Melody valve to replace the mitral valve in small children: Lessons learned

Vilius Dranseika, Rene Pretre, Oliver Kretschmar, Hitendu Dave

Children's Heart Centre and Children's Research Centre, University Children's Hospital, Zurich, Switzerland

ABSTRACT

Objective	:	Infants requiring mitral valve replacement have few viable options. Recently, stented bovine jugular vein graft (Melody) has been surgically implanted in such cases. Herein, we report our experience, elaborating on evolution of implantation technique, pitfalls, as well as long-term outcome (including late dilatability).
Methods	:	Seven Melody valves were implanted (2013–2019). The median patient age and weight were 6.7 (1.8–30.5) months and 5.8 (4.6–9.5) kg, respectively. The indications for implantation were mitral stenosis and/or regurgitation postatrioventricular septal defect (AVSD) repair (5), congenital mitral valve dysplasia (1), and Shone's complex (1). Operative technique involved shortening the valve and creating a neo-sewing ring at 2/3 (atrial)–1/3 (ventricular) junction. Implantation was followed by intraoperative balloon dilatation.
Results	:	Five out of seven patients survived the perioperative period (one death due to technical failure and the other due to acute respiratory distress syndrome postcardiopulmonary bypass). Two out of five medium-term survivors got transplanted (1) or died due to acute myeloid leukemia (1). No valves were replaced. The mean echo gradient at discharge was a median 4 (2–6) mmHg. None of the patients showed left ventricular outflow tract or pulmonary venous obstruction. Two Melody valves were dilated late (5 months and 3 years postoperatively), resulting in decreasing mean gradients from 6 to 1 and from 17 to 4 mmHg. At last follow-up, surviving Melody had a mean gradient of 4 (1–9) mmHg.
Conclusions	:	Mitral valve replacement with a Melody valve is feasible in infants, is reproducible, shows good immediate results, and offers the possibility of later dilatation. This technique offers a better solution compared to the existing alternatives for infants requiring a prosthetic mitral valve.
Keywords	:	Bioprosthesis, complete atrioventricular septal defect, congenital valvular disease, Melody valve, mitral valve replacement in infants and children

Address for correspondence: Prof. Dr. Hitendu Dave, Congenital Cardiovascular Surgeon, Children's Heart Centre and Children's Research Centre, University Children's Hospital, Zurich, Switzerland. E-mail: hitendu@hotmail.com

INTRODUCTION

Options to replace irreparable mitral valves in infants are limited. Mechanical valves are often too big, especially for infants. They pose challenges to implantation technique, unhindered function, effective anticoagulation, and pannus formation, in addition to predestining them to multiple reoperations. Bioprosthesis do not need anticoagulation, but are hard to get (especially in small sizes), and degenerate quickly, thus necessitating replacements.[1,2] Several groups have proposed the use of stented biological valves considering their potential for catheter dilatation as the child grows.[3] One such valve is the Melody® (Medtronic Inc., Minneapolis, USA) valve, a stented bovine jugular vein graft, developed for use as a transcatheter pulmonary valve substitute. We have pursued an "off-label" surgical-hybrid implantation of the Melody valve in mitral position for small children since 2013.[4] Herein, we describe our 6-year experience of 7 Melody implantations in mitral position.[5]

METHODS

Patient and public involvement

Based on ethical approval for reporting this technique as a part of a multicentric study (15), written informed consent for off-label use of Melody valve as a life-saving strategy was obtained preoperatively from parents of the children. The Cantonal Ethics Committee of Zürich waived the need for ethical approval for an assimilated report of a small number of such procedures (when not performed or published as a systematic study)

Patients

Melody valve was implanted using a surgical-hybrid approach in 7 patients (2013–2019). The first patient received an 18 mm Melody model; all others received a 20 mm Melody model. The choice was not deliberate but rather on the logistics of availability. The median age and weight were 6.6 (1.7–30.5) months and 5.1 (4.6–9.5) kg, respectively. The indications for implantation were severe left atrioventricular (henceforth referred to as mitral) valve regurgitation and/or stenosis (5 patients) following repair of complete atrioventricular septal defect (AVSD), congenital mitral dysplasia (1 patient), and Shone's complex (1 patient). A mitral valve repair was always attempted, and a replacement was considered when the repair was unsatisfactory and unlikely to achieve a satisfactory clinical outcome. Valve function (gradient and regurgitation), pulmonary veins, and left ventricular outflow tract (LVOT) were analyzed intraoperatively with transesophageal echocardiography and postoperatively with transthoracic echocardiography at regular intervals. Follow-up was complete at a median of 11 (4–58) months (excluding 1 death on the table due

to technical failure and 1 death on postoperative day 11 due to acute respiratory distress syndrome (ARDS) unrelated to Melody).

Surgical technique

Since the description of surgical Melody implantation,[5] the technique has evolved. While describing our technique, we shall refer to the potential pitfalls, which we have learned to avoid using certain modifications.

Once the decision to replace the valve is made (sometimes intraoperatively after a failed repair), the atriotomy can be quickly closed and the heart can be allowed to be perfused (kept beating). Rarely, a decision to replace can be made beforehand, allowing valve preparation before instituting cardiopulmonary bypass.

Preparing the valve

The high profile of the Melody poses the first challenge when considering the small infants, where this valve is likely to be used most often. The Melody is shortened from 28-30 to about 20 mm, by bending the distal and proximal stent struts backward, thus facilitating implantation in the left heart, which is not yet enlarged, to the extent seen in bigger children or adults with chronic mitral regurgitation (MR) [Figure 1a]. Caution is warranted to avoid distortion of the valve at the commissures as well as at the scallops. A water test of the valve confirms the competence of the valve. We now routinely suture a sewing ring made of a strip of xenopericardium on the outer surface of the Melody [Figure 1b]. One should be careful while stitching the sewing ring to the thin-walled conduit, in order to avoid stitching through the leaflets. In view of the small size of the patients, we have of late exclusively created this neo-sewing ring at the premarked junction of distal 1/3 and proximal 2/3 of the valve. However, this may be modified depending on the confidence of accommodating ventricular part of the valve without causing LVOT obstruction (LVOTO).

Implantation

At this stage, cardioplegia is accomplished. We have effectively used trans-septal as well as left atriotomy
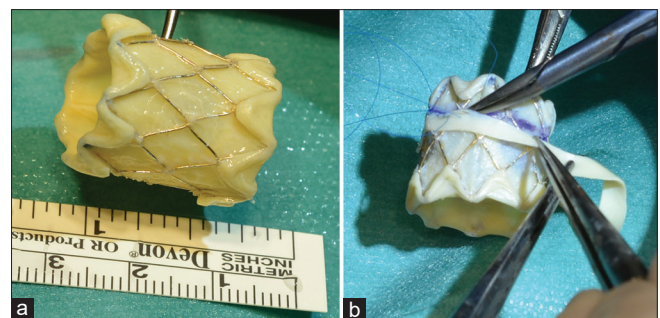

Figure 1: (a) Foreshortened Melody valve by turning back the struts. (b) Creation of a neo-sewing ring at the junction of proximal 2/3rd and distal 1/3rd of Melody® valve

(Waterston's groove) approaches for the implantation, depending on how dilated the left atrium is. The body of the native valve tissue is resected in its entirety. In one of our first cases where subvalvular apparatus was completely resected, we encountered an early LV dysfunction, which eventually recovered. Hence, we do consider preserving the subvalvular apparatus whenever possible. Islands of tissue hosting primary chordae of the anterior leaflet are retained and easily incorporated in the annular Ticron mattress stitches. If the posterior leaflet tissue is thin, and does not occupy annular space, it can be completely retained. Retaining both the anterior and the posterior subvalvular apparatus has not hindered the ventricular part of the Melody, thanks to only about 5 mm ventricular profile of the Melody in our technique. Pledgeted 5-0 Ticron stitches are placed first at the mitral annulus in horizontal mattress fashion with pledgets placed at the atrial side. The Melody valve is crimped by circumferential finger pressure on a 5 ml syringe and positioned into the annulus. Thereafter, preplaced mitral annular sutures are pierced and tied onto the sewing ring. Placing sutures on the sewing ring first and then parachuting it down may lead to entangling of sutures around the struts, leading to significant valve dysfunction (encountered in one of our early patients).

Balloon dilatation and septal fenestration
A partial dilatation of the valve may be performed before tying the sutures, if necessary. Once tied, Melody valve is progressively dilated to 14 or 16 mm, considering patients' expected valve size as well as the size of the available annulus. Although not encountered by us, overzealous dilatation can cause AV block or stretching/compression of the left circumflex artery. For the same reasons, the placement of stitches at the 2 o'clock position as well as along the posterior annulus (especially in infants) should be carefully titrated. The valve and the subvalvular ventricular cavity are inspected and valve competence is confirmed. A 3 mm opening in the fossa ovalis is created with a punch at a preferably posterior location, thus facilitating future catheter access of the left atrium and balloon dilatation of the Melody. The left atrium or the interatrial septum, as the case may be, is often enlarged with a xenopericardial patch to increase left atrial volume. A brief inspection of both sided pulmonary veins ensures unhindered flow into the valve.

Postoperative management
All patients received therapeutic anticoagulation after mitral valve replacement (MVR). Considering the challenges of managing Coumadin anticoagulation in infancy, crystalline heparin therapy was started immediately postoperatively. This was replaced by therapeutic enoxaparin subcutaneously after discharge from the intensive care unit. In older infants, enoxaparin

gave way to Coumadin with a target INR of 2–3. For lack of systematic studies and the high valve profile in the left atrium, we plan therapeutic anticoagulation for 12 months and aim to replace it thereafter with aspirin. Despite this protocol, the oldest child with Melody at 5 years underwent therapeutic anticoagulation on insistence of the parents.

RESULTS

Implantation was successful in all but 1 case. Table 1 depicts the demographics and outcome of the patient cohort.

Mortality and transplantation

A 1.7-month-old child with congenital mitral dysplasia (mixed lesion) as well as tricuspid dysplasia suffered LVOTO during Melody implantation. Intraoperative attempt to correct this led to LV rupture and death on the table. A 2.4-month-old child undergoing complete AVSD repair developed severe MR and shock lung requiring postoperative Extra Corporeal Membrane Oxygenation (ECMO). Despite a successful salvage MVR with Melody, the child succumbed to ARDS on ECMO (day 11). One child was diagnosed with acute myeloid leukemia after a successful AVSD repair. He developed late Mitral dysfunction at 30.5 months of age, which was successfully treated with MVR using a Melody. Despite well-functioning Melody, the child succumbed to sepsis, 11 months postimplantation at a district hospital. One child with Shone's complex (status post-Ross–Konno operation) underwent MVR with Melody at 6.6 months of age and was successfully transplanted at 8.5 months due to LV diastolic dysfunction. Three children with Melody *in situ* are alive and free from replacement or transplantation.

Pulmonary vein and left ventricular outflow tract obstruction

None of the acute survivors showed Melody-induced pulmonary venous obstruction. The first implantation (nearly half of the valve protruding in the ventricular cavity) developed an initial LVOT gradient (maximum 40–60 mmHg); this reduced spontaneously after cessation of adrenaline and better preloading. None of the other patients where the ventricular part was about 7 mm developed any such gradient [Figure 2].

Melody function

In situ duration of Melody in acute survivors was 11 (4–58) months. None of the valves needed replacement. None of the valves suffered more than trivial/mild regurgitation. Mean postoperative gradients were a median of 4 (2–6) mmHg at discharge and of 4 (1–9) mmHg at follow-up. Figure 3a and b depicts the two-dimensional echo as well as color Doppler flow profile through the longest surviving Melody valve *in situ* for 5 years.

Table 1: Patient characteristics

Chronological Serial number	Diagnosis	Age at index operation	Duration index operation to MVR	Age at MVR (months)	Weight at MVR (kg)	Postoperative mean gradient	Fup mean gradient	Fup months	Late transcatheter dilatation	Death/Melody removed duration	Cause of death/transplant
1	Postcomplete AVSD repair	5.2	4.1	30.5	9.5	4	4	12.7	Ø	Late death at 13 months	Sepsis post-AML
2	Congenital mitral (stenosis and regurgitation) and tricuspid dysplasia	1.7	0	1.7	4.7	Death on table at 0 months					Ventricular rupture during Melody implantation
3	Postcomplete AVSD repair	3.0	3.5	5	5.1	2	9	58	3.1 years	Alive at 58 months	Alive
4	Shone's complex; Post-Ross-Konno operation and severe MR	2.8	2.3	6.6	4.6	2	1	8.5	Ø	Transplant at 9 months	Alive Transplanted Severe LV diastolic dysfunction
5	Postcomplete AVSD repair (early)	4.2	2.4	1.8	6.5	On ECMO			Early death at 11 days		ARDS/shock lung during AVSD repair
6	Postcomplete AVSD repair	4.6	25.9	6.8	9.5	6	9	11	5 months	Alive at 11 months	Alive
7	Postcomplete AVSD repair	1.7	0.1	9.2	4.6	4	4	4	Ø	Alive at 4 months	Alive
Median		3.6	3.5	6.7	5.8	4	4	9.8			

MVR: Mitral valve replacement; AML: Acute myeloid leukemia, AVSD: Atrioventricular septal defect, LV: Left ventricular, ARDS: Acute respiratory distress syndrome, MR: Mitral regurgitation, ECMO: Extra Corporeal Membrane Oxygenation
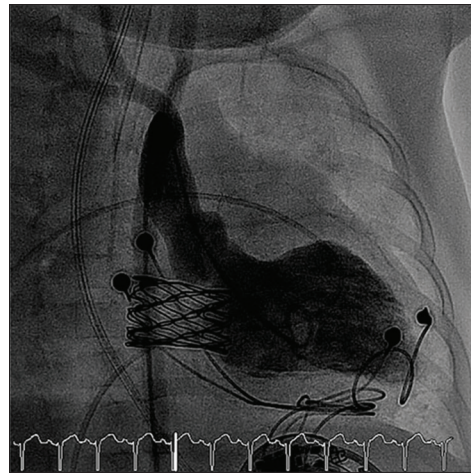

Figure 2: Left ventricular angiogram demonstrating an unobstructed left ventricular outflow tract at 3.1 years postimplantation

Late dilatation

Late balloon dilatation was successfully performed in 2 patients (5 months and 3 years postoperatively). In the former, balloon dilatation was undertaken intraoperatively during re-repair of a *de novo* pulmonary vein ostial stenosis, existing before Melody implantation (unrelated to the Melody®) [Figure 4]. In the second case, successful transfemoral balloon dilatation (16 mm) could be performed through a trans-septal access to the left atrium [Figure 5]. This resulted in an immediate decrease in mean gradient from 6 to 1 mmHg and from 17 to 4 mmHg, respectively. The z value dynamics of the mitral valve from the time of MVR to follow-up are depicted in Table 2. Notable is the fact that while the median weight of the cohort increased by nearly 20%, the median z value of the Melody remained normal (change from 0.8 at implant to 0.4 at follow-up), thanks to the possibility of secondary balloon dilatation.

DISCUSSION

Surgically implanted Melody is a viable and life-saving option for infants needing mitral valve replacement. They offer good immediate results and can be re-dilated using transvenous catheter technique as the child grows. This being a new operation, several aspects of Melody in mitral position are still evolving.

Surgical considerations

The Melody valve construct
Most groups working with Melody follow similar principles. The length of the valve needs to be decreased either by bending the stent struts backward[6,7] or by trimming the outermost parts of the valve.[8] We avoided any resection of stent struts so as to avoid impairing the integrity of the stent valve and thereby its radial and longitudinal stability. We have not resorted to cutting

Table 2: Impact of secondary balloon dilatation on the *Z* value of the Melody valve

Serial number	Weight at MVR (kg)	*Z* at MVR	Dilatation	Weight at dilatation (kg)	*Z* before dilatation	*Z* after dilatation	Fup (months)	Fup weight (kg)	Fup *Z*
1	9.45	0.3	No				12.7	12.5	−0.09
2	4.7	1.65	No				Death on table		
3	4.55	0.88	3.1 years	11.65	−0.86	−0.12	58	14.1	−0.47
4	6.47	1.2	No				8.5	8.5	0.64
5	4.57	0.98	No				Early death at 11 days		
6	5.08	0.72	5 months	7.35	0.2	0.95	11	7.3	0.77
7	6.58	0.21	No				4	6.93	0.15
Median	5.08	0.8						7.3	0.64

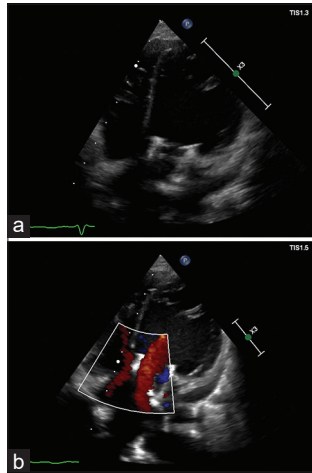MVR: Mitral valve replacement

Figure 3: (a) Two-dimensional echo and (b) color Doppler image of the Melody valve in mitral position at 61 months postimplantation
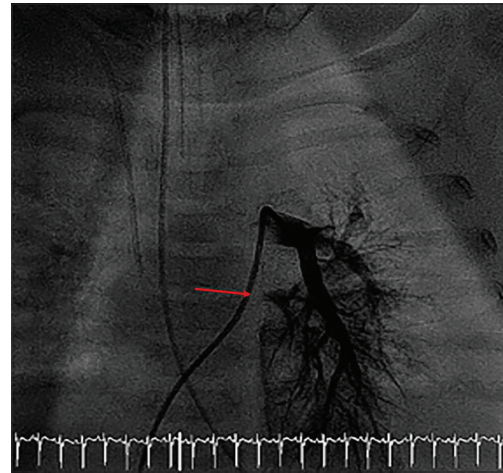

Figure 4: *De novo* left pulmonary vein ostial stenosis (red arrow) in patient 5; preceding mitral valve replacement

away the LVOT facing sinus, as it may destabilize the valve geometry, and exact positioning may be difficult. We have instead used less ventricular profiling to avoid LVOTO.

Presently, we are convinced about the advantages of creating a neo-sewing ring. A prestitched sewing ring facilitates putting the stitches as well as tying them efficiently. It minimizes the risk of paravalvular leak.[4,6,7,9]

Profile of the valve in the atrium versus the ventricle
Differences exist in the positioning of the sewing ring and hence the valve profile in the mitral inflow. It involves finding a balance between the requirement of good pulmonary venous return on the atrial side and the risk of LVOTO on the ventricular side. Positioning the valve entirely in the atrium[6] or even supra-annularly[7] has been described when LVOTO is feared. It appears attractive when the atrium is hugely dilated, as is the case in older children. Supra-annular placement has been associated with increased early mortality in conventional valves, possibly due to consequences of impaired disc motion.[10] Melody valve, in contrast, does not carry the risks of hindrance to disc motion and pannus formation. Positioning the sewing cuff half-way or at 2/3rd (atrial)–1/3rd (ventricular) junction of the Melody appears to ensure[4,9] unhindered pulmonary venous

return as well as unobstructed LVOT. With this approach, we have not found it necessary to place a ventricular stitch to drag the valve toward the interventricular septum and away from the LVOT.[8] Considering the relatively short exposure to MR (median 3.5 months in our cohort), in small infants (median 5.8 kg), some sort of left atrial/interatrial septal enlargement is usually performed to increase LA volume.[6,7]

Preservation of the subvalvular apparatus
Preservation of the subvalvular apparatus during MVR has been shown to positively influence LV function both in the short and long term.[3,11] However, interaction of the small LV cavities, high profile Melody valve, and its impact on LVOT in infants has attracted caution. Acceptable results have been published despite subvalvular apparatus resection.[6] Since experiencing short-term LV dysfunction in one of our first patients, we now pursue at least partial preservation of subvalvular apparatus. We believe that subvalvular preservation prevents systolic tilting of the Melody into the LVOT.

Anticoagulation
Usually, biological valves do not require long-term therapeutic anticoagulation. Considering the long experience with Melody in mitral position, risk of thromboembolism due to Melody *per se* seems to be
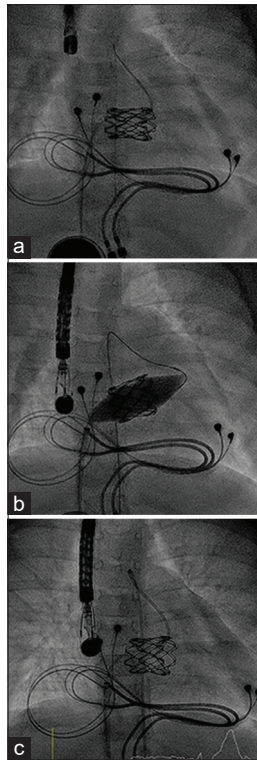
Figure 5: Melody valve balloon dilatation: (a) before (b) during (c) after dilatation

low.[12] Recommendations of anticoagulation for Melody in mitral position are evolving. This reflects in variation in practice from aspirin monotherapy to aspirin plus clopidogrel[6-8] and enoxaparin.[13] Considering the high profile of valve we leave in the atrium, the small and short-term experience, we have been cautious in favor of therapeutic anticoagulation for 1 year. Thereafter, we recommend the use of aspirin monotherapy once echocardiographic result of valve and LV function remain favorable.

Dilatability
Future dilatability lies at the heart of attractiveness of this concept. Leaving a small fenestration in the atrial septum has been practiced by most groups.[1,5,8] A multicenter study showed that 24 out of 59 patients underwent balloon dilatation at a median of 6.9 months postimplantation, 10 of them undergoing multiple interventions. Similar to other groups, balloon dilatation in 2 of our patients achieved a significant reduction in transvalvular gradient without experiencing new regurgitation.[12] Fortunately, we did not encounter any of the reported complications such as distortion of valve (ventricular end) and hemodynamic collapse.[4]

Valve degeneration/longevity
Considering our own experience with the Contegra valve in pulmonary position, we believe that Contegra valve leaflets have continued to function well beyond 10 years *in vivo*.[14] The Melody concept is a value addition of

the Contegra, where the leaflets (the biggest asset of Contegra) are retained and a dilatability is bestowed upon. Some question the ability of the venous valves to withstand systemic pressures. Considering the short follow-up, it is too early to predict the longevity of Melody in mitral position. Histological analysis of postmortem specimen in one of our patients (dying of leukemia 13 months postimplantation) demonstrated good biocompatibility, neo-endothelialization, and minimal neo-intima formation. The cusps remained thin, pliable, and intact.[15] The only multicenter study showed that 16/59 Melody valves underwent replacement at 23 months of follow-up. Reasons included stenosis, endocarditis, structural valve deterioration (without infection), stent fracture, and paravalvular leak.[12] Considering the 55% freedom from death, transplant, structural valve degeneration, or valve replacement reported in this series,[12] our experience of no structural valve degeneration, death, replacement, and severe regurgitation stands favorably in comparison.

Alternatives
A possible alternative to the Melody is the Sapien 3® valve (a stented bovine transcatheter valve); however, we have no personal experience with surgical implantation of the Sapien valve.[8,16,17]

Mechanical valves, by virtue of their known poor prognosis in infants, lend itself to no comparison. In addition to high risk of mortality, significant morbidity including permanent pacemaker implantations, paravalvular leaks, valve thrombosis, as well as the significant loss of "quality of life" rightfully has fuelled the drive for better solutions.[10,18,19] A recent Dutch experience with the smallest 15 mm mechanical mitral valve implanted in 3 neonates reported perioperative death in 1, the other two requiring one or two re-replacements before adolescence.[18,19] In contrast, older children have a better prognosis. Children <2 years reportedly have a 26% inhospital mortality compared to 4% in older children.[20]

Biological valves are attractive as they require no anticoagulation; however, they degenerate faster in young children.[21] The median time to replacement ranges from 2.5 to 5 years. In addition, they pose the same size issues as the mechanical valves, especially since some models have even higher profiles compared to their mechanical counterparts.[1,2] The Ross II procedure (pulmonary autograft in mitral position) offers the benefits of biological valves. However, since 2 valves are potentially jeopardized, it has hardly found acceptance.[1] In the midst of this outlook, Melody in mitral presents itself as a concept with a new ray of hope for infants needing MVR. Only time will tell how far this hope turns into reality.

CONCLUSION

Mitral valve replacement in infants remains extremely challenging. Conventional valves are marred by significant morbidity and mortality. Melody valve implantation has opened up new avenues to treat infants needing a prosthetic mitral valve. Melody implantation in mitral position is feasible and safe and the dilatability to accommodate child growth is a reality. Although not a life-long solution, it provides a ray of hope for infants and small children, in the least to bridge the gap, until other options become a viable option.

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Conflicts of interest

There are no conflicts of interest.

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