred in seven patients. There were three cases (10%) of confined conduit tears, which were treated with covered stents or the valve itself. There were no cases of catastrophic or unconfined tears. The rate of conduit disruption in this study is similar to reported rates in other studies which have ranged from 6 to 22%.[12,18,19] At 6-month and 1-year follow-up, there were no reports of stent fracture or endocarditis.

4.1 | Limitations

The sample size for this study was small which limits to the ability to perform sub-analyses. The stated duration of follow-up out to 1 year limits the ability to perform time sensitive analysis on topics such as stent fracture and endocarditis which are known to occur beyond 1 year. This limits the ability to comment on risk for these outcomes with the PB1016 valve although it is likely these outcomes will be similar to other reports. The analysis of patients with small conduits (<16 mm) is largely descriptive as the number of patients in this subgroup is too small to power any significant comparisons.

5 | CONCLUSIONS

The Melody PB1016 valve can be safely and effectively implanted into patients with dysfunctional RVOT conduits with outcomes similar to prior studies of the original Melody PB1018 valve. This increases the availability of the Melody TPV across a broad range of patient ages and sizes. Longer follow-up is needed for this valve, specifically focusing on valve durability, risk of valve stent fracture and infective endocarditis. Additionally, more data are needed on the success and durability of TPVR in patients with smaller conduits.

CONFLICT OF INTEREST

Dr. Morray is a consultant for Medtronic. Dr. Jones receives research grant support and is a consultant for Medtronic. Dr. Coe is a proctor for Medtronic, and a consultant for NuMed, Inc. Dr. Gitter is a proctor for Medtronic. Dr. Zunzunegui Martinez is a proctor for Medtronic. Dr. Turner has no relationships to disclose. Dr. Gray has no relevant disclosures. Dr. Lung is an employee and shareholder of Medtronic. Dr. Berman is a consultant for Medtronic. Dr. Levi is a consultant for Medtronic.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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