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ORIGINAL ARTICLE

Outcomes Following Melody Transcatheter Pulmonary Valve Implantation for Right Ventricular Outflow Tract Dysfunction in Repaired Congenital Heart Disease: First Reported Australian Single Centre Experience

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Background Transcatheter pulmonary valve implantation (TPVI) with the Melody® transcatheter pulmonary valve (TPV) has demonstrated good haemodynamic and clinical outcomes in the treatment of right ventricular outflow tract (RVOT) conduit dysfunction in patients with repaired congenital heart disease CHD. 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 haemodynamic outcomes in patients with RVOT dysfunction treated with the Melody TPV (Medtronic Inc, Minneapolis, United States).

Results Seventeen patients underwent TPVI with Melody TPV at The Prince Charles Hospital between January 2009 and February 2016 with a median (range) age of 34 (R: 15–60). Fifteen (88%) were NYHA Class 2 dyspnoea and 11 (59%) had corrected Tetralogy of Fallot. Indication for TPVI was stenosis in eight (47%), regurgitation in two (12%) and mixed dysfunction in seven (41%). Device implantation was successful in all patients. Peak RVOT gradient was significantly reduced and there was no significant regurgitation post procedure. There was one (6%) major procedural adverse event and two (12%) major adverse events at last recorded

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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.

Keywords Cardiac catheterisation • Pulmonary valve implantation • Heart valve prosthesis • Conduit

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 haemodynamic 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 haemodynamic 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 haemodynamic 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 ≥16 mm and ≤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 ≥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). Postdilation 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 transoesophageal 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 catheterisation post pulmonary angiography, and/or transoesophageal echocardiography. Patients would have transthoracic echocardiogram the following day and be examined by the implanting cardiologist each day during their admission.

Patients were reviewed at 1, 6 and 12 months and annually thereafter. At each review, patients underwent routine electrocardiography, transthoracic echocardiography and

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