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ORIGINAL ARTICLE

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# Leaflet morphology classification of the Melody Transcatheter Pulmonary Valve

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## Abstract

**Objective**: We sought to describe the leaflet morphology variation in the Melody Transcatheter Pulmonary Valve (TPV) and evaluate associated outcomes. The Melody TPV is constructed from harvested bovine jugular venous valves which have been rigorously tested. Natural anatomic leaflet variations are seen in the Melody TPV but have not been evaluated.

**Design**: A Melody TPV leaflet morphology classification system was devised after reviewing a subset of photographed and implanted TPVs. All images were blindly reviewed by implanters and classified. Midterm hemodynamic outcomes and complications of the Melody TPVs were compared by leaflet morphology.

**Results**: Photographed Melody TPVs implanted between 2011 and 2016 (n = 62) were categorized into the following leaflet morphology types: A—symmetric trileaflet (47%); B—asymmetric trileaflet with a single small leaflet (32%); C—asymmetric trileaflet with a single large leaflet (16%); D—rudimentary leaflet with near bicuspid appearance (5%). Acceptable hemodynamic function at 6 months postimplantation was seen in 97.5% of valves. Over a median follow-up of 1.5 years (range 0-4.4 years), two TPVs (Type A) had > mild regurgitation. Nine TPVs developed complications (endocarditis, 3; stent fracture, 2; refractory arrhythmia, 1; conduit replacement, 2; death, 1), of which 6 required reintervention. There was no significant difference in outcomes based on Melody TPV leaflet morphology type.

**Conclusions**: The Melody TPV can be classified into one of four categories based on leaflet morphology. Study outcomes were not associated with leaflet morphology. Further documentation and evaluation of Melody TPV morphology may lead to better understanding of this technology.

KEYWORDS
congenital catheterization, transcatheter valve implantation

## 1 | INTRODUCTION

The Melody Transcatheter Pulmonary Valve (TPV) (Medtronic, Dublin, Ireland) is designed to treat right ventricular outflow tract (RVOT) conduit dysfunction and was the first implanted transcatheter heart valve in 2000.[1] Since the United States Investigational Device Trial in 2007, the Melody TPV has been utilized in a variety of patients and anatomic locations. As of 2016, more than 10 000

  

Melody TPVs have been implanted in patients worldwide. Multiple studies have demonstrated the excellent function of implanted Melody TPVs.[2-5]

The Melody TPV is constructed from a harvested bovine jugular vein sutured within a platinum/iridium stent. The native bovine jugular venous valve contains naturally thin leaflets with deep commissures, which provide adequate coaptation over a wide range of implanted diameters and geometric configurations.[6] Early prototypes of the Melody TPV were initially described as either bicuspid or tricuspid.[7] Currently, all harvested valves must pass a rigorous testing process before being released for patient use. During this process, all true bicuspid valves are removed. Despite this, varying valve morphologies of the Melody TPVs have been noted but never systematically described. We sought to devise a Melody TPV morphology classification system and evaluate associated outcomes.

## 2 | METHODS

This single center retrospective study was performed to evaluate the Melody TPV morphologies. Study approval with waiver of written consent was granted by the Institutional Review Board. All patients in this study underwent Melody TPV implantation. The implantation technique for the pulmonary position has been previously described.[2] All patients received 24 hours of periprocedural prophylactic antibiotic therapy, and the procedure was performed with systemic anticoagulation. Our institution routinely captures intraprocedural Melody TPV images, consisting of both still photographs and videos during the rinsing process. Valves are imaged down-the-barrel to assess leaflet appearance.

All photographed or video recorded Melody TPVs were included in the evaluation of valve morphology. A random cohort of the Melody TPV images was reviewed to create a morphology classification system. All Melody TPV images were blindly reviewed and classified according to the classification system by the five implanters at our center. Melody TPVs were assigned to a classification based on the consensus of the coauthors (the same classification assigned by ≥3 implanters).

Melody TPVs implanted in a non-pulmonary position were excluded from the outcome analysis. Midterm outcomes were collected retrospectively. The primary outcome evaluated was acceptable hemodynamic function, as defined by the Melody Post-Approval Study[4] (mean RVOT gradient ≤ 30 mm Hg and ≤ mild regurgitation as measured by echocardiography) over the first 6 months following valve implantation. Given the known association of RVOT obstruction with factors unrelated to valve morphology such as high preimplantation gradient, lack of prestenting, and frame fracture,[5,8,9] Melody TPV regurgitation was assessed independently over the follow-up period. Secondary outcomes were the development of a Melody TPV complication: including endocarditis (either presumed or per the modified DUKE criteria[10,11]), stent fracture,[8] refractory arrhythmia, RVOT obstruction or regurgitation requiring Melody TPV replacement (surgical or transcatheter), and death. Outcomes were compared across valve morphologies.

Descriptive patient and procedural demographics are reported as appropriate. Categorical data are reported as number (%), and continuous variables are described as mean ± SD. Data were compared between pediatric and adult patient cohorts using the definition for adult patients as >18 years of age. Two sample *t* tests or Wilcoxon rank-sum tests were used to examine differences between the two age groups. To assess factors associated with outcomes, Fisher's exact tests and linear regression analysis were used. Freedom from events Kaplan-Meier curves were generated for both the entire study population and by valve morphology. Melody TPV implantation was the entry date, with the censor set as the date of event or last date of follow-up. Holm-Bonferroni adjustment was used to adjust for multiple comparisons. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, North Carolina) and Prism 7 (GraphPad Software, Inc., La Jolla, California), with two-sided *P* values <.05 considered statistically significant.

## 3 | RESULTS

From 2011 to 2016, a total of 62 Melody TPVs were photographed or video recorded and implanted within 61 patients. A random selection of 20 Melody TPVs was used to devise the morphology classification system. This classification system separated valves into four morphologies based on the appearance of the valve leaflets. The definition of the classification system is listed below. Figure 1 depicts schematic and real examples for each valve type.

### 3.1 | Melody TPV classification system

1. Type A—Symmetric Trileaflet. All three leaflets approximately equal in size.
2. Type B—Asymmetric Trileaflet with Single Small Leaflet. Trileaflet valve with one leaflet being significantly smaller than the other two.

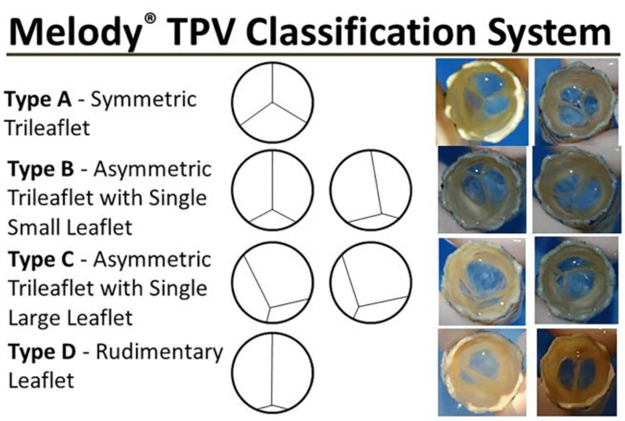


**FIGURE 1** Description, diagrams, and photographic examples of the four types of Melody TPVs

3. Type C—Asymmetric Trileaflet with Single Large Leaflet. Trileaflet valve with one leaflet being significantly larger than the other two.
4. Type D—Rudimentary Leaflet. Two leaflets clearly seen with a rudimentary third leaflet.

Figure 2 displays the breakdown of 62 imaged Melody TPV by classification type. The most common morphology seen was Type A (n = 29, 47%), followed by Type B (n = 20, 32%) and Type C (n = 10, 16%). Type D valves were the least common morphology seen in our study cohort (n = 3, 5%).

The outcome analysis cohort consisted of 55 Melody TPVs implanted in 54 patients, as 7 patients were excluded for TPV implant in a non-pulmonary position. Demographic and procedural data at the time of Melody TPV implantation are depicted in Table 1. The

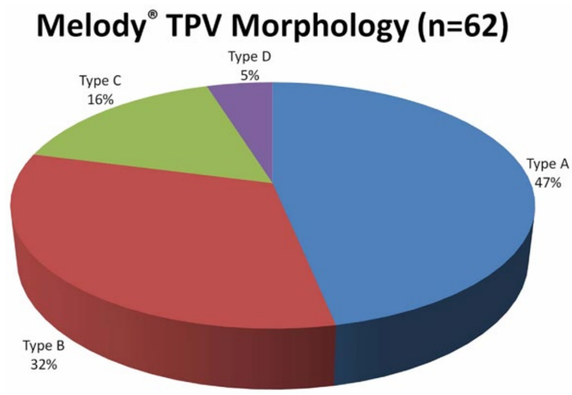


**FIGURE 2** Distribution of Melody TPV morphology within the study population

**TABLE 1** Patient demographics and procedural data by age

| Variable | All Patients (n = 55) | Patients ≤ 18 years of Age (n = 28) | Patients > 18 years of Age (n = 27) | *P* Value[a] |
|---|---|---|---|---|
| Age | 21.6 ± 13.4 | 12.3 ± 3.5 | 31.5 ± 12.9 | <.0001 |
| Height | 154.9 ± 22.5 | 149.2 ± 19.6 | 160.9 ± 23.9 | .0511 |
| Weight | 55.5 ± 22.2 | 43.9 ± 18.6 | 67.5 ± 19.3 | <.0001 |
| Gender | | | | .4230 |
| Female | 27 (49.1%) | 12 (42.9%) | 15 (55.6%) | |
| Male | 28 (50.9%) | 16 (57.1%) | 12 (44.4%) | |
| Diagnosis | | | | .2317 |
| RVOT obstruction | 42 (76.4%) | 22 (78.6%) | 20 (70.1%) | |
| Left heart disease s/p Ross procedure | 7 (12.7%) | 2 (7.1%) | 5 (18.5%) | |
| Truncus arteriosus | 3 (5.5%) | 1 (3.6%) | 2 (7.4%) | |
| Transposition of the great arteries | 3 (5.5%) | 3 (10.7%) | 0 (0%) | |
| RVOT Type | | | | 1 |
| Conduit | 36 (65.5%) | 18 (64.3%) | 18 (66.7%) | |
| Surgically augmented RVOT | 11 (20%) | 6 (21.4%) | 5 (18.5%) | |
| Bioprosthetic pulmonary valve | 8 (14.6%) | 4 (14.3%) | 4 (14.8%) | |
| Primary indication for Melody TPV | | | | .7087 |
| Mixed: PR and obstruction | 25 (45.5%) | 12 (42.9%) | 13 (48.2%) | |
| PR | 16 (29.1%) | 8 (28.6%) | 8 (29.6%) | |
| RVOT obstruction | 14 (24.5%) | 8 (28.6%) | 6 (22.2%) | |
| Number of prestents | 1.3 ± 1.3 | 1.3 ± 1.3 | 1.3 ± 1.4 | .9717 |
| Implanted Melody diameter | 20.7 ± 1.8 | 19.9 ± 2.1 | 21.4 ± 1.1 | .0048 |
| Melody TPV morphology | | | | .0549 |
| A | 24 (43.64%) | 14 (50%) | 10 (37.1%) | |
| B | 19 (34.55%) | 12 (42.9%) | 7 (25.9%) | |
| C | 9 (16.36%) | 2 (7.1%) | 7 (25.9%) | |
| D | 3 (5.45%) | 0 (0%) | 3 (11.1%) | |

Abbreviations: RVOT, right ventricular outflow tract; PR, pulmonary regurgitation.
Data are presented as mean ± standard deviation or number (%). Indication for Melody TPV implantation as previously described.[2,3]
[a]Comparison of pediatric and adult cohorts.

population was evenly divided between pediatric and adult patients. The cohorts differed in the demographic variables related to the groups' definition (age and weight). The most common diagnosis was right ventricular outflow tract obstruction which consisted of tetralogy of Fallot, pulmonary stenosis, and double outlet right ventricle with pulmonary stenosis. The second most common diagnosis was left heart disease treated with a Ross procedure. All valves were successfully implanted within the pulmonary position. As expected, the implanted diameter of the Melody TPV was significantly larger in the adult cohort.

Six-month follow-up data were available for 41 of the 55 Melody TPVs in the pulmonary position. Acceptable hemodynamic function at 6 months postimplantation was seen in 40 (97.5%) valves. The valve with unacceptable hemodynamic function (stenosis) was a Type B implanted in an 18-mm Hancock valved (Medtronic, Minneapolis, Minnesota) RV-PA conduit which required surgical conduit replacement.

Over a median follow-up period of 1.5 years (range 0-4.4 years), 2 (4%) Melody TPVs developed > mild regurgitation. The freedom from > mild Melody valve regurgitation was 97% at 2 and 4 years post-implantation (Figure 3A), with no difference in > mild regurgitation based on valve morphology (Figure 3B). Both of the regurgitant valves were Type A occurring at 10 and 17 months following implantation. The cases of valvar regurgitation were associated with either endocarditis or conduit stenosis and required intervention.

Complications were seen in nine (16.4%) Melody TPVs implanted in eight patients over the follow-up period (Table 2). Three valves developed endocarditis; two valves had frame fracture; one valve with multiple prestents caused refractory arrhythmia in a patient requiring surgical pulmonary valve replacement; two patients underwent conduit replacement secondary to stenosis, and one death. All cases of endocarditis required explantation of the Melody TPV. The death occurred in a 36-year-old patient with pulmonary atresia and intact ventricular septum who had undergone surgical repair with a 22-mm pulmonary homograft and 27 mm St. Jude mechanical (St. Jude Medical, St. Paul, Minnesota) tricuspid valve replacement. In addition, the patient had severe kyphoscoliosis and restrictive lung disease. The patient developed a respiratory arrest secondary to restrictive lung disease the day following the procedure and died. Autopsy showed severe hemorrhagic pulmonary edema and alveolar hemorrhage which likely lead to the respiratory failure.

All complications occurred in Type A (n = 4) and Type B (n = 5) valves. Six of the complications required reintervention (five surgical valve replacements and one transcatheter valve-in-valve procedure). Freedom from Melody valve complication was 81% at 2 years and 70% at 4 years (Figure 4A). There was no significant difference in Melody valve complications based on valve morphology (Figure 4B), and no identified patient or procedural variables were associated with the development of Melody TPV complications.

## 4 | DISCUSSION

The various Melody TPV morphologies can be classified into one of four categories based on leaflet morphology. Our system is based on the appearance of the valve leaflets and can easily be applied during the rinsing process prior to implantation.

During the photography or video recording review process, we found that off-axis images (ie, not directly down-the-barrel) could alter appearance of the Melody TPV morphology. Video clips of the Melody TPVs simulated the inspection process during rinsing and allowed for a more thorough evaluation of morphology. The video clips provided a more accurate and reproducible retrospective assessment of valve morphology compared to photographs. Our institution continues to capture photographic images and videos of all opened Melody TPVs prior to implantation. We are now prospectively classifying all Melody TPVs prior to implantation.

The collective experience of the Melody TPV has led to an improvement in knowledge of the stent frame and valve functions. As a result, there is better understanding on the practice of prestenting,

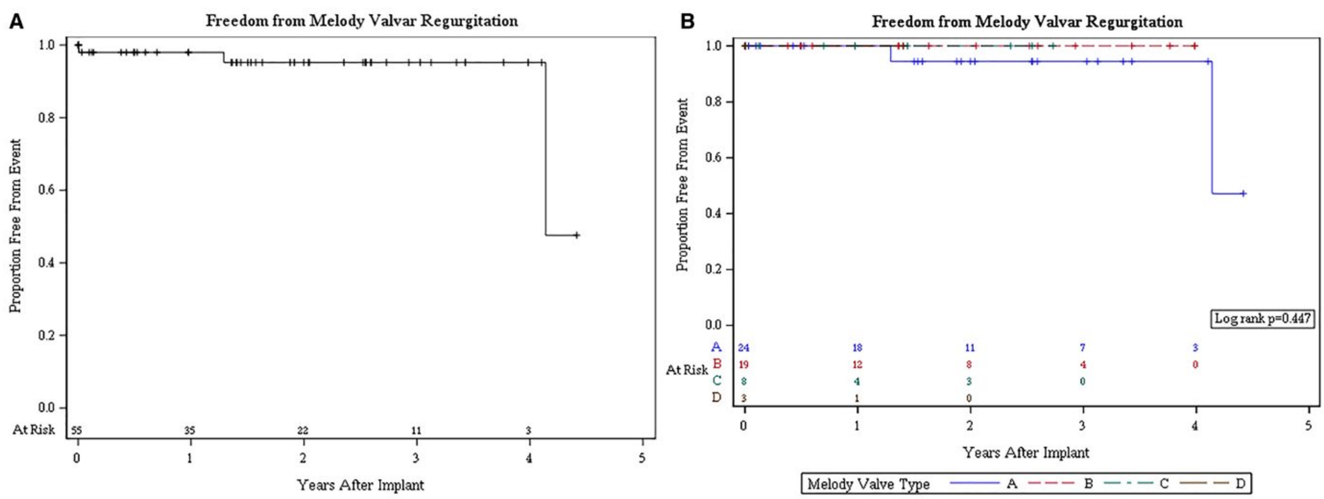


**FIGURE 3** Kaplan-Meier curves depicting the freedom from > mild Melody valve regurgitation for the entire patient population (A) and separated by valve morphology (B)

**TABLE 2** Melody TPV complications

| Patient number | Valve type | Age (yr) | Weight (kg) | Gender | Diagnosis | Complication | TPV Duration (months) | Treatment |
|---|---|---|---|---|---|---|---|---|
| 1 | A | 19 | 42.3 | F | PA/VSD/MAPCAs s/p unifocalization, and open VSD. Pregnancy resulted in significant cyanosis from worsening conduit stenosis, and regurgitation | Endocarditis (*Enterobacter cloacae*) | 10 | Medical therapy. Developed severe regurgitation and underwent transcatheter valve-in-valve 42 months later |
| 2 | B | 14 | 66 | M | Shone's complex s/p Ross-Konno procedure | Endocarditis (*Bartonella henslae*) | 17 | Conduit replacement after 7 months of medical therapy |
| 3 | B | 18 | 89.3 | M | TGA/VSD/PS s/p Rastelli operation | Endocarditis (*Staphylococcus lugdunensis*) | 42 | Conduit replacement |
| 4 | A | 11 | 42.9 | M | Aortic regutitation s/p Ross procedure | Stent fracture (2 prestents) | 7 | Followed clinically then lost to follow-up |
| 5 | B | 17 | 63.4 | F | PS s/p pulmonary valvotomy | Stent fracture (0 prestent) | 5 | Transcatheter valve-in-valve |
| 5 | A | 18 | 65.6 | F | PS s/p valvotomy and Melody TPV | Refractory ventricular arrhythmia | 0 | Melody TPV explantation with PVR |
| 6 | B | 9 | 26.5 | M | PA/VSD s/p complete repair with 18-mm Hancock conduit | Conduit stenosis (0 prestent) | 13 | Conduit replacement. |
| 7 | A | 14 | 69.1 | F | PA/IVS, Ebstein's anomaly s/p 20 mm Hancock conduit and tricuspid valve repair | Conduit stenosis and regurgitation (0 prestent) | 17 | Conduit replacement and TV repair |
| 8 | B | 36 | 50.6 | F | PA/IVS s/p repair with 22-mm pulmonary homograft conduit and 22-mm mechanical TV. Restrictive lung disease | Death secondary to respiratory arrest and pulmonary hemorrhage | 0 | |

Abbreviations: PA, pulmonary atresia; VSD, ventricular septal defect; MAPCA, major aortopulmonary collateral arteris; s/p, status post; TGA, transposition of the great arteries; PS, pulmonary stenosis; PA, pulmonary atresia; IVS, intact ventricular septum; TV, tricuspid valve.

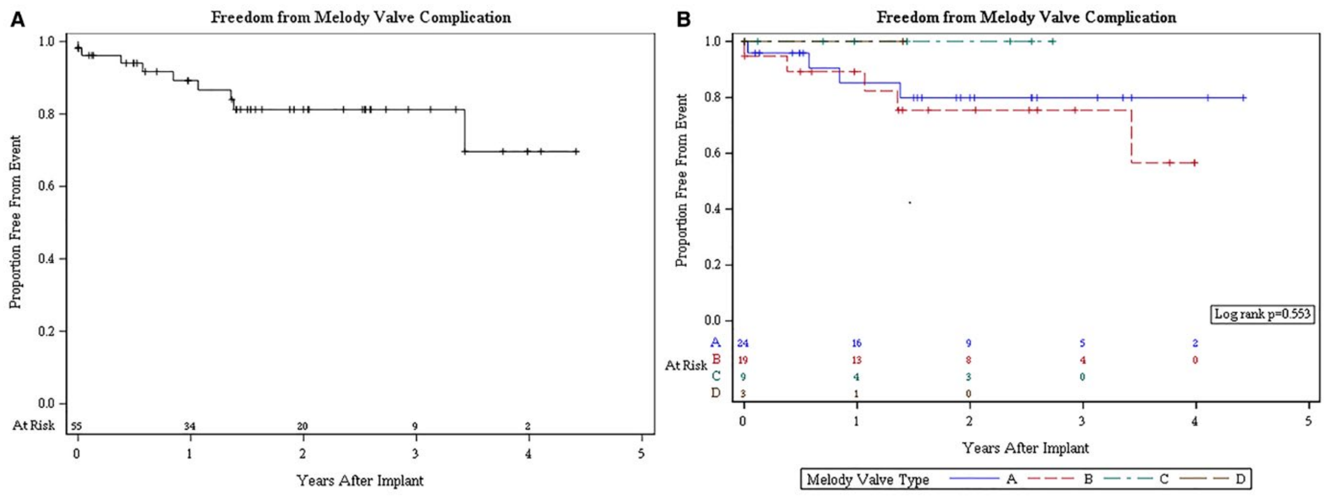


**FIGURE 4** Kaplan-Meier curves depicting the freedom from Melody valve complication for the entire patient population (A) and separated by valve morphology (B)

the off-label use of the valve outside of the RV-PA conduit, and the risk of endocarditis. Documentation of the type of valve implanted may improve our understanding of this technology and lead to further insight into associated outcomes.

Our study demonstrated excellent hemodynamic function at 6 months, consistent with published acute and medium-term results.[2-5] Significant valvar regurgitation (> mild) was found in 4% of valves (Type A) over a median follow-up period of 1.5 years and was associated with Melody valve complications (stenosis and endocarditis). Melody TPV complications were overall low in our study population with similar rates of reinterventions compared to prior studies.[5,12] All complications were seen in the two most common types of Melody valve morphology: Type A and B. Study outcomes were not associated with valve morphology, secondary to the relatively small cohort and lack of statistical power. Prospective multicenter or registry data may provide the power to adequately study Melody TPV morphology.

Endocarditis is a well-documented long-term risk for patients following Melody TPV implantation[5,13-17] and, aside from valvar stenosis or regurgitation, is the only complication with biological plausibility related to valve morphology. Evaluation of three prospective Melody TPV studies found the incidence of infective endocarditis to be 5.1% with an annualized rate of 2.4% per patient-year.[13] Endocarditis was seen in 5.4% of our study cases with an annualized rate of 3.2% per patient-year. It is our institutional practice to recommend lifelong aspirin and subacute bacterial endocarditis prophylaxis (SBE) for all patients who receive a TPV. Multiple studies have identified possible factors associated with Melody TPV endocarditis including prior episodes of endocarditis, male gender, multiple right ventricular outflow tract stents, right ventricular outflow tract obstruction, invasive procedures, and discontinuation of antiplatelet medication.[13,14,16,17] Though our study is the first to evaluate Melody TPV morphologies, bicuspid aortic valves have been shown to have a higher rate of infective endocarditis in the adult population.[18-20] In addition, there is an increased incidence in infective endocarditis in bovine jugular venous conduits compared to homograft conduits.[21] This suggests a correlation to the bovine tissue, but this increased incidence may be due to conduit stenosis and not due to the tissue itself.[22-24] Bovine jugular venous valve morphology deserves further investigation to determine if there is an association with endocarditis.

In conclusion, this first description of Melody TPV morphology has identified four valve classifications. Outcomes were not associated with morphology in this single center study, which is in large part due to the excellent midterm function and low rate of Melody TPV complications. Our study provides a Melody TPV morphologic classification system on which to base further research. Prospective classification of morphology type and further study of Melody valve morphology may lead to better understanding of associated outcomes.

## 5 | LIMITATIONS

The results of this study must be interpreted with the limitations in mind. Most importantly, our outcome analysis was underpowered due to the low rate of study end points. We were unable to improve the power of our analysis using a composite definition for complications. More widespread documentation of valve morphology will allow for a more robust study of these rare, undesirable outcomes. As our knowledge of TPV implantation has grown, practice patterns have evolved (eg, prestenting) in our efforts to obtain the best outcomes for our patients. Any change in practice can confound outcomes. Lastly, though we recommend lifelong aspirin and SBE prophylaxis following transcatheter valve implantation at our center, we cannot accurately measure patient compliance which can affect study outcomes.

## 6 | CONCLUSION

Melody TPV morphology can be classified into four valve classifications. Outcomes were not associated with morphology in this single center study, which is in large part due to the excellent midterm function and low rate of complications of the Melody TPV. Our study provides a Melody TPV morphologic classification system on which to base further research. Prospective classification of morphology type and further study of Melody valve morphology may lead to better understanding of associated outcomes.

## DECLARATION OF INTEREST

Dr. Sharon L. Cheatham is a consultant for Medtronic Inc. Dr. Armstrong receives research grants and is a proctor for both Medtronic Inc. and Edwards Lifesciences. Dr. John P. Cheatham is a proctor, consultant, and principal investigator for Medtronic Inc. Dr. Darren P. Berman is a proctor for Edwards Lifesciences.

### AUTHOR CONTRIBUTIONS

All authors contributed significantly to the research study and article as follows:

*Brian A. Boe*—conception and design, analysis and interpretation of data, drafting of the manuscript, critically revising the manuscript, final approval of the submitted manuscript.

*Aimee K. Armstrong*—conception and design, critically revising the manuscript, final approval of the submitted manuscript.

*Darren P. Berman*—critically revising the manuscript, final approval of the submitted manuscript.

*Joanne L. Chisolm*—analysis and interpretation of data, critically revising the manuscript, final approval of the submitted manuscript.

*Sharon L. Cheatham*—conception and design, critically revising the manuscript, final approval of the submitted manuscript.

*John P. Cheatham*—conception and design, critically revising the manuscript, final approval of the submitted manuscript.

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