

## **Abstract**

**Background:** Transcatheter pulmonary valve implantation (TPVI) with the Melody® transcatheter pulmonary valve (TPV) has demonstrated good hemodynamic and clinical outcomes in the treatment of right ventricular outflow tract (RVOT) conduit dysfunction in patients with repaired congenital heart disease CHD.

**Aim:** we present the first Australian single centre experience of patients treated with Melody TPV.

**Method:** A prospective, observational registry was developed to monitor clinical and hemodynamic outcomes in patients with RVOT dysfunction treated with the Melody TPV (Medtronic Inc, Minneapolis, United States).

**Results:** 17 patients underwent TPVI with Melody TPV at The Prince Charles Hospital between Jan 2009 and Feb 2016 with a median (range) age of 34 (R: 15-60). 15 (88%) were NYHA Class 2 dyspnoea and 11 (59%) had corrected tetralogy of Fallot. Indication for TPVI was stenosis in 8 (47%), regurgitation in 2 (12%) and mixed dysfunction in 7 (41%). Device implantation was successful in all patients. Peak RVOT gradient was significantly reduced and there was no significant regurgitation post procedure. There was 1 (6%) major procedural adverse event and 2 (12%) major adverse events at last recorded follow-up. There were no patient deaths. Follow-up cardiac magnetic resonance imaging revealed a significant reduction in indexed right ventricular end diastolic volume.

**Conclusion:** This study confirms the safety and effectiveness of TPVI with Melody TPV for RVOT dysfunction in repaired CHD.

**Key words:** cardiac catheterisation, pulmonary valve implantation, heart valve prosthesis, conduit

## **Manuscript**

### **Outcomes following Melody transcatheter pulmonary valve implantation for right ventricular outflow tract dysfunction in repaired congenital heart disease: First reported Australian single centre experience**

#### **Introduction**

Long-term durability of surgical intervention on the right ventricular outflow tract (RVOT) for congenital heart disease (CHD) is highly variable, with allograft or bioprosthetic valves becoming dysfunctional and requiring further intervention over time (1). Transcatheter pulmonary valve implantation (TPVI) with the Melody® transcatheter pulmonary valve (TPV) (Medtronic Inc, Minneapolis, United States) has demonstrated good hemodynamic and clinical outcomes in the treatment of RVOT conduit dysfunction in patients with repaired CHD (2, 3). Numerous trial and registry data have demonstrated reduced RVOT gradients, elimination of pulmonary regurgitation or stenosis and good clinical outcomes early after implantation (4-7). This report presents immediate and long-term clinical and hemodynamic outcomes after TPVI with the Melody TPV in patients with repaired CHD in a single centre as a first reported Australian experience. We aim to describe the procedural outcomes, to detail any complications, with early and late follow-up of this Australian cohort of TPVI recipients.

#### **METHODS**

##### **Study Design**

A prospective, observational registry was developed to monitor clinical and hemodynamic outcomes, procedural indications and complications, and long-term follow up in patients with RVOT dysfunction treated with the Melody TPV up to last recorded follow-up. Prior to TPVI, all patient cases were presented at a multidisciplinary meeting and required consensus agreement from congenital cardiologists, interventional cardiologists, cardiothoracic surgeons with expertise in CHD, congenital radiologists and allied health staff.

##### **Inclusion Criteria**

To be eligible for TPVI with the Melody TPV patients needed an original RVOT conduit and/or pulmonary artery diameter  $\geq 16$ mm and  $\leq 22$ mm. Patients needed to be either a) symptomatic with dyspnoea, mean RVOT gradient  $>35$ mmHg and/or moderate pulmonary

valve regurgitation, or b) NYHA class 1 with mean RVOT gradient  $\geq 40$  mmHg and/or severe pulmonary valve regurgitation. Patients without contraindications underwent cardiovascular magnetic resonance imaging (CMR) to determine right ventricular end-diastolic volume indexed to body surface area (RVEDVi), right ventricular ejection fraction (RVEF) and to quantitate pulmonary regurgitation prior to intervention. Coronary artery relationship to the RVOT conduit was assessed either via CMR, computed tomography coronary angiography (CTCA) or cardiac catheterisation. Patients were excluded from TPVI with the Melody TPV if they were pregnant, had active infection, psychosocial dysfunction precluding implantation and follow-up, or structural and anatomical malformations that prevented percutaneous access and/or device deployment. Patients with native (primary) RVOT dysfunction were excluded.

### **Procedure**

Procedures were performed under general anaesthesia by a single operator with extensive experience in percutaneous structural intervention (DLW). All patients underwent right heart catheterisation and pulmonary angiography accessed via the right/left femoral vein. A Cournand catheter (Medtronic, Minneapolis, United States) with a stiff Meier wire (Boston Scientific, Massachusetts, United States) was used as a guide. Simultaneous RVOT balloon sizing and aortic root angiography was performed to rule out coronary artery compression in all patients. Dyna CT (CT scan using the cath lab C-arm) was used in the majority of patients to assess the best radiographic view and angle for deployment. All patients underwent pre-stenting of the RVOT with either a covered CP stent (Numed, New York, United States) or an eV3 stent (eV3 Endovascular Inc, Minneapolis, United States). Post-dilation was performed with a Mullins-X balloon (BV Medical, Leicestershire, United Kingdom). An Ensemble Delivery system (Medtronic, Minneapolis, United States) was then used to deploy the Melody TPV under fluoroscopy or trans-oesophageal echocardiography guidance. Post procedural right heart catheterisation measurements were obtained to determine residual gradients across the valve and pulmonary angiography was performed to confirm Melody TPV competency.

### **Data Collection and Follow-up**

Procedural data along with baseline demographics was collected at the time of procedure. Successful device insertion was defined as deployment of single Melody TPV in the RVOT conduit with no significant regurgitation or gradient and no procedural mortality. Valve

function was assessed post deployment by right heart catheterization post, pulmonary angiography, and/or trans-oesophageal echocardiography. Patients would have transthoracic echocardiogram the following day and be examined by the implanting cardiologist each daily during their admission.

Patients were reviewed at one, six and 12-months and annually thereafter. At each review, patients underwent routine electrocardiography, trans-thoracic echocardiography and completed a questionnaire to capture adverse events. Serial chest x-rays were performed annually to look for stent fractures. Adverse events were recorded retrospectively when follow-up was performed at other institutions. Major adverse events were defined as death, cardiovascular death, stroke/transient ischaemic attack, myocardial infarction or device malfunction (need for repeat procedure, failed deployment, significant residual stenosis, significant valvular or paravalvular regurgitation, strut/stent fracture, infection or embolisation). Major vascular complications were defined as those requiring interventional/surgical correction, blood transfusions or prolonged hospital stay. Major procedural adverse events were defined as any major adverse event that occurred during the procedure or within 24 hours after Melody TPV deployment. Minor adverse events were all adverse events that did not fall into an aforementioned group and did not cause significant harm. NYHA class and functional status were also recorded at each review.

### **Imaging**

Pre-procedural echocardiographic evaluation was performed per American Society of Echocardiography guidelines including: RVOT sizing, 2D pulmonary valve imaging, continuous and pulsed wave Doppler analysis for pulmonary valve mean and peak gradients, right and left ventricular size and systolic function and colour flow mapping of the RVOT to assess valvular regurgitation. Intra-procedural imaging was performed with trans-oesophageal echocardiography using a matrix array transducer with 3D imaging capability (X7-2t, Philips Healthcare Andover, MA). Follow-up CMR was performed on a 1.5T system using steady state free precession cine imaging, and phase contrast flow quantitation in patients with no contraindications (pacemaker or defibrillator).

### **Statistical Analysis**

Descriptive data are presented as means  $\pm$  standard deviation when normally distributed or as medians with range when abnormally distributed. Categorical variables are reported as

frequencies and compared with Chi-Square ( $\chi^2$ ) statistic and continuous variables were compared with a two-tailed t-test. A p-value  $<0.05$  was considered as significant. Statistical analyses were performed using GraphPad Prism version 5.0 (GraphPad, San Diego, United States).

### **Ethics**

Ethical permission for this study was obtained through The Prince Charles Hospital Human Research Ethics Committee (HREC/16/QPCH/207).

## **RESULTS**

### **Patient and Procedural Characteristics**

17 patients with a median age of 34 (R: 15-60) years underwent TPVI with Melody TPV at The Prince Charles Hospital between Jan 2009 and Feb 2016 and were included in the analysis. Baseline characteristics are summarised in Table 1.

All patients had access via the right or left femoral vein with an Ensemble delivery system, pre-dilatation of the stenosis, and deployment of a covered stent in the RVOT conduit. Median procedure time was 106 minutes. Procedural data are described in Table 2.

### **Procedural and Haemodynamic Outcome**

A Melody TPV was successfully deployed in all patients. Invasive hemodynamic measurements showed a significant improvement in RVOT peak gradient and right ventricular systolic pressure (RVSP) post TPVI (41mmHg vs 13mmHg,  $p<0.001$  and 69mmHg vs 43mmHg,  $p<0.001$ ). There was no significant residual pulmonary regurgitation in any patient post procedure.

### **Complications**

There was one major procedural adverse event; this involved an RVOT conduit tear resulting in a small loculated pericardial haemorrhage adjacent to the Melody TPV and pulmonary haemorrhage with air leak into the pleural and mediastinal space that was either a complication of the TOE probe, intubation or pulmonary artery catheter. The event occurred in a 27-year-old male with a stenosed RVOT homograft conduit created to correct congenital pulmonary atresia 20 years prior. A 20mm Ensemble delivery system was used with right femoral vein access using a 14 French sheath. A 14 French Mullins sheath was advanced to

the pulmonary conduit stenosis and an 18mm x 4.5cm Cristal balloon was inflated across the valve with a simultaneous aortogram showing satisfactory coronary anatomy. An 18mm CP stent was deployed with a 30mm x18mm BIB. A 20mm Ensemble delivery system was used to deploy a 18mm Melody TPV. No significant pulmonary stenosis or regurgitation was noted on intraprocedural transoesophageal echocardiography. No dye hang-up or contrast extravasation was noted on pulmonary angiography post deployment to suggest conduit rupture or peripheral arterial perforation. Furthermore, there was no major hemodynamic compromise during or immediately after the procedure. The following day the patient became hypoxic. Chest CT was performed which demonstrated the aforementioned findings of pneumo-mediastinum. The patient was treated conservatively without any surgical intervention and under close observation in the Coronary Care Unit. Interval chest CT after 48 hours demonstrated reduction in size of pneumomediastinum with the small loculated pericardial haemorrhage stable in size. He remained haemodynamically stable, oxygenation improved and he was discharged day 6 post-procedure, and was well at clinical follow-up.

There were four minor procedural adverse events. The first was a residual stenosis of 21mmHg across the RVOT conduit at the end of the procedure in a 28-year-old female with corrected Tetralogy of Fallot and RVOT conduit stenosis; given the predefined endpoint of procedural success being absence of a significant residual gradient, this therefore was defined as an adverse event. An 18mm Ensemble delivery system was used via the right femoral vein within an 8Fr 24cm long arrow sheath. The length of the stenotic conduit was pre-procedurally sized at 30mm using CT imaging and pulmonary angiography. A 39mm CP stent was mounted on a 22mmx5.0cm BIB and deployed through a 12Fr Mullins sheath. The delivery system was used to deploy an 18mm Melody TPV and the valve post dilated with a 22x40mm Mullins-X balloon (4 inflations at 12 atmospheres). A residual pulmonary peak gradient of 21mm was noted on post-procedural right heart catheter measurements.

Other minor procedural events included; failure of the RVOT stent to be deployed this was retrieved with a 'gooseneck' snare and a Melody TPV successfully implanted thereafter. In another patient the valve was unable to be uncovered due to rupture of the plastic delivery system. The delivery system was then removed, the Melody TPV reloaded and successfully implanted. Finally one patient had a burst balloon during implantation, but the device was successfully implanted with no clinical complications. Procedural outcome are described in Table 3.

## **Clinical Outcome**

Mean follow up was 34.9 months (R: 3.1-69.6 months). All patients were alive at last recorded follow-up. NYHA class improved or remained stable in all patients at last recorded follow-up. NYHA was unknown in 3 patients at last recorded follow-up. One patient remained NYHA class 1 having had TPVI for elevated RVOT gradients only. There was one case of minor Melody TPV stent fracture detected at last recorded follow-up on routine chest x-ray. This did not result in any device malfunction or any clinical adverse event.

There were two cases of late device malfunction at last recorded follow-up. Both events occurred in the same patient; a 21-year-old male with repaired tetralogy of Fallot, previous splenectomy and Melody TPV for mixed stenosis and regurgitation through an RVOT conduit. The first event was *Streptococcus mitis* bacteraemia at 12-months post index procedure. Septic screening tests along with transthoracic and transoesophageal echo could not identify an infective source of bacteremia. It was presumed to be Melody TPV infective endocarditis and treated with 6-weeks of intravenous penicillin. The patient experienced no further recurrence of infection since treatment.

Melody TPV stenosis occurred in the same patient 18-months post index procedure. Transthoracic and transoesophageal echocardiogram indicated thrombotic pannus as the likely cause with transthoracic echocardiogram demonstrating a mean gradient of 54mmHg through the Melody TPV. Therapeutic anticoagulation with warfarin was initiated and mean gradient through the Melody TPV reduced to 37mmHg.

Other notable events not directly related to TPVI included out of hospital cardiac arrest in a 27-year-old male 3 years after index procedure. The patient had initially presented with pulmonary regurgitation after Rastelli's procedure for levo-transposition of the great arteries. At time of the arrest his sub-pulmonic left ventricle was normal in size and function and the systemic right ventricle was severely dilated with mild systolic dysfunction. CTCA revealed no significant coronary disease. It was treated as primary ventricular fibrillation arrest secondary to systemic right ventricular dysfunction and a cardiac defibrillator was implanted with great difficulty due to his anatomy. He subsequently developed pocket site infection of

the defibrillator which was treated with a short course of intravenous antibiotics and resolved without any further intervention required.

### **Imaging outcomes**

CMR data revealed significant improvement in right ventricular remodelling as evidenced by reduction in RVEDVi (122mls/m<sup>2</sup> vs 108mls/m<sup>2</sup>, p<0.001) with no significant change in RVEF (43% vs 45%, p=0.42). Echocardiographic data demonstrated improvement in RVOT mean pressure gradient post procedurally and persisted out to last recorded follow-up. Serial transthoracic echocardiography revealed significant reduction in mean RVOT gradient and RVSP pre-procedurally compared with last follow-up (57mmHg vs 27mmHg, p<0.001 and 60mmHg vs 33mmHg, p<0.001). There was no significant change in left ventricular systolic function pre procedurally versus last recorded follow-up (Figure 1).

### **Discussion**

This study is the first reported Australian experience of TPVI with Melody TPV for RVOT dysfunction in repaired CHD and confirms its safety and effectiveness in this context. In this report, we have detailed the indications, the procedural complications, and early- and late-follow up with clinical, imaging, and haemodynamic outcomes.

These data are consistent with other reported studies (4, 5, 7-9). The registry of the Italian Society of Paediatric Cardiology included 63 patients who underwent TPVI with Melody TPV (5). Median age was 24 years (R: 11-65) with a median of 3 previous surgeries (R:1-5) and mixed aetiology of repaired CHD. Successful device insertion occurred in 61 (97%), mean procedure time was 170 minutes (R:85-360), pre-stenting was performed in 53 (85%). Procedural complications occurred in 9 (14%) including one death. This registry had higher rates of procedural complications compared to ours and is likely due to the higher risk patients in which TPVI was attempted. 8 (13%) had associated procedures including ventricular septal defect closure, aorto-pulmonary artery embolisation and pulmonary artery stent implantation versus none in our registry. There was one early mortality which occurred in the context of TPVI performed on compassionate grounds in a patient with septic shock and 4 previous cardiac surgeries. As contrast in our registry all patients were clinically stable and performed as elective procedures. 23 (37%) of patients from the Italian registry were either NYHA III or IV class dyspnoea prior to TPVI as compared to 1 (6%) in our registry.

A second registry based in France included 64 patients who underwent TPVI for RVOT dysfunction in repaired CHD (4). Median age 21.4 years (R:10.5-77.3), median procedure time was 92 minutes (R: 25-250). 62 (96.9%) had access via femoral vein, 62 (96.9%) had pre-stenting and no patient was NYHA IV. Procedural success occurred in all patients and there were no major complications. Minor procedural complications occurred in 11 (17.2%) patients and included; confined tear in RVOT conduit treated with covered stent, minor bleeding from orotracheal tube and access site pseudoaneurysm. Comparatively, our registry had one likely confined tear in the RVOT conduit, the risk of which was minimised with routine pre-stenting before deployment of Melody TPV. Indeed Melody TPV itself has been used to correct RVOT conduit rupture following balloon angioplasty (10).

In the French registry 3 patients died in the follow-up period; two from infective endocarditis and one from heart failure. The two cases of infective endocarditis occurred at 2.6 and 28.3 months after TPVI and involved RVOT conduit obstruction from valve vegetation. Late infective endocarditis with Melody TPV has been reported in other studies with the most common organisms being Staphylococcus or Streptococcus species (5, 7, 11). Abrupt aspirin discontinuation and additional unprotected invasive procedures have been described as independent predictors of Melody TPV infective endocarditis (12). Our registry had one possible case of device infection. The event must be considered in the context of baseline immunocompromise with the patient having previously had a splenectomy. Furthermore, only one blood culture was positive with several subsequent negative blood cultures prior to the initiation of antibiotics makes the diagnosis of Melody TPV presumptive. Nevertheless there remains a long term risk of infective endocarditis, as for any prosthetic valve.

The patient who died from heart failure in this French registry presented 23.7 months after TPVI and had the index procedure in the setting of advanced heart failure with severe biventricular dysfunction. Comparatively all except one of our patients had normal left ventricular ejection fraction at baseline and likely contributes to the low incidence of heart failure and death in the follow-up period.

Stent fracture for Melody TPV has a reported prevalence of  $33\pm 4\%$  at 1 year after TPVI when assessed with routine chest radiography and multiplane fluoroscopy and need for RVOT reintervention was  $14\pm 4$  at 2 years in the early studies (13). TPV compression and apposition to the anterior chest wall were associated with shorter freedom from stent fracture

and need for RVOT reintervention (13). Our registry had lower rates of stent fracture than other early registries which was likely due to routine pre-stenting prior to Melody TPV deployment. Pre-stenting has demonstrated significant reductions in percutaneous pulmonary valve stent fractures as compared to percutaneous pulmonary valve implantation alone and has become standard in the modern era (HR 0.35, 95% CI 0.14-0.87, p=0.024)(13). By providing a defined conduit for placement of Melody TPV and absorbing radial load, pre-stenting appears to be a safe and effective means of improving outcome in TPVI. A limitation from this study was that no routine CT or fluoroscopic investigations were performed, other than chest Xray, to assess for stent strut fracture. This may have led to an under-reporting of stent fracture in the follow up period.

Patients with abnormal coronary anatomy tend to be at a non-statistically significant higher risk of coronary artery compression due to aberrant arterial courses running close to the conduit, compared to those with normal coronary arterial anatomy (14). A US registry looked at the incidence and predictors of coronary artery compression with Melody TPV and found 5% of patients had evidence of coronary artery compression during simultaneous RVOT and coronary angiography and 71% of this subset had abnormal coronary anatomy. These patients did not undergo TPVI. Patients with history of Tetralogy of Fallot and transposition of the great arteries were at increased risk of coronary artery compression (15). Coronary artery compression after Melody TPVI has been described up to 3 months post TPVI (16). In our experience, cross-injection via selective engagement of the aberrant coronary artery during balloon inflation allowed careful intra-procedural evaluation of compression, and in all cases allowed safe delivery of the Melody TPV without complication. Pre-procedural planning with CTCA or MRI was also important in preventing coronary artery compression.

DynaCT (CT scan performed using the hybrid lab C-arm) was employed to image the RVOT conduit and optimise fluoroscopic implant angles. This technique has been used in imaging the aortic root and the ilio femoral system in transcatheter aortic valve replacement with proven benefit for successful valve deployment and access site complications (17). Our experience suggests that it may also be of benefit in TPVR. Comparison between major Melody TPV registries and this study are described in Table 4.

Cost analysis of percutaneous pulmonary valve replacement has been performed through comparison to standard surgical conduit replacement. Cost of Melody TPV was \$30,500 USD

higher than surgical conduit cost of \$8,700 USD, however the total procedural costs were nearly identical at just less than \$50,000 USD. Over the subsequent years, given the need for repeat re-intervention, surgical conduits resulted in modest cost savings (18). The anatomic variability of the RVOT conduit and its mechanical variability in the chest still need to be addressed in the design and development process of percutaneous valve intervention (19). These benefits must be taken in context of improving percutaneous technology techniques which will hopefully result in reduced long term costs.

**Limitations:** The lack of standardised single centre follow-up at the treating institution was a limitation of this study, which may have impaired the accuracy of long term outcome data. This was largely unavoidable. Due to the highly specialised nature of the procedure, a number of patients in this series were referred from interstate or from distances over 1000km. Follow-up within the first year was typically performed at our hospital, however after that most patients chose to have annual follow up with a local cardiology service and/or via telehealth link. As such serial data parameters such as echocardiograms and ECG were not standardised. This issue was addressed in best part through phone calls performed prior to data collection for this study to ensure no adverse events had been missed.

### **Conclusion**

This study presents the first reported Australian longitudinal data using the Melody TPV and confirms the safety and effectiveness of TPVI with Melody TPV for RVOT dysfunction in repaired CHD. Multidisciplinary input, careful pre-procedural imaging to identify suitability as well as variant coronary anatomy, and intra-procedural imaging with angiography, fluoroscopy +/- trans-oesophageal echocardiography allowed for minimal adverse events with excellent long-term outcomes when performed electively in appropriately selected patients for treatment of RVOT dysfunction.

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