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Fifteen years of experience with the melody™ TPV for percutaneous pulmonary valve replacement

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ABSTRACT

Background: The Melody™ TPV has been used as an alternative to surgical pulmonary valve replacement; limited medium-term follow-up data are available.

Aims: To report the follow-up data of all Melody™ TPVs implanted locally over a 15-year period (2006–2021).

Methods: Single-centre non-randomised prospective observational study of all implanted Melody™ valves in the pulmonary position.

Results: 234 Melody™ valves were implanted at a mean age of 20.8±24.6y. Indications for valve implantation included: pulmonary stenosis (47.2%,) regurgitation (30.9%), and mixed pathology (21.9%). The implant zone substrate consisted of homograft in 52.6%, patched right ventricular outflow tract in 33.8%, and bioprostheses in 13.6% of the cases. Valve survival at 10 years was 89% and 72% at 15 years follow-up. Pulmonary stenosis and pulmonary and tricuspid valve regurgitation demonstrated no significant evolution over the 15-year follow-up. Over the study period, there were 7 deaths at a mean age of 54.2±21.1y; none was valve related. Valve failure was observed in 22 cases (9.4%), mainly due to endocarditis 13/22 (59.0%). The overall incidence of endocarditis was 1.5% per patient-year and occurred in 10.2% ($n=24$) of patients 2.7±1.6y after TPV, mostly in younger men (median 18.3, range 8.1−49.5 y). Balloon dilatation to accommodate for somatic growth was successful in all 17 (7.3%) attempted cases.

Conclusion: The Melody™ valve had a low risk for valve failure with overall well-preserved valve function over up to 15 years of follow-up. Endocarditis remains a concern. The Melody™ valve is competitive with other surgical and percutaneous conduits.

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Introduction

The Melody™ valve (Medtronic Inc., Minneapolis, MN, US) is the first transcatheter pulmonary valve (TPV) that became available for the treatment of dysfunctional right ventricular outflow tracts (RVOT). The valve received CE marking in 2006 and FDA approval in 2010.

Percutaneous pulmonary valve implantation (PPVI) with the Melody™ TPV has been established to be safe and effective [1–3]. The initial experience illustrated the importance of pre-stenting of the RVOT to prevent stent fractures and subsequent valve failure [4–6]. Short to medium-term outcomes appeared to be satisfactory and indicated that stent fractures, implantation at a young age (<21 years), and infective endocarditis were the main risk factors for reintervention [5–10]. The Melody™ TPV can be used to treat large, dilated dysfunctional patched right ventricular outflow tracts but with several technical challenges due to the limited diameter of the valve [11–14]. However, larger valves such as the balloon-expandable SAPIEN 3, the self-expanding Medtronic Harmony™, and the MedTech Venus-P™ valves have become available, facilitating safer implantation in large outflow tracts [15–18].

Although the Melody™ TPV appears to compare favourably with surgical conduits, longer-term data is required. The present study reports the medium to long-term follow-up data of all Melody™ TPVs implanted at our institution over a 15-year period.

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Methods

Patients

This is a single-centre non-randomised prospective observational study of all Melody™ valves implanted between 2006 and December 2021. Standard techniques for implantation were used and all procedures were performed under general anaesthesia as previously described [8]. Landing zone was carefully prepared by aggressive pre-stenting until no twisting or torsion of pre-stents was observed; usually, multiple pre-stents were placed in stenotic conduits and as experience grew, we aimed to abolish any residual gradient. In stenotic lesions pre-stenting and valve implantation were performed during the same procedure. In large or conduit-free outflow tracts pre-stenting was performed followed 6–8 weeks later by PPVI in order to allow ingrowth of the pre-stent. Standard prophylactic antibiotic regimens were followed [8].

Follow up

The follow-up was at 1, 3, 6 and 12 months followed by annual visits thereafter. Serial echocardiography was performed with assessment of the following: peak instantaneous gradient (Continuous wave Doppler (CW)) across the RVOT in m/s, pulmonary regurgitation (0 = none, 1 = trivial, 2 = mild, 3 = moderate and 4 = severe) and tricuspid valve regurgitation (0 = none, 1 = trivial, 2 = mild, 3 = moderate and 4 = severe) as well as peak gradient (CW) of the tricuspid regurgitation signal. Two patients were lost during follow-up and ten patients are in follow-up abroad in whom no follow-up data are available.

Outcome

Primary outcome measures were Melody™ TPV failure, valve dysfunction, freedom from valve-related reoperation, catheter reintervention or death. Secondary outcome measures included infective endocarditis, stent fractures, non-valve related reinterventions (e.g. pacemaker implantation, etc.), and balloon dilatation of the valve for somatic growth of the patient. Valve failure was defined as the need for surgical explantation or redo PPVI.

Ethics

Approval for the study was granted by the local ethics committee of the University Hospitals, Leuven (project no. S67496). Assent and informed consent were obtained from patients, their parents or legal guardians.

Statistical analysis

SPSS version 26 (IBM) was used and GraphPad Prism (graphics). Continuous variables are summarised by means with standard deviation and median with range or interquartile range (IQR). Categorical values were summarised as numbers and percentages of the total. Paired data was analysed by a paired *t*-test or Anova for multiple comparisons. Kaplan-Meier estimates were used for survival analyses, presented as mean with a 95% confidence interval (CI).

Results

Patients

A total of 234 Melody™ valves were implanted over the study period. The mean age at PPVI was 20.8 ± 14.2 years with a male preponderance of 63.6% (male $n = 149$, female $n = 84$). The primary heart lesion in the vast majority of patients was tetralogy of Fallot ($n = 120/234$, 51.9%) followed by pulmonary valvar stenosis ($n = 31/234$, 13.4%), double outlet right ventricle ($n = 24/234$, 10.4%), common arterial trunk ($n = 17/234$, 7.4%) and Ross operation for aortic valve stenosis ($n = 39/234$, 6.9%). The main indication for PPVI in these patients was pulmonary stenosis (PS) in 110/234 (47.2%), regurgitation in 73/234 (30.9%) and mixed in 51/234 (21.9%). About half of the valves were implanted in previously placed surgical homografts (52.6%, $n = 123$), native or patched RVOT in a third (33.8%, $n = 79$) and bio-prosthesis (e.g. Contegra™) in 32 (13.6%). Pre-implant diameter of the intended landing zone varied from 10–25 mm.

In one patient, immediate surgical removal of the valve was required as a result of coronary compression. Seven patients were demised over the study period, but none of the deaths were procedure or valve related. The median age at death was 54.2 years (IQR 20.7 – 74.0) and the median time of death after the PPVI procedure was 3.1 years (IQR 1.5 – 8.1).

Valve function

During follow-up, the mean RVOT Doppler gradient was 25 ± 12 mmHg after 5 years, 28 ± 11 mmHg at 10, and 34 ± 12 mmHg at 15 years follow-up (Figure 1(A and B)). None of these quinquennial increases reached statistical significance. Likewise, pulmonary and tricuspid valve regurgitation essentially remained unchanged and trivial at 5, 10, and 15 years of follow-up. Estimated right ventricular systolic pressures were a mean of 33 ± 10 mmHg at ten years and 37 ± 13 mmHg at 15-year follow-up ($p = 0.116$).

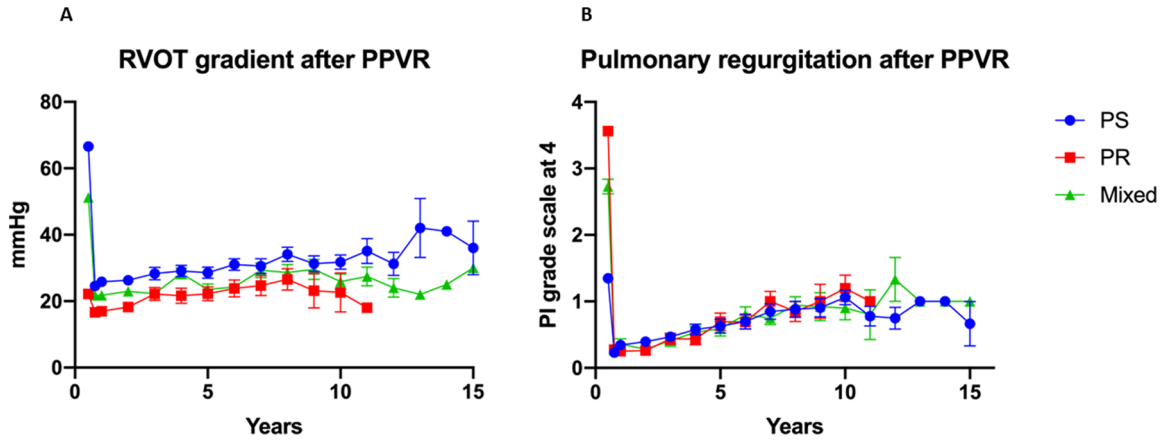

Figure 1. (A) Evolution of the gradient expressed in mmHg across the RVOT measured by means of echocardiography. (B) The evolution of valve regurgitation (scale at 0–4) measured by means of echocardiography. The error bars express the 95% CI.

Valve-related reintervention

Balloon dilatation to accommodate for somatic growth was carried out in 17 cases (7.3%) a mean of 4.0 ± 2.1 years after the original PPVI, which was implanted at a mean age of 12.6 ± 3.8 years. The mean age at the time of balloon angioplasty was 16.6 ± 4.3 years. An 18 mm Ensemble™ was used for the original PPVI in two, a 20 mm in eight, and a 22 mm in seven children. In one case, repeat PPVI was performed six years after balloon dilatation due to a stent fracture.

Endocarditis

Endocarditis occurred a mean time of 2.7 ± 1.6 years after implantation in 10.2% ($n = 24$) of patients. The earliest IE occurred 7 months and the latest IE 9 years after PPVI. In 7 cases, IE occurred within 2 years after PPVI. The median age at the event of IE was 18.3 (range 8.1 – 49.5 years) and occurred dominantly in males (75%, 18/24). The annualised incidence of endocarditis was 1.5% with a peak of 3.5% in 2013 to 2015 (Figure 2). After new endocarditis protocols, it has declined to 0.9% per patient year in 2021. Bacteria could be identified in 87.5% (21/24) of cases: S. viridans (4/21 – 19.0%), S. aureus (7/21 – 33.3%) and the vast majority was the HACEK group (10/21 – 47.7%). All patients received antibiotic treatment according to the international guidelines [19]. In thirteen (54.2%) of IE cases, the Melody™ valve needed early replacement at median 41.5 days (IQR 4–855) after diagnosis of IE. In ten (10/13) cases, the valve was surgically replaced using a homograft and redo percutaneous valve replacement was performed in the remaining three cases. Seven patients underwent late valve replacement (median: 6.1 mo; IQR 4.7–116.8) after the IE event due to progressive valvular and subvalvular stenosis. In three, the valve was replaced by a homograft and a redo PPVI was performed in four. There were no IE-related deaths.

Valve failure

Valve failure was observed in 22 of 234 valves (9.4%) with overall freedom from explant of 89% at 10 years and 72% at 15 years follow-up (Figure 3). The main cause of valve failure in this cohort was early after endocarditis in 59.0% ($n = 13$) of the cases. Other reasons for valve failure were progressive pulmonary valvular stenosis in 22.7% ($n = 5$, late endocarditis group), sub-pulmonary obstruction in 13.6% ($n = 3$, two associated with late endocarditis), and a hemodynamic important stent fracture in one case (4.5%). Surgical explant was performed in thirteen patients and repeat PPVI in nine.

Redo PPVI

Redo PPVI was performed with the Melody™ TPV in 6 patients and with the Edwards SAPIEN 3 (Edwards Lifesciences, Irvine, US) in three other patients. Prior to the redo PPVI procedure, pre-stenting was performed in each patient using 1 pre-stent in seven patients, 2 in one patient, and 4 pre-stents in another patient. For the redo PPVI, a 22 mm Ensemble™ was used in 3 cases and a 24 mm BIB-balloon (Numed NY, US) in 1 case. One 23 mm and two 26 mm SAPIEN 3 valves were implanted.

Other treatments

Seven patients required a pacemaker and 4 patients ICD implantation at a median of 3.8 years (IQR

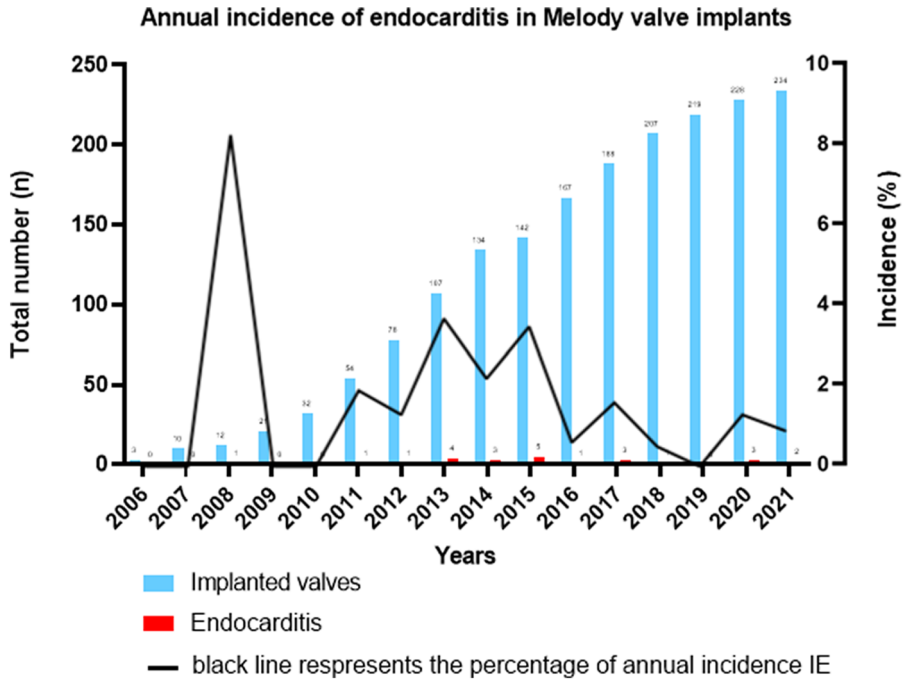

Figure 2. Annual incidence of infective endocarditis. The numbers of endocarditis (red) are displayed with the number of implanted valves (blue). The percentage of annual incidence is displayed by the black line.

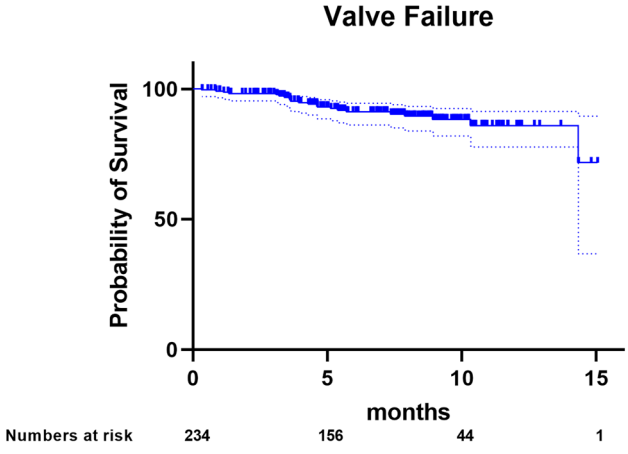

Figure 3. Freedom from valve failure. Kaplan–Meier curves depict the freedom from valve explant (blue line) and redo PPVI (red line). Estimates displayed with 95% CI.

0.2–10.0) after PPVI. Six patients underwent an electrophysiological exam and/or ablation a median of 2.0 years (IQR 0.5–11.5) after PPVI. The indication for ablation was an intra-atrial re-entrant tachycardia in all cases.

Discussion

The study is currently one of the larger and longest follow-up investigations of the Melody™ TPV for percutaneous pulmonary valve replacement. The data show a low risk of valve failure with preserved valve function up to 15 years after valve implantation. The fact that the valve can be expanded to accommodate somatic growth is an advantage of the Melody valve. Endocarditis remains a concern and is an important cause of valve failure. Adequate pre-stenting is important to prevent and avoid early failure of the valved stent [4, 6, 20].

Valve function

The mean gradient over the RVOT increased slightly in the years following implantation but remained relatively unchanged with a mean of 34 mmHg after fifteen years of follow-up. Pulmonary and tricuspid valves also did not show any significant increase in regurgitation.

The data closely matches the data from the US investigational Device Exemption Trial where a mean gradient <30 mmHg was seen at 10 years follow-up [7].

In PPVI studies, the description of the causes of valve failure and the long-term durability of the relevant bio-prostheses are inconsistent. It would be important to accurately describe structural and non-structural valve dysfunction to make accurate comparisons of pulmonary valve failures possible similar to studies conducted in mitral and aortic valves [21, 22]. Structural valve dysfunction is defined as changes intrinsic to the valve which can be either leaflet disruption, flail leaflet, thickening, stent fracture, or deformation of the valved stent leading to hemodynamic changes [21, 22].

Redo interventions

The vast majority of cases that required balloon dilatation had the need to increase the valve diameter to accommodate for somatic growth. Most of these patients were fairly young at initial PPVI (12 y). This is a noteworthy advantage of the Melody™ TPV which allows progressive dilatation up to 24 mm. This feature is of interest, certainly for use in a paediatric population [23].

It is also possible to dilate the stent of the Melody valve beyond the nominal diameter which enables the implantation of a larger percutaneous valve. In this series, two 26 mm Edwards Sapien valves could be fully expanded at redo PPVI. Dilating beyond the nominal diameter appears not possible with the SAPIEN valve and it is not described with the current self-expanding valves [15, 24].

Valve failure

Freedom from valve replacement of the Melody™ TPV in the present study was 89% at 10 years and 72% at 15 years which compares favourably to other conduits. Dang Van et al. reported freedom from failure of 81.6% at 10 years after implantation of large pulmonary homografts (mean 24.9 ± 1.9 mm) in the RVOT [25]. The data from the surgical ESPOIR trial demonstrated better freedom from explant and less structural valve degeneration at 10 year follow-up of a decellularized pulmonary homograft (95.5%) compared to the cryopreserved homografts (83.0%) [26]. Pulmonary valve replacement with the bioprosthetic Freestyle valve showed freedom from re-intervention of 71% at 10 years and freedom from structural valve dysfunction of 61% at 10 years [27]. A recent comparison between pericardial and porcine valves showed a higher reoperation-free rate for porcine valves of 81.3% versus 60.6% at 15 years FU for pericardial valves [28]. Boethig et al. compared 226 transcatheter valves to surgical conduits for pulmonary valve replacement and concluded that transcatheter valve performance was equal to homografts and significantly extended durability, doubling freedom from explant [29].

It is difficult to compare with the other percutaneous pulmonary valves as follow-up is limited. To date, the longest published follow-up of the SAPIEN valve for PPVI is 5 years [30]. The reported follow-up data of the self-expanding valves are even less and only short-term outcomes have been reported for the Venus-P and Harmony valves [15, 16].

Endocarditis

The main reason for valve dysfunction and failure in our cohort was endocarditis with an average incidence of 1.5% per year and tended to occur dominantly in younger males. Young age at IE appears to be a consistent finding in other reports. In the US multicentre trial, the median age was 22 years in patients where the valve did not need to be explanted and 17 years when explant was required similar to our results [31]. Likewise, the median age of IE was 24.9 years in a French comparative study [32]. It should be mentioned that endocarditis guidelines and their interpretation and implementation changed significantly over the study period. In our centre, we followed the guidelines of the European Society of Cardiology with amendments and revisions in 2009 and 2015 [33, 34]. We observed a peak incidence in 2015 of 3.5%, which then was drastically reduced by employing multiple measures including thorough education of patients, parents, health professionals, and advanced implantation techniques aiming to maximally reduce RVOT turbulence and gradients. Hascoet et al. compared the risk of IE after PPVI with the Melody and predominantly larger SAPIEN valves in 79 patients. All cases of IE were observed after Melody TPV (25% vs 0%) with an implant ratio of 40.5% Melody TPV and 59.5% Sapien valves [32]. The incidence of IE in this study was substantially higher than our results at 5.7% per patient-year with a cumulative incidence risk of 30.1% after 6 years [32]. In the US trial, freedom from IE was 81% at 10 years with an annualised rate of 2.0% per patient-year [7]. The Edwards SAPIEN XT has a freedom from IE of 98.4% at 5-year follow- up in the French registry [30]. However, in a review of adult transcutaneous aortic valves which uses the same valve, endocarditis was observed and reported in this older population in 0–14.3% with a mean of 3.25% [35]. In decellularized pulmonary homografts, the ESPOIR trial showed an IE incidence of 0.15% per patient year [26].

The bovine jugular vein valves, Melody™ and Contegra™ did show to have the highest risk for IE after pulmonary valve replacement in the German nationwide registry-based analysis (Hazard ratio 5.49 and 6.72, respectively) [36]. In a total of 203 stented porcine bioprotheses (Hancock, Mosaic and Epic) used for pulmonary valve replacement 4 patients developed IE [37]. The plausible mechanism for higher susceptibility for IE remains unclear. Explanted Melody™ valves for IE did show persistent acute inflammation with presence of granulocytes in the graft wall despite antibiotic treatment. The authors hypothesised that the space between the valved stent and the 'old' conduit may represent an area that antibiotics cannot reach well due to only sparse neo-vascularization [38]. Residual turbulent flow has been suggested as another potential risk factor for IE after PPVI [39].

In 13 patients, the valve needed to be replaced either surgically or percutaneously in days or weeks after diagnosis of IE. Another seven patients underwent late valve replacement in the months to years after the IE event due to progressive valvular and subvalvular stenosis. In the present study, there were no deaths due to endocarditis or procedure-related issues. Jones et al. reported 5/149 (3.3%) deaths because of endocarditis after PPVI with the Melody™ TPV and in the French registry, 3 patients died from IE [7, 40].

Use in large native or patched outflow tracts

In patients with large native or patched outflow tracts the use of the Melody™ valve with a maximal functional outer diameter of 24.1 mm has decreased the last years. Although it is feasible to use the Melody™ TVP to a certain extent in this subset of patients, larger balloon- expandable valves such as the SAPIEN and, more recently, the self-expanding Medtech Venus- P and Harmony TVP valves are more appropriate for this specific anatomy [14–16, 41, 42].

Limitations

The data are from a single institution which limits the number of implants. The study is non- randomised and the valve was not compared to surgically implanted valves over the same study period in the centre. Although IE is reported in other centres to various extent, extrapolating these data should be done with caution as local policies about IE prophylaxis might vary among hospitals and geographic areas. The cathlab team and follow-up was consistently the same, which is a strength of the study.

Conclusion

The Melody™ TPV shows a low risk for valve failure with overall well-preserved valve function up to 15 years of follow-up. The main reason for valve failure was endocarditis. It is feasible to increase the valve size to accommodate for somatic growth and the stent can be over- dilated to allow redo PPVI with other, larger valves. Our results show that the Melody™ TPV is comparable to surgical options and other percutaneous bio-prostheses for PPVI.

Impact on daily practice

The Melody TPV has good freedom of graft survival up to 15 years after implant. The development of endocarditis remains a concern. The valve can be expanded according to somatic growth. The Melody TPV is at least comparable to surgical options and other percutaneous bio-prostheses for PPVI

Disclosure statement

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