Multicenter Experience Evaluating Transcatheter Pulmonary Valve Replacement in Bovine Jugular Vein (Contegra) Right Ventricle to Pulmonary Artery Conduits

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Background—Follow-up of transcatheter pulmonary valve replacement (TPVR) with the Melody valve has demonstrated good short-term and long-term outcomes, but there are no published studies focused on valve performance in the Contegra bovine jugular vein conduit.

Methods and Results—This is a retrospective, multicenter study of the short- and intermediate-term outcomes of Melody TPVR within the Contegra conduit in the right ventricle to pulmonary artery position. Data from 13 centers were included in the analysis. During the study period, 136 patients underwent 139 catheterizations for attempted Melody TPVR with a median follow-up of 3 years (1 day to 9.1 years). Of the 136 patients, 117 underwent successful Melody TPVR. Two patients underwent a second Melody TPVR. The majority of patients underwent placement of ≥1 stents before transcatheter pulmonary valve implantation. There was a significant reduction in peak conduit pressure gradient acutely after transcatheter pulmonary valve implantation (39 versus 10 mm Hg; $P<0.001$). At most recent follow-up, the maximum pulmonary valve gradient by echocardiogram remained significantly reduced relative to prevalve implant measurements (65.9 versus 27.3 mm Hg; $P<0.001$). The incidence of Melody transcatheter pulmonary valve stent fracture (3.4%) and infectious endocarditis (4.3%) were both low. Serious adverse events occurred in 3 patients.

Conclusions—Melody TPVR in Contegra conduits is safe and effective and can be performed in a wide range of conduit sizes with preserved valve function and low incidence of stent fracture and endocarditis. (***Circ Cardiovasc Interv*. 2017;10:e004914. DOI: 10.1161/CIRCINTERVENTIONS.116.004914.**)

Key Words: adult ■ aneurysm ■ angioplasty ■ endocarditis ■ hemodynamics

The first transcatheter pulmonary valve replacement (TPVR) was reported in 2000.[1] Drawing from that experience, the Melody valve (Medtronic, Inc, Minneapolis, MN) was developed and approved by the US Food and Drug Administration in 2010 for use in patients with obstructed or regurgitant right ventricular (RV) outflow tract (RVOT) conduits. The results from the US IDE trial (Investigational Device Exemption) demonstrated substantial improvements in RVOT gradient, conduit regurgitation, and RV pressure after valve implantation.[2,3]

The majority of Melody valves implanted early in the experience were within cryopreserved homograft conduits. A relatively common alternative to homograft conduits for RVOT reconstruction is the Contegra pulmonary valve conduit, a glutaraldehyde-preserved bovine jugular vein conduit (Medtronic, Inc), which is available in a range of sizes (12–22 mm) for use

Received December 22, 2016; accepted May 17, 2017.

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Guest Editor for this article was Theodore A. Bass, MD.

The Data Supplement is available at http://circinterventions.ahajournals.org/lookup/suppl/doi:10.1161/CIRCINTERVENTIONS.116.004914/-/DC1.

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WHAT IS KNOWN

- Transcatheter pulmonary valve replacement (TPVR) with the Melody valve is safe and effective in patients with synthetic or bioprosthetic right ventricle to pulmonary artery conduits and valves.
- Studies of the Contegra bovine jugular vein conduit have provided conflicting data on valve durability, risk of dissection or aneurysm, and risk of infective endocarditis (IE).

WHAT THE STUDY ADDS

- The study is the first to specifically examine Melody transcatheter pulmonary valve performance within the Contegra conduit.
- Although the duration of follow-up is relatively short, this study demonstrates similar rates of successful TPVR relative to other conduit and valve types. It also demonstrates similar rates of conduit injury with dilation and similar rates of IE during the follow-up period.
- The overall incidence of IE in patients before TPVR was similar to previous reports. However, history of endocarditis was not associated with a risk of IE after TPVR. The annualized risk of IE after TPVR was similar to previous studies.
- Although TPVR was less successful in small conduits (<16 mm nominal diameter) relative to larger conduits, over half of patients with small conduits underwent successful TPVR.

in neonates up to adults and is available in unsupported and ring-supported models. The supported model has 2 external polypropylene rings sutured to the adventitial layer of the conduit. Although one study found that transcatheter stent implantation was more successful in relieving obstruction of Contegra conduits than homografts, little is known about postprocedural outcomes of Melody TPVR within Contegra conduits, which comprised a small percentage of the overall implants in the early experience.[3–5] Although one study found Contegra conduits to have superior durability to homograft conduits, the majority of studies have shown no significant differences in performance between the conduit types.[5–11] A small number of studies have reported higher risks of infective endocarditis (IE), distal conduit obstruction, and aneurysm formation as mechanisms of Contegra failure relative to homograft conduits.[12–17]

The purpose of this retrospective multicenter study was to expand our understanding of outcomes after TPVR within the Contegra conduit, including responsiveness to angioplasty and stenting; procedural complications such as conduit disruption, hemodynamic results, intermediate-term valve performance, and endocarditis risk.

Methods

Patients and Study Protocol

This cross-sectional multicenter retrospective study included patients from 13 institutions who underwent catheterization for intended Melody TPVR in a previously placed Contegra conduit. Aside from patients enrolled in the original IDE trial, precatheterization evaluation and patient selection were at the discretion of individual implanters.

Catheterization and Valve Implantation

The technique for Melody TPVR has been previously described and did not differ specifically for Contegra conduits.[2] Patients who met criteria for TPVR underwent catheterization with hemodynamic and angiographic evaluation of the RVOT conduit and coronary compression assessment. Predilation of the conduit or valve was prescribed by the US IDE protocol, but placement of a bare metal stent before valve implant was not allowed during the first 35 patients, after which it was permitted but not required. After US Food and Drug Administration approval of the Melody transcatheter pulmonary valve (TPV), these conduit preparation steps were 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 previously described.[4]

Data Analysis

Study investigators from each study center reviewed hemodynamic and angiographic data for each patient. Measurements from all relevant imaging studies were made by the individual centers. All patients who were taken to the catheterization laboratory with the intention of implanting a Melody TPV in a Contegra RVOT conduit were included in the analysis. Basic descriptive variables were collected, including age, diagnosis, history of IE, and previous conduit interventions. Imaging data and procedural variables were also collected, including the degree of conduit calcification, the use of prestenting, the occurrence of conduit disruption, and changes in hemodynamics after TPVR. Conduit disruption or injury was defined 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).[18] Mild-to-moderate conduit calcification was defined as incomplete circumferential calcium deposits on fluoroscopy, whereas severe calcification was defined as complete, dense circumferential calcium deposits on fluoroscopy. Follow-up events included the development of TPV stent fractures, the occurrence of IE, and RVOT reintervention. On the basis of previously published guidelines, stent fractures were characterized as type 1, strut fracture with no loss of integrity; type 2, strut fracture with loss of stent integrity; and type 3, fracture associated with embolization of stent fragments.[19] Continuous variables were expressed as median (minimum–maximum) or mean±SD, and categorical variables were expressed as frequency (%). Data analysis was performed to compare pre- and postintervention information using the paired *t* test. Comparisons of categorical variables were performed using Fisher exact test. Freedom-from-event estimates were generated using the Kaplan–Meier method. The incidence rate of IE was calculated as a percent per patient-year, which is equivalent to event rate per 100 patient-years. The study was approved by the Institutional Review Board at each participating center. Informed consent was not obtained from research subjects. All authors had access to the data and approved the article as submitted.

Results

Patients and Conduit-Related Data

Data were collected on 136 patients who underwent 139 catheterizations from 13 centers across the United States and Europe. Two patients underwent a second TPVR after failure of the first valve and 1 patient underwent TPVR at a second catheterization after an initial catheterization demonstrated some concern for coronary artery compression. The baseline demographics are depicted in Table 1. The median age and weight at catheterization were 14.5 years and 53 kg, respectively. The median conduit size was 20 mm, although Melody

Table 1. Baseline Demographics

	n=139
Age at catheterization, y	14.5 (3–52)
Male sex, n (%)	95 (68%)
Weight, kg	53 (15.5–117)
Original cardiac diagnosis, n (%)	
Tetralogy of Fallot	70 (50)
Truncus arteriosus	27 (20)
Aortic valve disease, previous Ross procedure	17 (12)
Double-outlet right ventricle	8 (6)
Transposition of the great arteries	7 (5)
Pulmonary atresia with intact ventricular septum	3 (2)
Valvar pulmonary stenosis	1 (1)
Other	6 (4)
Original conduit size, mm	20 (12–22)
Duration of conduit placement, y	8 (0.9–15.4)
History of bacterial endocarditis, n (%)	14 (10.1)
Contegra associated, n (%)	7 (5)
Non-Contegra associated, n (%)	7 (5)
Previously placed conduit stent, n (%)	
No	123 (88)
Single stent	12 (9)
Multiple stents	4 (3)
Indication for valve implantation, n (%)	
Stenosis	63 (45)
Regurgitation	7 (5)
Mixed	69 (50)
Degree of conduit calcification	
None	46 (33)
Mild to moderate	62 (45)
Severe	30 (22)

Data are presented as median (minimum–maximum) or n (%).

valves were successfully implanted in conduits with a nominal diameter (ie, at the time of surgical implant) as small as 12 mm as an off-label indication. Data on the type of Contegra were available for 112 of the 136 patients (82%). The Contegra conduit was ring-supported type in 19 and non–ring-supported type in 93 patients. The median duration from surgical conduit placement to TPVR was 8 years (0.9–15.4 years). Before TPVR, 14 patients (10.1%) had a reported history of IE, half of which directly involved the Contegra conduit.

Baseline echocardiographic and magnetic resonance imaging data are depicted in Table 2. In the majority of patients, the indication for TPVR was conduit stenosis or mixed stenosis and regurgitation. Data on the level of obstruction were available for 92 patients: the obstruction was proximal in 22%, valvar in 36%, distal in 17%, and multilevel in 25% (Figure 1). In nearly half of patients, the degree of conduit calcification was described as mild to moderate. Severe or dense

Table 2. Imaging Data

	Preprocedure	1-y Follow-Up (n=77)	Most Recent Follow-Up (n=97)*
Echocardiography (n=133)			
Mean RVOT gradient, mm Hg	35±13	15±8	15±10
Maximum instantaneous RVOT gradient, mm Hg	65±23	23±12	27±17
MRI (n=62)			
Indexed RV end-diastolic volume, mL/m^2	120±35	…	…
RV ejection fraction, %	44±11	…	…
PR fraction, %	28±14	…	…

Data are presented as mean±SD, median (minimum–maximum), or n (%). MRI indicates magnetic resonance imaging; PR, pulmonary regurgitation; RV, right ventricle; and RVOT, right ventricular outflow tract.

*Most recent follow-up may have occurred before the 1-y period for some patients.

circumferential calcification of the conduit was described in 30 patients (22%).

Procedural Details

TPVR was successful in 117 of the 139 (84%) catheterizations performed (Table 3). Coronary artery compression, unfavorable conduit dimensions, and lack of hemodynamic indication were all reasons for not implanting a valve. In patients with 12- and 14-mm Contegra conduits, the rate of successful TPVR was significantly lower than that in patients with larger conduit sizes (56% versus 88%; P=0.001). Prestenting with single or multiple stents at the time of TPVR was performed in 94% of cases. Of the 7 patients who did not receive a prestent at the time of TPVR, 4 had undergone RVOT stenting at a previous procedure. Only 3 patients did not undergo any stent implantation before TPVR. Postdilation of the Melody valve after implantation was performed in 60 patients (51%).

Acute Outcomes

There was a significant reduction in peak conduit pressure gradient and RV to aortic pressure ratio acutely after TPVR (38 versus 10 mm Hg; P<0.001 and 0.71 versus 0.39; P<0.001, respectively). Preimplant RVOT pressure gradients were significantly higher in patients with severe conduit calcification relative to those with mild-to-moderate calcification. However, there was no difference in peak conduit gradient or RV to aortic pressure ratios after TPVR when comparing patients with different degrees of conduit calcification. There was no difference in hemodynamic outcome according to the level of conduit obstruction although the study was not sufficiently powered to fully evaluate the relationship between location of obstruction and gradient relief. The degree of conduit obstruction did not have an impact on the ability to successfully implant a valve. When comparing the ratio of preintervention narrowest angiographic conduit dimension to the nominal conduit diameter for patients who underwent

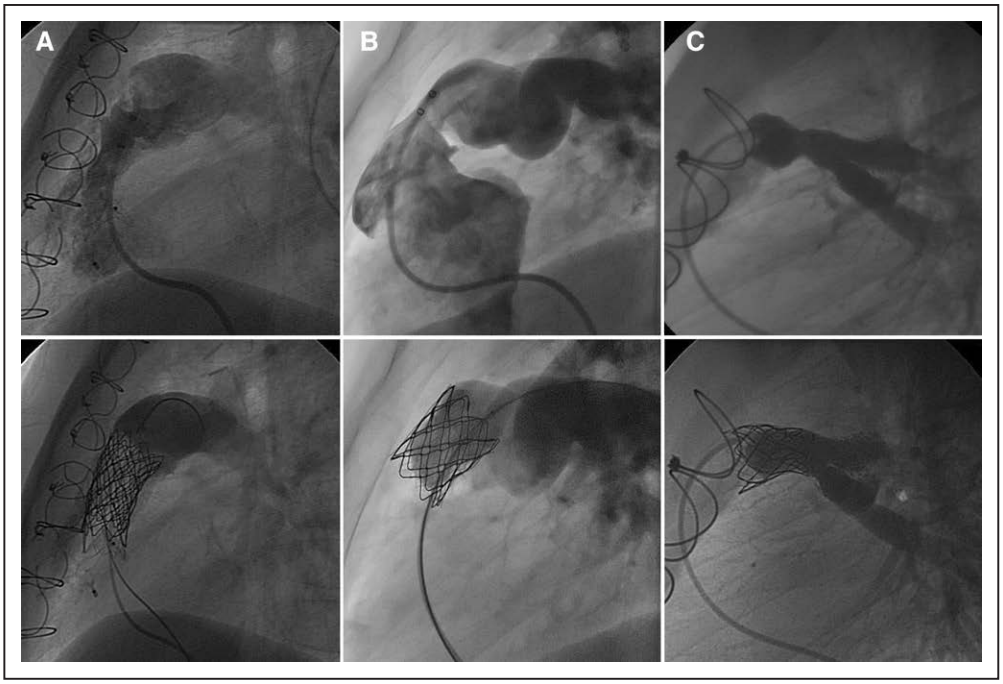

Figure 1. Lateral angiographic projections demonstrate different levels of obstruction along the Contegra conduit before and after transcatheter pulmonary valve (TPV) replacement. **A**, Proximal stenosis of a 20-mm Contegra conduit below the valve leaflets. After prestenting, the Melody TPV was deployed on a 20-mm delivery balloon. **B**, Mid-conduit or valvar stenosis of a 16-mm Contegra conduit. After prestenting, the Melody TPV was deployed on a 20-mm delivery balloon. **C**, Distal obstruction of a 20-mm Contegra conduit. After prestenting, the Melody TPV was deployed on a 20-mm delivery balloon.

successful TPVR and those who did not, the ratio was actually smaller for those patients who underwent successful TPVR compared with those who did not receive a TPV (0.63±0.19 versus 0.82±0.26; $P<0.001$).

Comparing patients with ring-supported conduits to those with unsupported conduits, there was no difference in patient age, weight, conduit size, degree of conduit calcification, or echocardiographic RVOT gradients before TPVR. The duration of conduit placement was shorter with ring-supported conduits (6.7±2.8 versus 8.4±2.9 years; $P=0.02$). At the time of catheterization, patients with ring-supported conduits had greater degrees of RVOT obstruction with narrower conduit diameters and higher RVOT gradients and RV to aortic pressure ratios (Table 4). Despite greater degrees of obstruction with ring-supported conduits, there was no difference in the number of patients receiving >1 stent before TPVR, and rates of successful valve implantation were similar between the 2 groups. However, patients with ring-supported conduits had significantly higher residual RVOT gradients and RV to aortic pressure ratios than patients with unsupported conduits after TPVR (16±8 versus 9±5 mm Hg; $P<0.001$ and 0.49±0.1 versus 0.38±0.1; $P<0.001$).

Patients undergoing attempted TPVR in 12- and 14-mm conduits were significantly younger and smaller than patients with conduits ≥16 mm (Table I in the Data Supplement). There was no difference in the duration of conduit placement, degree of conduit calcification, or conduit obstruction as measured by echocardiography. Both groups had similar angiographic conduit dimensions, and the ratio of narrowest conduit diameter to nominal conduit diameter was greater in the small conduit group (0.89±0.26 versus 0.63±0.19; $P<0.001$). Additionally, the RVOT gradient was lower in the small conduit group. Following TPVR, RVOT gradients were similar between the 2 groups (8 versus 10 mm Hg; $P=0.17$). Rates of successful TPVR were lower in the small conduit group. Of the 7 patients in the small conduit group who did not undergo TPVR, only 1 failed because conduit dimensions were felt to be inadequate for TPV after predilation and another failed because the delivery system could not be advanced through the RVOT despite numerous attempts. Three patients did not undergo TPVR because of inappropriate hemodynamics, and 2 patients demonstrated coronary artery compression with compression testing. However, 1 of these patients was brought back at a later date and underwent successful TPVR in a different position within the conduit that did not compress a coronary artery.

There was no evidence of conduit aneurysm, dissection, or tear by angiography before any intervention. Confined tears occurred in 5 patients (4.3%) during preimplant angioplasty or stent placement. There were no uncontained or catastrophic tears. One center used covered stents before all TPV implants, and, therefore, the data may underestimate the incidence of conduit disruption in this population. There were no covered stents specifically implanted to treat a conduit tear. There was no difference in nominal conduit diameter, degree of conduit calcification, or ratio of conduit diameter to balloon diameter between patients who developed conduit tears and those who did not. Concomitant procedures, such as branch pulmonary artery angioplasty or stent placement, were performed in 16 patients (11.5%).

Serious procedural adverse events were reported in 3 patients (2.2%): 1 patient received a blood transfusion for significant bleeding from the access site; 1 developed a femoral arteriovenous fistula that required surgical repair; and 1

Table 3. Procedural Data

Procedural Data	
No. of attempted Melody valve implantations (n)	139
No. of implants, n (%)	117 (84)
Indications for not implanting, n (%)	
CA compression	9 (6.4)
Unfavorable conduit dimensions	4 (5)
No hemodynamic indication	6 (4.3)
Other	3 (2.2)
Preimplantation stent placement, n (%)	
None	7 (6)
Single	70 (60)
Multiple	40 (34)
Conduit disruption, n (%)	
None	112 (95.7)
Confined tear	5 (4.3)
Unconfined tear	0
Additional procedures performed, n (%)	
Balloon pulmonary artery angioplasty	6 (5.1)
Pulmonary artery stent placement	6 (5.1)
Other	4 (3.4)
Preimplantation peak RVOT gradient, mm Hg	38±19
Preimplantation RV:Ao pressure ratio	0.71 (0.32–1.89)
Postimplantation peak RVOT gradient, mm Hg	10±6
Postimplantation RV:Ao pressure ratio	0.39 (0.2–0.76)
Serious adverse events, n (%)	3 (2.2)

Data are presented as mean±SD, median (minimum–maximum), or n (%). Ao indicates aorta; CA, coronary artery; RV, right ventricle; and RVOT, right ventricular outflow tract.

developed a hemothorax from a wire injury in the right lung requiring placement of a 10-mm Amplatzer Vascular Plug II in the affected lung segment and chest tube placement.

Follow-Up

The median duration of follow-up was 3 years (1 day to 9.1 years). Of the 117 patients who underwent TPVR, 30 (26%) had <1-year follow-up data available. Reintervention was performed in 13 patients, 9 of which were for a TPV-related indication. Two patients received a second TPV for RVOT obstruction associated with stent fracture (both patients underwent prestenting before initial TPV implant), 2 underwent a separate postprocedural balloon dilation of the TPV for recurrent obstruction, and 5 underwent explant and surgical valve replacement for obstruction (n=1) or endocarditis (n=4). Four reinterventions were not primarily for TPV-related indication: 1 patient underwent heart transplant; 1 had reexpansion of a bare metal stent proximal to the TPV; and 2 underwent surgical aortic valve replacement and had the well-functioning TPV replaced with a surgical valve at the same operation. The patient who underwent heart transplant developed significant

Table 4. Contegra Conduit Models

	Ring-Supported Conduits (n=19)	Non–Ring-Supported Conduits (n=93)	*P* Value
Age at catheterization, y	14.5±3.7	15.2±6.6	0.65
Weight, kg	50.4±10.5	50.4±19.7	0.99
Original conduit size, mm	20 (16–22)	20 (12–22)	0.4
Duration of conduit placement, y	6.7±2.8	8.4±2.9	0.02
Severe conduit calcification, n (%)	6 (32)	23 (25)	0.53
Preprocedure echocardiography			
Mean RVOT gradient, mm Hg	39±12	35±14	0.41
Maximum instantaneous gradient, mm Hg	66±21	65±23	0.84
Catheterization			
Narrowest conduit dimension, mm	10.6±3	12.4±3.6	0.05
Ratio narrowest:nominal dimension	0.56±0.2	0.69±0.2	0.03
Pre-RVOT peak gradient, mm Hg	49±25	37±18	0.01
Pre-RV:Ao pressure ratio	0.91±0.3	0.71±0.2	<0.001
Post-RVOT peak gradient, mm Hg	16±8	9±5	<0.001
Post-RV:Ao pressure ratio	0.49±0.1	0.38±0.1	<0.001
Multiple prestents placed, n (%)	7 (47)	22 (29)	0.19
Melody valve placed, n (%)	15 (79)	75 (81)	0.86
Post dilation performed, n (%)	9 (60)	38 (51)	0.51
Echocardiography, most recent follow-up			
Mean RVOT gradient, mm Hg	16±13	16±12	0.94
Maximum instantaneous RVOT gradient, mm Hg	29±16	28±19	0.81

Data are presented as mean±SD, median (minimum–maximum), or n (%). Ao indicates aorta; and RVOT, right ventricular outflow tract.

RV dysfunction after Fontan takedown to a superior cavopulmonary circulation with an RV to pulmonary artery conduit and developed biventricular failure despite relieving residual RVOT obstruction with TPVR.

A total of 5 patients (4.3%) were diagnosed with IE a median of 3 years after Melody valve implant (1.8–3.9 years). The total duration of follow-up from implant to diagnosis of IE or most recent evaluation was 256 patient-years, giving an annualized

rate of IE of 1.95% per patient-year (or 1.95 cases per 100 patient-years). Freedom from a diagnosis of IE after TPVR by Kaplan–Meier analysis was 100% at 1 year and 87% at 5 years. The infection involved the valve itself in 4 cases, all of which were managed with surgical explant and conduit replacement according to the practice of the treating institution. The single case of IE not related to the TPV was treated medically without surgical explant. None of these 5 patients had a history of IE before TPVR. The 14 patients with a history of IE were IE-free a median of 1.8 years (1 day to 6.1 years) after TPVR.

Melody valve stent fracture was diagnosed in 4 patients (3.4%) a median of 2.6 years (0.2–5.3 years) after TPVR. Prestenting was performed at the time of TPVR in 3 of these 4 patients with 2 patients receiving multiple stents before TPVR. The 2 patients with multiple RVOT stents were diagnosed with type 2 fractures and underwent a repeat Melody valve implantation (Melody valve-in-Melody valve). There were no type 3 fractures. Freedom from a diagnosis of stent fracture after TPVR by Kaplan–Meier analysis was 99% at 1 year and 89% at 5 years. There was no difference in fracture rate between those patients with ring-supported conduits and those with unsupported conduits and no association with postdilation of the Melody valve at the initial procedure.

Discussion

Recent follow-up of the original Melody TPV cohort has demonstrated stable valve function, with limited progression of RVOT obstruction and preserved competence.[20] The advent of prestenting and greater focus on conduit preparation before TPVR has improved the reintervention free survival and the ability to implant larger valves. These studies have focused largely on homograft conduits and bioprosthetic valves. This study was designed to evaluate Melody TPV performance specifically within the Contegra conduit.

The high rate of successful TPVR in this study was similar to previous studies of Melody valve replacement.[4] Overall, there were statistically significant reductions in peak RVOT gradient and RV to aortic pressure ratios and low postimplant gradients that were comparable to patients with homograft conduits or bioprosthetic valves in other studies. There was no significant progression of RVOT obstruction, and valve function was preserved at most recent follow-up, with no significant change in echocardiogram-based gradients at 1 year and most recent follow-up. There were only 6 patients (5.1%) discharged with TPV gradients >20 mm Hg, which is significantly better than the follow-up of the early Melody cohort in which one third of patients were discharged with gradients >20 mm Hg.[20] Much of this stems from more aggressive and focused conduit preparation and prestenting. In this current cohort, conduit prestenting at the time of TPVR or at a previous procedure was performed in 97% of patients. This represents a significant increase in prestenting, relative to earlier reports, and is reflective of the overall evolution of this procedure.[21] For this reason, Melody TPV stent fractures were uncommon in this study with only 4 total fractures and a freedom from stent fracture of 89% at 5 years.

Patients with ring-supported conduits had a shorter duration from conduit placement to TPVR, higher measured RVOT gradients at the time of catheterization, and higher residual gradients after TPVR relative to patients with unsupported conduits. Despite these findings, there was no difference in the balloon size used for predilation or delivery system size, and echocardiographic measurements of valve function at most recent follow-up were similar between the 2 groups. The numbers of patients with ring-supported conduits was small, but these data suggest that the ring-supported models do not achieve the same relief of obstruction as the unsupported models. More follow-up is needed to determine whether there are any effects on the long-term function of the valve.

A notable difference between this Contegra cohort and cohorts comprised primarily of homograft conduits is the relatively large number of patients with small conduits (12 and 14 mm at the time of surgical implant) who underwent catheterization for consideration of TPVR. Although there were fewer successful procedures in patients with smaller conduits, 56% were able to undergo TPVR, which suggests that Contegra conduits can be expanded beyond nominal size to accommodate the Melody TPV with hemodynamic results that are similar to larger conduits (Figure 2). Interestingly, despite similar durations of conduit placement and degrees of conduit calcification, patients with smaller conduits exhibited less conduit obstruction, and the primary modes of procedural failure were inadequate hemodynamics and coronary compression and not the inability to dilate the conduit to an adequate dimension for TPVR as might be expected. This may have important implications for how we think about the lifelong management of patients who require RVOT conduit placement in infancy. Namely, if an infant mediastinum can accommodate a 12- or 14-mm Contegra conduit and there is a >50% likelihood that a Melody TPV can be implanted within that conduit with a good hemodynamic result, this may be an attractive strategy for minimizing the number of open-heart surgeries in some patients.

There are reports of distal obstruction and aneurysm formation in Contegra conduits, such that the placement of Contegra conduits has been described as a risk factor for shorter time to conduit replacement, compared with homograft conduits, in some analyses.[12–14,22] However, the data comparing homograft and Contegra performance are mixed with other studies showing comparable conduit longevity.[5–10] In this study, the primary indication for TPVR was stenosis or mixed stenosis and regurgitation. There was relatively even distribution of obstruction location along the length of the conduit, and there were no reported cases of distal conduit aneurysm or dissection before TPVR. Although data were not available for all patients, it seemed that stenosis could be relieved and a TPV implanted successfully regardless of the location of the Contegra conduit obstruction. A conduit tear or injury with predilation or prestenting was uncommon in this cohort, with only 4% (5 patients) experiencing confined tears before TPVR, which is lower than reported in previous studies in which the rates of conduit injury ranged from 6% to 33%.[18,23] There were no instances of unconfined or catastrophic tears of the conduit.

IE is often believed to be more common in Contegra conduits. The largest follow-up study of the Contegra conduit documented 5 cases of IE in a cohort of 165 patients followed for ≤7 years, although recent data from Edmonton reported a significantly higher risk of IE in Contegra conduits relative

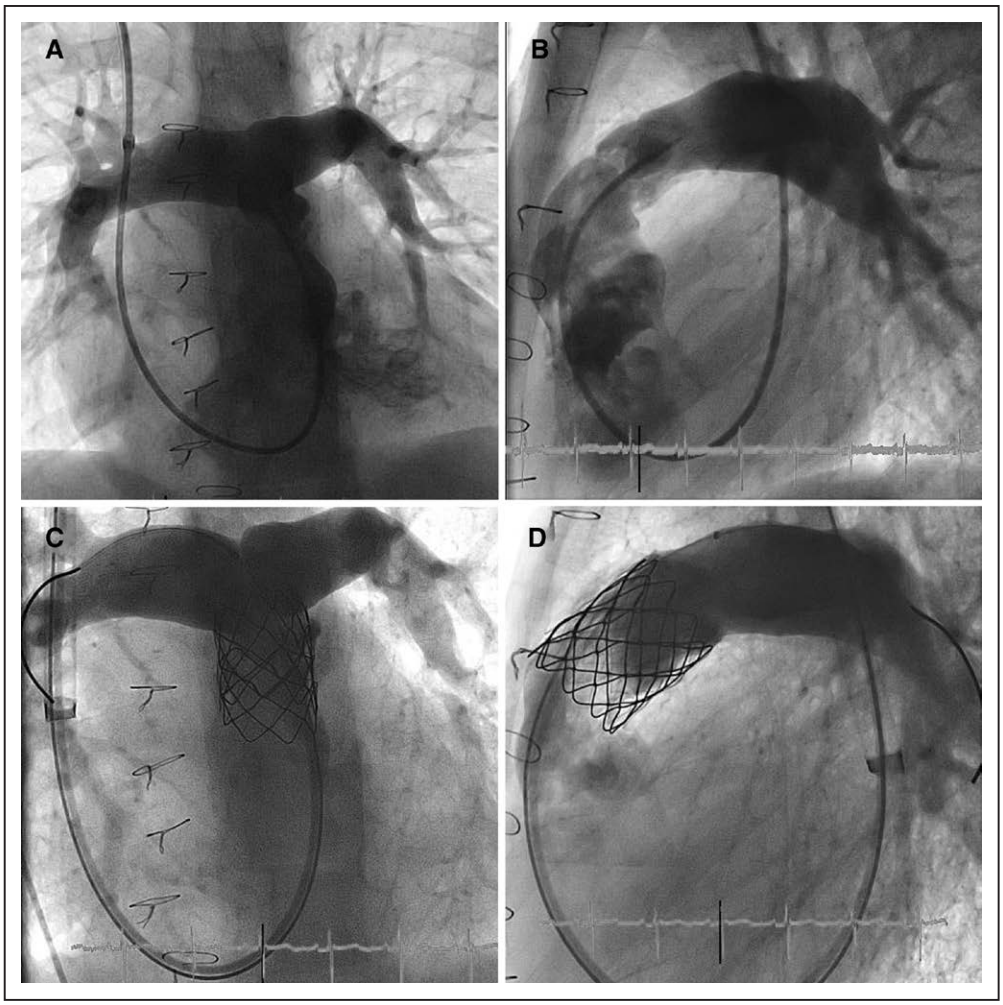

Figure 2. AP/cranial (**A**) and lateral (**B**) angiographic projections of a 14-mm Contegra conduit that had been in for 10 years with severe stenosis and regurgitation and severe intraluminal narrowing. The Contegra conduit was dilated serially with 10-, 12-, 14-, 16-, and 18-mm high-pressure balloons and then prestented with a 3110 PalmazXL stent (Cordis, Johnson and Johnson, Miami Lakes, FL) using an 18-mm balloon. A Melody transcatheter pulmonary valve was subsequently deployed on an 18-mm Ensemble delivery system and further balloon dilated with a 20-mm high-pressure balloon (**C**) and (**D**).

to homograft conduits.[15,22] However, a study specifically looking at IE after Melody TPVR did not suggest a difference in IE incidence based on conduit type.[24] In this report, 10.1% of patients were diagnosed with IE before Melody TPVR, which is similar to a recent follow-up study of Contegra performance.[15] After Melody TPVR, the overall incidence and annualized rate of IE reported in this study is comparable to studies of IE after Melody TPVR in general.[24,25] Additionally, a diagnosis of IE before TPVR was not associated with an increased risk of IE after Melody TPVR; in fact, none of the patients who developed IE after Melody valve implant were among those with a known history of IE pre-TPVR, which suggests that Melody-in-Contegra implants do not confer a heightened risk of this complication. Although the incidence of IE was low, the clinical implications of valve-associated IE were significant, as all patients with IE involving the valve underwent TPV explant.

Limitations

As with many studies of this type, this analysis was limited by the small number of patients and the retrospective design. The primary limitation of this study was the short duration of follow-up relative to recent multicenter studies of TPVR, which was likely due in part to the fact that experience with the Contegra conduit in many centers has been shorter and more limited compared with homografts and bioprosthetic valves. This may make it difficult to compare the incidence of stent fracture and IE in this cohort with the outcomes reported in other TPV studies.

Conclusions

In this multicenter experience, Melody TPVR in Contegra conduits was safe and effective. The Contegra conduit responded well to angioplasty and stent placement, with low rates of conduit injury and gradient reduction that were comparable to other TPV studies. Although the numbers are small, ring-supported conduits did not respond as well to TPVR. Small conduits responded well to dilation and offer an intriguing option for possible TPVR even though the success rates were lower compared with larger conduit sizes. IE before TPVR was reported in ≈10% of patients but was not associated with an increased risk of IE after Melody TPVR. The overall and

annualized risks of IE were comparable to previous studies. Although the duration of follow-up was limited in some cases, there were few instances of stent fracture, minimal progression of RVOT obstruction, and preserved valve competence at most recent follow-up.

Acknowledgments

All the authors were directly involved in the study design, data analysis, interpretation of findings, and article completion. All the authors reviewed the article in detail and have approved it in its submitted form.

Disclosures

Drs McElhinney, Boudjemline, and Jones serve as consultants and proctors for Medtronic, Inc. The remaining authors have no conflicts.

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Multicenter Experience Evaluating Transcatheter Pulmonary Valve Replacement in Bovine Jugular Vein (Contegra) Right Ventricle to Pulmonary Artery Conduits

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Circ Cardiovasc Interv. 2017;10:
doi: 10.1161/CIRCINTERVENTIONS.116.004914
Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 1941-7640. Online ISSN: 1941-7632