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Risk of infective endocarditis after hybrid melody mitral valve replacement in infants: the French experience

Paul Padovani^{a,b}, Zakaria Jalal^{c,d,e}, Virginie Fouilloux^f, Nadir Benbrik^{a,b}, Céline Grunenwald^{a,b}, Jean-Benoit Thambo ^{c,d,e}, Philippe Aldebert ^f, Maha Tagorti^{a,b}, François Roubertie^{c,d,e}, Olivier Baron ^a, Caroline Ovaert ^{f,g}, Mohamedou Ly^a and Alban-Elouen Baruteau ^{a,b,h,i,*}

^a Department of Pediatric Cardiology and Pediatric Cardiac Surgery, FHU PRECICARE, Nantes Université, CHU Nantes, Nantes, France

^b INSERM, Nantes Université, CHU Nantes, Nantes, France

^c Electrophysiology and Heart Modeling Institute, IHU Liryc, Fondation Bordeaux Université, Bordeaux, France

^d U1045, INSERM, Centre de Recherche Cardio-Thoracique de Bordeaux, Université de Bordeaux, Bordeaux, France

^e Department of Pediatric Cardiology, FHU PRECICARE, CHU Bordeaux, Bordeaux, France

^f Department of Pediatric Cardiology, FHU PRECICARE, AP-HM, Timone Infant Hospital Marseille, Marseille, France

^g Marseille Medical Genetics, INSERM U1251, Aix-Marseille Université, Marseille, France

^h Nantes Université, CHU Nantes, CNRS, INSERM, l'institut du thorax, Nantes, France

ⁱ Nantes Université, INRAE, UMR 1280, PHAN, Nantes, France

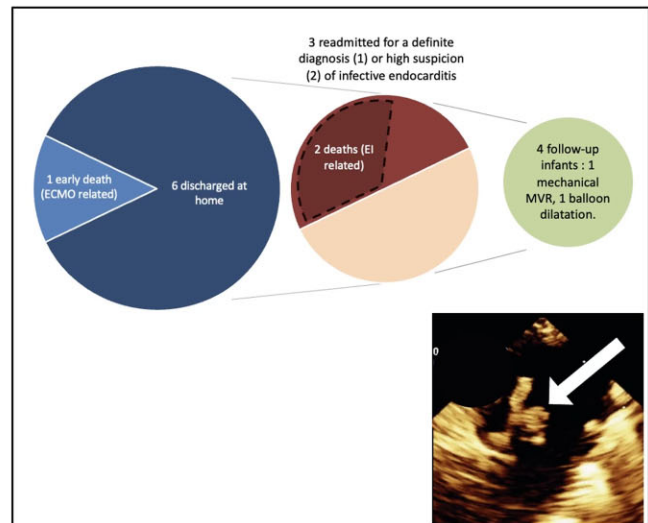
* Corresponding author. Département médico-chirurgical de cardiologie pédiatrique et congénitale, Centre Hospitalier Universitaire de Nantes, 7 Quai Moncoussu, 44093 Nantes cedex 01, France. Tel: +33-240-087-742; fax: +33-240-087-873; e-mail: albanelouen.baruteau@chu-nantes.fr (A.-E. Baruteau).

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Risk of infective endocarditis after hybrid Melody mitral valve replacement in infants : The French experience

Summary

In a retrospective cohort study reporting the French experience with Melody Mitral Valve replacement, we showed a 100% implantation success in 7 symptomatic infants (3 months, 4.3 Kg) with complete atrioventricular septal defect n=4 or hammock mitral valve n=3. There was one early ECMO-related death. Of the 6 discharged patients, 3 were readmitted for a definite diagnosis (1) or high suspicion (2) of infective endocarditis, of which 2 died.



Legend: Figure show transesophageal echocardiography demonstrating a vegetation on the atrial side of the Melody valve (white arrow).

Abstract

OBJECTIVES: Surgical management of mitral valve disease is challenging in infants <1 year old. We aimed at reviewing the French experience with Melody mitral valve replacement in critically ill infants.

METHODS: A retrospective cohort study reporting the French experience with Melody mitral valve replacement.

RESULTS: Seven symptomatic infants [complete atrioventricular septal defect ($n = 4$, Down syndrome: $n = 3$), hammock valve ($n = 3$)] underwent Melody mitral valve replacement [age: 3 months (28 days to 8 months), weight: 4.3 kg (3.2–6.4 kg)] because of severe mitral valve regurgitation (6) or mixed valve disease (1) and 14 mm (11–16 mm) mitral valve annulus. In 2 patients whose valve was felt irreparable, Melody mitral valve replacement was performed straightaway. The others underwent 2 (1–3) previous attempts of valve repair; 3 were on extracorporeal membrane oxygenation. Melody mitral valve replacement led to competent valve and low gradient [3 mmHg, (1–4 mmHg)]. One patient died 3 days post-implant from extracorporeal membrane oxygenation-related stroke. Of the 6 discharged home patients, 3 (50%) were readmitted for a definite diagnosis (1) or high suspicion (2) of infective endocarditis, of which 2 died. Over the follow-up, 1 underwent balloon expansions of the valve at 9- and 16-months post-implant, and mechanical mitral valve replacement at 2 years; another is currently planned for transcatheter Melody valve dilation.

CONCLUSIONS: Melody mitral valve replacement may be considered in selected infants with small mitral valve annulus as an alternative to mechanical mitral valve replacement. Our experience highlights a high-risk of late infective endocarditis that deserves further consideration.

Keywords: Melody valve • Atrioventricular valve • Infant • Hybrid intervention • Infective endocarditis • Outcomes

ABBREVIATIONS

IE	Infective endocarditis
LVOT	Left ventricular outflow tract
MV	Mitral valve
MVR	Mitral valve replacement
TTE	Transthoracic echocardiography

INTRODUCTION

Surgical management of mitral valve (MV) disease is challenging in infants, and options for mitral valve replacement (MVR) are limited in infants with irreparable mitral valve, especially for mitral annular size <15 mm [1]. The Melody valve is a stent-mounted valved bovine jugular vein graft that is indicated for use in a dysfunctional right ventricular outflow tract conduit or surgical bioprosthetic pulmonary valve that has a greater than or equal to moderate regurgitation and/or a mean RVOT gradient ≥ 35 mmHg [2]. Since its 1st report in 2012 [3], the Melody valve has been occasionally implanted in the mitral position in infants with small MV annuli [4, 5]. Although the worldwide experience is limited, the Melody valve (Medtronic, Minneapolis, MN, USA) has shown promising potential for atrioventricular valve replacement in that setting [6, 7]. We aimed at reviewing the French experience with Melody MVR in critically ill infants.

MATERIALS AND METHODS

Ethical statement

The study was reviewed and approved by the Institutional Ethics Committee of Nantes University (GNEDS 23-01-10 VA), and all parents granted their written informed consent to be included in the database.

Study design and data collection

A retrospective cohort study was conducted at the 3 French tertiary centres that have performed Melody MVR so far (namely Nantes, Bordeaux, and Marseille University Hospitals). De-identified clinical and echocardiographic data were collected with the consent of the families.

Hybrid Melody valve implantation

Preprocedural planning was based on careful transthoracic echocardiography (TTE) assessment in all patients and the use of 3D-printed models derived from cardiac computed tomography scans in 1 patient [8] (Fig. 1).

Melody valve was implanted using a surgical hybrid approach in all patients. The indication and timing for Melody MVR was at the discretion of the team, after multidisciplinary team discussion. To facilitate surgical implantation and reduce the risk of left ventricular outflow tract (LVOT) obstruction, the Melody valve was folded, i.e. prepared by bending the proximal and distal stent struts backward thus shortening it from 28–30 mm to 20 mm (Fig. 2). A water test of the folded valve confirmed its competence before implantation. Then a sewing cuff of xenopericardium was added externally to the stent using interrupted sutures, usually at the junction of distal one-third and proximal two-thirds of the valve. Then through a median sternotomy, cardiopulmonary bypass was established through aortic and dual venous cannulation, and the MV was exposed through a trans-septal approach. The native valve tissue and chordal attachments were resected in their entirety. The Melody valve was then crimped by circumferential finger pressure on a 5-ml syringe and positioned into the annulus. Preplaced mitral annular sutures were tied onto the sewing ring. Balloon dilation of the valve to the desired size was performed. Balloon sizing was based on preoperative TTE measurement of the annulus size



Figure 1: Preprocedural planning. A 3D-printed model was used in a 3.9 kg infant (case #4), allowing for a Mock implantation of a folded Melody valve in the mitral annulus.

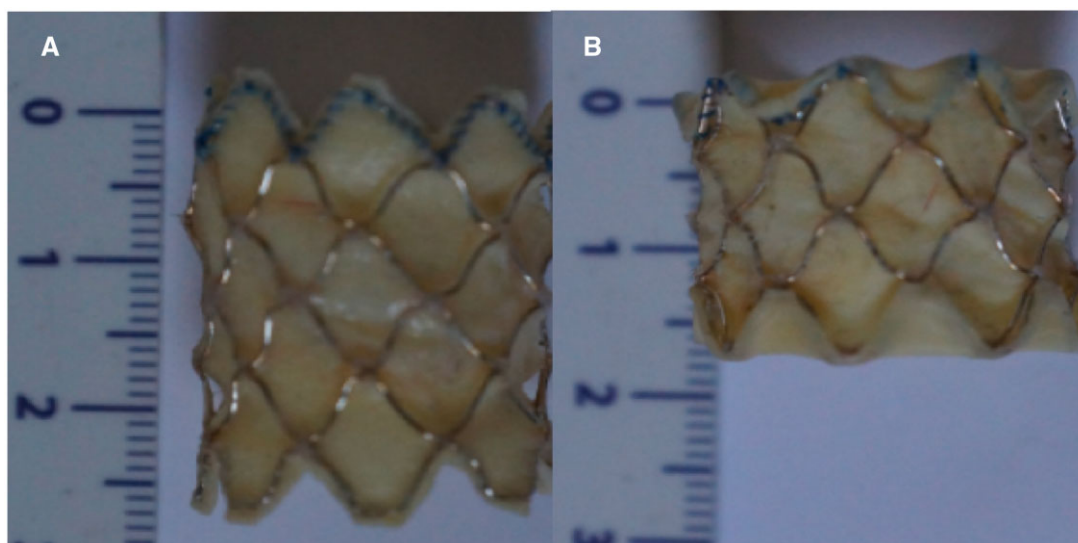


Figure 2: Folded Melody valve. In all patients, the Melody valve was folded. It was prepared by bending the proximal and distal stent struts backward thus shortening it from 28 to 30 mm (A) to 20 mm (B).

and intraoperative sizing, aiming at a balloon of 1 mm + antero-posterior annular diameter. Finally, to facilitate subsequent percutaneous access to the left atrium for transcatheter MV dilatation over the follow-up, the atrial septal defect was closed with a fenestrated patch of bovine pericardium. Valve function (mitral regurgitation and transmitral gradient), pulmonary veins patency and LVOT patency were carefully analysed intraoperatively with transoesophageal echocardiography and postoperatively with regular TTE.

Postoperative care

All patients received therapeutic anticoagulation with enoxaparin during the 1st postoperative month along with long-term aspirin. After hospital discharge, regular TTE and cardiology visits were performed on a weekly basis for 1 month, then on a monthly basis up to the 6th postoperative month and then according to institutional policies. The decision to further dilate the Melody valve was left at the discretion of the referring team.

RESULTS

From 2018 to 2023, 7 symptomatic infants underwent successful Melody MVR at a median age of 3 months (28 days to 8 months) and a median procedural weight of 4.3 kg (3.2–6.4 kg).

Preoperative characteristics

Preoperative characteristics are summarized in Table 1. The indications for Melody MVR were grade 4 left atrioventricular valve regurgitation (referred to as mitral regurgitation) following repair of complete atrioventricular septal defect in 4 patients, including 3 with Down syndrome; the 3 other infants had a dysplastic MV with the primary mechanism of mitral regurgitation in 2 and mixed disease in 1. Five patients underwent 2 (1–3) failed attempts of MV repair (Fig. 3, Video 1), whereas Melody MVR was performed straightaway in 2 infants whose MV was felt

unsuitable for repair. The MV annulus was measured at 14 (11–16) mm. In 5 patients, Melody MVR was done as a salvage procedure in critically ill infants requiring either inotropic (2 patients) or extracorporeal membrane oxygenation circulatory support (3 patients).

Pre- and early postoperative characteristics

Pre- and postoperative characteristics are summarized in Table 2. All patients received a 20-mm folded Melody valve (TPV20) inflated on various balloon catheter types, with excellent immediate MV function [no regurgitation and minimal gradient of 3 (1–4) mmHg] and no LVOT obstruction. All patients were started on aspirin along with a 48-h postoperative course of anticoagulation. One patient died 3 days post-implant from extracorporeal membrane oxygenation-related stroke. The other patients had favourable outcomes with de-escalation of respiratory and circulatory support and were discharged home on aspirin.

Late infective endocarditis

Of the 6 patients who were discharged home, 3 (50%) were readmitted for a late sepsis attributed to either confirmed (1 patient) or suspected (2 patients) infective endocarditis (IE) at 4.5-, 3.5- and 4-months post-implant, respectively. Two of them had Down syndrome. All 3 were on aspirin and had a previous regular, uneventful follow-up with unmodified TTE assessment of the MV.

The 1st patient (case #2) had been implanted with a Melody MVR at 2 months, 3.2 kg, with no mitral regurgitation and no significant gradient. She was re-hospitalized in paediatric intensive care unit because of septic shock with fast-evolving respiratory and haemodynamic deterioration and multi-organ failure. Even though she received immediate extensive antibiotic therapy, bacteriological samples showed *Stenotrophomonas maltophilia* in the trachea, which was treated with moxifloxacin, but the blood cultures remained sterile. TTE showed a competent Melody

Table 1: Preoperative characteristics

Case	Gender	Procedural age (months)	Procedural weight (kg)	Comorbidity	Congenital heart defect	Previous surgical valve reconstructions	MV function	MV annulus (mm)	Circulatory support
#1	Male	2	4.6	None	Complete AVSD	2	Grade 4 MR	11	Central ECMO
#2	Female	2	3.2	Down syndrome	Complete AVSD	3	Grade 4 MR	14	Central ECMO
#3	Male	4	5.8	None	Hammock MV	1	Grade 4 MR	16	Central ECMO
#4	Male	4	3.9	Down syndrome	Complete AVSD	3	Grade 4 MR	13	Inotropic support
#5	Male	1	3.6	None	Hammock MV	0	Grade 4 MR	14	None
#6	Male	3	4.3	Down syndrome	Complete AVSD	2	Grade 4 MR	17	Inotropic support
#7	Male	8	6.4	None	Hammock MV	0	Grade 3 MR, mean gradient = 20 mmHg	15	None

AVSD: atrioventricular septal defect; ECMO: extracorporeal membrane oxygenation; MR: mitral regurgitation; MV: mitral valve.

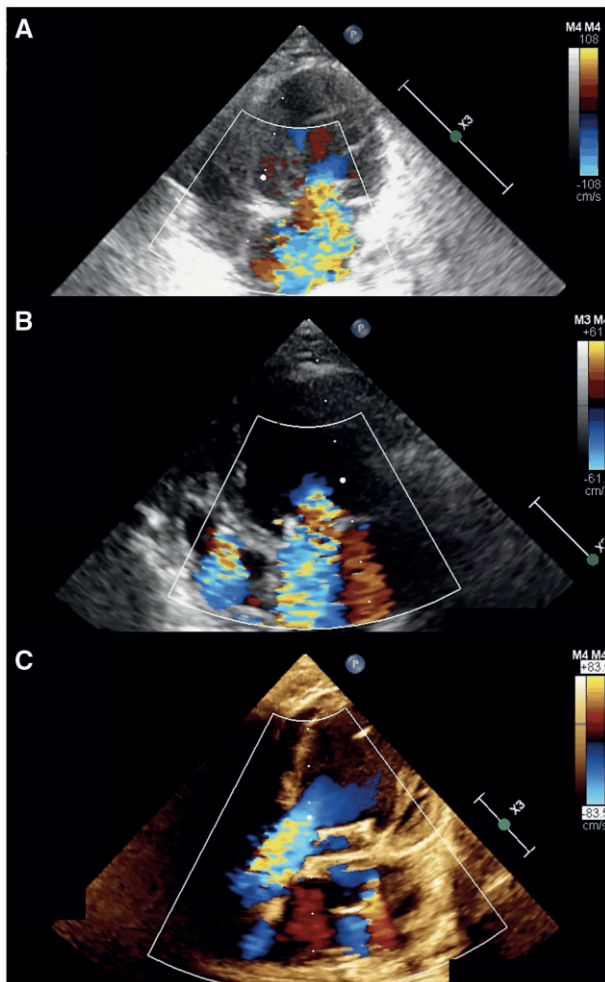
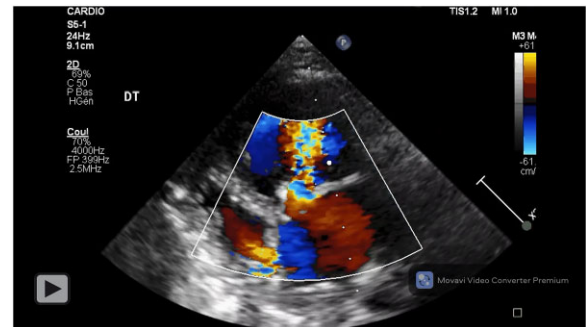


Figure 3: Salvage Melody mitral valve replacement. Melody mitral valve replacement was performed as a rescue intervention in a 5.8 kg infant (case #3) with a Hammock valve and massive mitral valve regurgitation at birth (A) and after failed mitral valve repair whilst supported by central extracorporeal membrane oxygenation (B). This eventually led to Melody mitral valve replacement with excellent immediate result, no mitral valve regurgitation and no left ventricular outflow tract obstruction (C).

valve but a significant increase of the transmitral gradient with a mean gradient at 15 mmHg. Transoesophageal echocardiography revealed a 10-mm vegetation on the ventricular side of the Melody valve, leading to broad-spectrum intravenous antibiotic



Video 1: Salvage Melody mitral valve replacement. Melody mitral valve replacement was performed as a rescue intervention in a 5.8 kg infant (case #3) with a Hammock valve and massive mitral valve regurgitation at birth and after failed mitral valve repair whilst supported by central extracorporeal membrane oxygenation. This eventually led to Melody mitral valve replacement with excellent immediate result, no mitral valve regurgitation and no left ventricular outflow tract obstruction.

treatments (Fig. 4, Video 2). However, the child presented refractory hypoxemia and died in intensive care 36 h after her admission. Parents declined autopsy.

The 2nd patient (case #4) had received a Melody MVR at 4 months, 3.9 kg, with a trivial perivalvular leak, no transmitral gradient and no LVOT obstruction. He was readmitted for a severe sepsis with an obstructive shock physiology, from unknown cause 4 months' post-implant and died at admission in the paediatric emergency department before any TTE could be done. Initial blood culture and lumbar puncture were negative. Parents declined medical autopsy so that suspected late IE could not be confirmed.

The third patient (case #5) had had a Melody MVR at 28 days of life, 3.6 kg, with good result as assessed by a trivial perivalvular leak and a 4 mmHg mean gradient. Four months later, he was readmitted for a sepsis of unknown cause that has been aggressively treated by broad-spectrum intravenous antibiotics for 4 weeks and favourable clinical outcomes. Blood cultures remain sterile and TTE revealed nothing but a transmitral gradient increase at 13 mmHg that led ultimately to delayed successful percutaneous Melody valve dilation 3 months later (i.e. at 9 months of age). The Melody valve was dilated again at 16 months to accommodate to the child's growth. At 2 years of age, the patient underwent mechanical valve replacement with a 19 mm Saint Jude Medical valve.

Table 2: Per- and postoperative characteristics

Case	Implanted valve	Valve preparation	Balloon expansion	Early MV function	Length of FU	FU events
#1	Melody TPV20 (PB1016)	Folded Melody valve	12×40 mm Powerflex balloon	No MR. Mean gradient = 3 mmHg	3 days	ECMO-related stroke leading to in-hospital death
#2	Melody TPV20 (PB1016)	Folded Melody valve	16×45 BiB balloon	No MR. Mean gradient = 4 mmHg	4.5 months	Confirmed late IE (postoperative month 4.5), multi-organ failure and death
#3	Melody TPV20 (PB1016)	Folded Melody valve	18×40 Atlas balloon	No MR. Mean gradient = 3 mmHg	2.5 years	Uneventful FU, no reintervention
#4	Melody TPV20 (PB1016)	Folded Melody valve	14×25 BiB balloon	Trivial perivalvular MR. Mean gradient = 2 mmHg	4 months	Suspected late IE (postoperative month 4), septic shock and death
#5	Melody TPV20 (PB1016)	Folded Melody valve	15×30 BiB balloon	Trivial perivalvular MR. Mean gradient = 4 mmHg	2.5 years	Suspected late IE (postoperative month 4), Transcatheter Melody valve dilatation at month 9 and month 16. Mechanical MV replacement (19 mm St Jude valve) at year 2
#6	Melody TPV20 (PB1016)	Folded Melody valve	18×40 Atlas balloon	No MR. Mean gradient = 2 mmHg	3 months	Uneventful FU, no reintervention
#7	Melody TPV20 (PB1016)	Folded Melody valve	16×40 Atlas balloon	Trivial perivalvular MR. Mean gradient = 1 mmHg	2 months	Uneventful FU, no reintervention

BiB: balloon-in-balloon; ECMO: extracorporeal membrane oxygenation; FU: follow-up; IE: infective endocarditis; MR: mitral regurgitation; MV: mitral valve.

Long-term outcomes

Of the 2 patients who were followed up more than 2 years, 1 had serial percutaneous dilatations of the Melody MVR at 9- and 16-months post-implant, to accommodate to the child's growth. At 2 years of age, he underwent mechanical MVR with a 19 mm Saint Jude Medical valve (Fig. 5). This approach enabled the patient to avoid the risk of thrombosis and haemorrhagic events before the age of 2. The 2nd patient is currently planned for transcatheter Melody valve dilatation after 2.5 years of uneventful follow-up.

DISCUSSION

Hybrid Melody MVR is a feasible and life-saving option in selected critically ill infants with irreparable MV and small mitral annulus. Its main advantages are that it can be tailored to annuli that are too small for currently available mechanical prostheses, it avoids long-term anticoagulation (unlike mechanical valve) and it allows for further expansion by balloon dilation in the catheterization laboratory, in order to adapt to somatic growth of the growing child. A few studies have reported promising results regarding the feasibility, safety, and efficacy of hybrid Melody MVR [1–3]. However, based on a limited worldwide experience, Melody MVR may be considered a promising alternative in infants <1 year of age, either as a bridge to mechanical MVR, which can be performed safely at an older age [7], or as a bridge to further mitral Melody valve-in-valve implantation [9, 10].

Inconsistently with previous reports on Melody MVR, we experienced a high rate of definite or suspected Melody valve IE,

according to the Duke Criteria [11]. This is the main finding of our series. Of the 6 survivors who were discharged home, 3 infants developed severe sepsis, rapid haemodynamic deterioration and increasing obstruction of the Melody valve. In all 3 cases, this occurred as a late complication, between 3.5- and 4.5-months post-implant. Our findings encourage to monitor closely for prevention and promptly manage any suspicion of infection in the postoperative months with immediate hospitalization, blood cultures, ultrasound scan and close monitoring along with aggressive treatment with broad-spectrum intravenous antibiotics.

Based on the histological workup of a postmortem removed Melody valve, which had been implanted 13 months before in a 2.5-year-old boy, Schmiady *et al.* shown good biocompatibility of the valve with well-preserved valve function, complete neo-endothelialization of the graft wall and no significant pseudo intimal proliferation [12].

Data regarding mitral Melody valve IE are scarce. Trezzi *et al.* first reported the case of a 10-year-old, 17 kg child with Shone complex and 5 previous open-heart surgeries, who received a Melody MVR because of subarachnoid Haemorrhage precluding curative anticoagulation and mechanical MVR. He was readmitted for mitral Melody IE with valve obstruction (transmitral gradient at 20 mmHg), a vegetation on Transoesophageal echocardiography and positive blood cultures with *Staphylococcus epidermidis* and *Escherichia coli* [13]. In an international cohort of 59 Melody MVR cases with a mean follow-up of 23 months, reoperation was performed in 2 patients with a definite diagnosis of IE, and 6 additional patients were reoperated on for structural valve deterioration with high index of suspicion for IE [4]. More recently, the Toronto group reported 1 case of IE out of 10 Melody MVR [7].

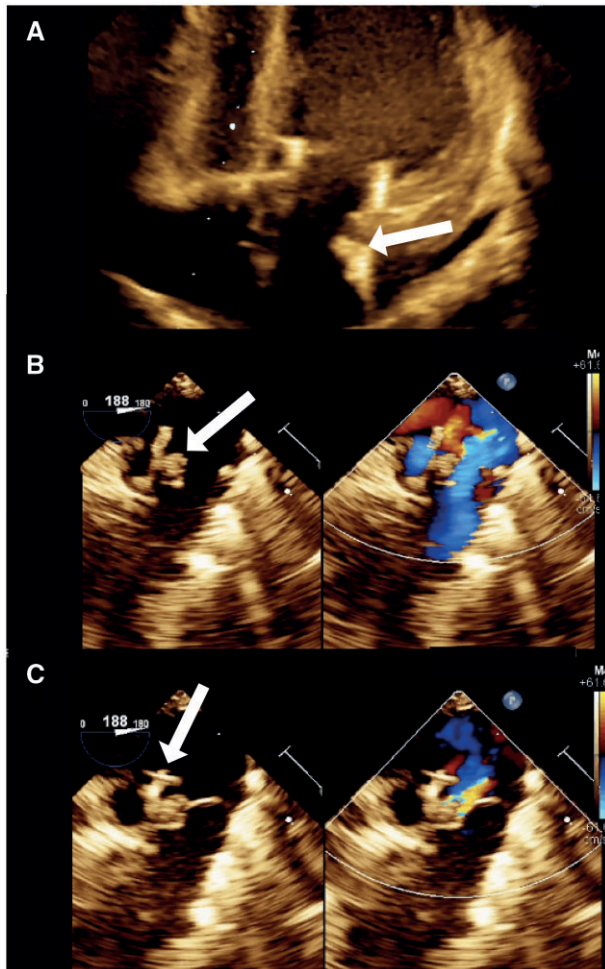
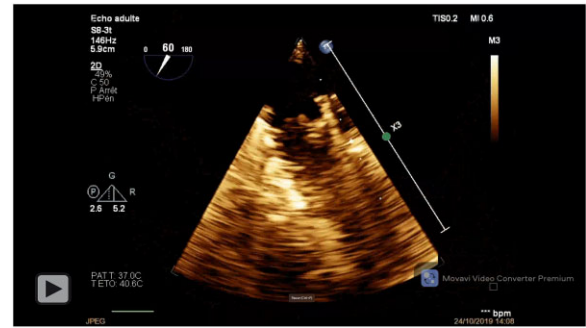


Figure 4: Melody mitral valve infective endocarditis. A successful Melody mitral valve replacement was performed in a 3.2 kg infant with Down syndrome and a complete atrioventricular septal defect, after 3 failed attempts of mitral valve repair, whilst on central extracorporeal membrane oxygenation (case #2). After 4.5 months of an uneventful follow-up, she was readmitted for severe sepsis and multiorgan failure. Transthoracic echocardiography showed an increased transvalvular mean gradient of 15 mmHg along with a neo-image evoking a vegetation (A) that was confirmed on transoesophageal echocardiography demonstrating a vegetation on the atrial side of the Melody valve (B and C).

The high rate of IE observed in our series may be explained by the conjunction of several predisposing factors.

Population-related risk factors

Our group of patients presented nearly all the risk factors for IE described in the literature: congenital heart defect, previous corrective intravenous alimentation, long intensive care unit stay, transcatheter device placement and sometimes immunodeficiency [14, 15]. In this group, IE remains both a diagnostic and therapeutic challenge [16]. Moreover, 2 of our patients had Down syndrome and as such they carried a higher risk of developing an infection [17]. Although Melody MVR had been performed as a salvage procedure in 2 patients who had undergone multiple open-heart surgeries beforehand, 1 patient with suspected IE had been implanted straightaway.



Video 2: Melody mitral valve infective endocarditis. A successful Melody mitral valve replacement was performed in a 3.2 kg infant with Down syndrome and a complete atrioventricular septal defect, after 3 failed attempts of mitral valve repair, whilst on central extracorporeal membrane oxygenation (case #2). After 4.5 months of an uneventful follow-up, she was readmitted for severe sepsis and multiorgan failure. Transthoracic echocardiography showed an increased transvalvular mean gradient of 15 mmHg along with a neo-image evoking a vegetation that was confirmed on transoesophageal echocardiography demonstrating a vegetation on the atrial side of the Melody valve.

Melody valve-related risk factors

The Melody valve has been the 1st valve inserted percutaneously in humans. This device is made of a bovine jugular vein valve (Contegra Pulmonary Valved conduit, Medtronic Inc., Minneapolis, MN, USA) sutured within a Cheatham-Platinum stent (CP stent, NuMED Inc., Hopkinton, NY) [18]. Several studies have indicated that the risk of IE associated with the Melody valve and Contegra conduit is similar, but greater than that associated with other types of surgical implants [19, 20]. In addition, an *in vitro* study has demonstrated a higher level of bacterial adhesion to the bovine jugular vein wall and leaflets, further contributing to the risk of IE associated with these materials. The largest meta-analysis to date concerned a total of 3616 patients treated with Melody valves, among whom 214 developed IE, as opposed to only 5 IE cases in the 501 patients treated with Sapien valves [19]. The meta-analysis showed a cumulative incidence of IE ranging from 3.2% to 25.0%, whereas the annualized incidence rate ranged from 1.3% to 9.1% per patient-year. Several studies have highlighted the risk of IE of the Melody valve in pulmonary position. A cohort of patients with congenital heart disease studied between 2007 and 2012 showed that 10% of patients suffered from subsequent bloodstream infection and 2.7% had Melody valve endocarditis [21]. The systematic review by Abdelghani *et al.* (2018) concluded that IE incidence after pulmonary Melody valve implantation was significant and that more than half of patients with IE underwent surgical and/or transcatheter reintervention. However, they pointed out that the incidence strongly varied between studies [22]. Moreover, a recent case report study raised concern about the increased IE risk caused by a Melody pulmonary valve, despite its early clinical success [23]. The incidence of IE after transcatheter pulmonary Melody valve implantation was found to be 13-91/1000 person-years in a recent review [24].

Procedure-related risk factors

Multiple factors act in conjunction to promote the development of IE, including modification of the cardiac valve surface to create an appropriate site for bacterial adherence and colonization,

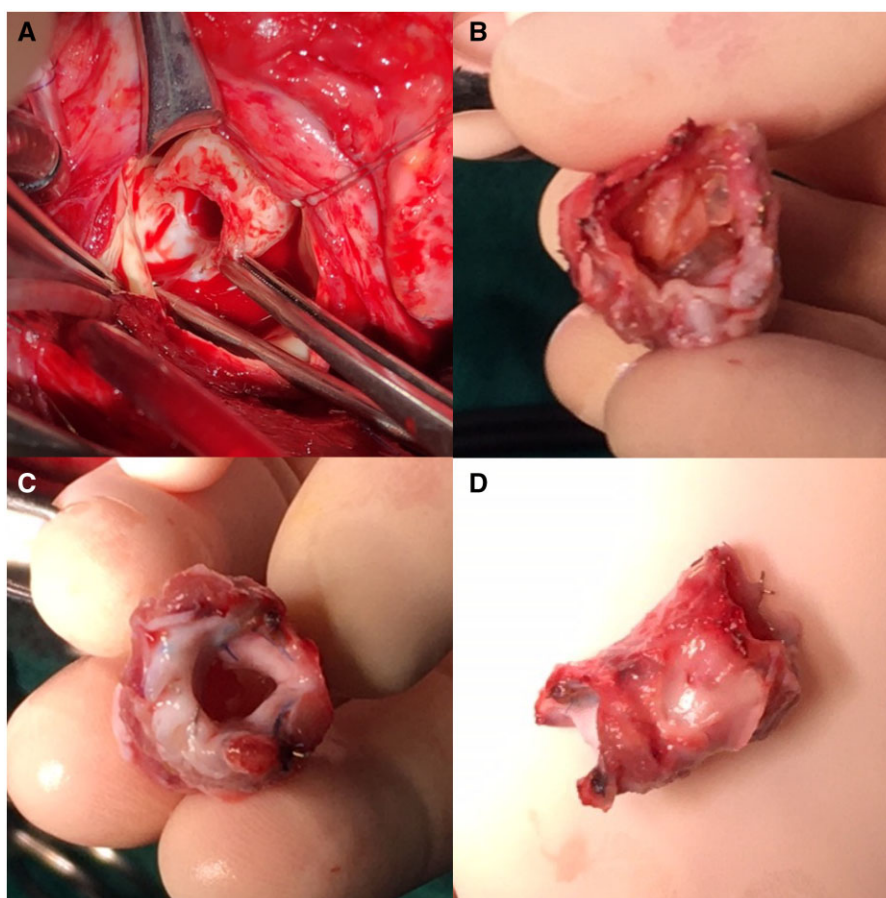


Figure 5: Explanted Melody valve. A Melody mitral valve replacement was performed in a 3.6 kg infant (case #5). After 4 months of follow-up, he was readmitted for a sepsis of unknown aetiology and an increase of the transvalvular mean gradient up to 13 mmHg with favourable outcomes thanks to aggressive, empiric antibiotic therapy. At 2 years of age, he underwent mitral valve replacement.

bacteraemia caused by a pathogen capable of attaching to and colonizing valve tissue and formation of the infected mass or vegetation through embedding of the multiplying organisms within a protective matrix of serum molecules, such as fibrin, and platelets. Turbulent blood flow or residual paravalvular leak might lead to endothelial damage, which can predispose to non-bacterial thrombotic endocarditis that may become infective due to transient bacteraemia [25]. Furthermore, there seems to be a link between the development of micro-thrombi on the valve upon antiplatelet therapy discontinuation and the increase in gradients that would facilitate bacterial aggregation, as shown in the Pavel series of four explanted hearts [26].

Although our study cannot demonstrate associations between IE and valve modification techniques before implantation, manipulation of the valve may contribute to structural valve deterioration. As previously shown in pulmonary valve replacement, one of the main differences between surgery and percutaneous pulmonary valve implantation is that percutaneous valves undergo several manipulations before (such as crimping) and during implantation, whereas surgical prostheses are placed with minimal handling. Traumatic injury of biological valve leaflets has been reported during valved stent preparation [27–29]. Jalal *et al.* reported that valved stent implantation procedural preparation could promote bacterial adhesion on the Melody valve substrate. They suggested that transverse fractures caused by *in vitro* manipulations could constitute a preferred location,

possibly acting as a sink/bacterial trap and thus increasing bacterial adhesion [27]. Therefore, we believe that all valve manipulations performed during the surgical procedure may contribute to a pre-existing additional risk.

CONCLUSION

Melody MVR may be considered in selected critically ill infants aged <1 year of age, with irreparable MV and small mitral annulus, as a valuable and promising alternative to mechanical MVR. However, our experience highlights a significant risk of late IE presenting with Melody valve obstruction and rapid haemodynamic compromise. Clinicians should be aware of this major but delayed risk and promptly manage Melody MVR patients presenting with possible IE.

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Conflict of interest: none declared.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author on reasonable request.

Author contributions

Paul Padovani: Data curation; Formal analysis; Writing—original draft. **Zakaria Jalal:** Data curation; Writing—original draft. **Virginie Fouilloux:** Data curation; Writing—review and editing. **Nadir Benbrik:** Data curation; Writing—review and editing. **Céline Grunenwald:** Data curation; Investigation; Writing—review and editing. **Jean-Benoit Thambo:** Data curation; Writing—review and editing. **Philippe Aldebert:** Data curation; Writing—review and editing. **Maha Tagorti:** Data curation; Writing—review and editing. **François Roubertie:** Data curation; Writing—review and editing. **Olivier Baron:** Data curation; Writing—review and editing. **Caroline Ovaert:** Data curation; Writing—review and editing. **Mohamedou Ly:** Data curation; Writing—review and editing. **Alban-Elouen Baruteau:** Conceptualization; Data curation; Formal analysis; Supervision; Writing—review and editing.

Reviewer information

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