

## Case Report

# Transhepatic Implant of a Trimmed Melody™ Valved Stent in Tricuspid Position in a 1-Year-Old Infant

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Percutaneous valved stent implantation is precluded in small infants because large delivery sheaths and large devices. We describe a procedure in a 1-year-old boy in whom a 19 mm Epic™ valve in tricuspid position had become dysfunctional. As the internal diameter of the prosthetic valve was about 16 mm, the only available valve was the Melody™ valved stent. Technical modifications were required to address issues like venous access, the bulky delivery system, and the length of the valved stent. The Melody™ valved stent was surgically trimmed and mounted on a 16 mm Tyshak balloon, access was provided transhepatically through a short 18 Fr sheath. After deployment, the intrahepatic route was sealed with two vascular plugs (8 and 10 mm) in tandem. The procedure was uncomplicated with perfect valve function 18 months after implant. © 2016 Wiley Periodicals, Inc.

**Key words:** transcatheter valve implantation; pediatric intervention; surgery; valvular; surgery; congenital heart disease

## INTRODUCTION

In small infants, some percutaneous interventions are off limit due to size mismatch of vessel-sheath, implant size, or bulky delivery system. Alternative vascular access can be very helpful in such situations. The transhepatic route up to 9 Fr has been used with success as alternative access even in young children [1–3].

Bioprosthetic valved stents have been reported to be implanted successfully in tricuspid and in mitral position both percutaneously and surgically [4–8].

We describe the transhepatic implantation of a trimmed Melody™ valve (Medtronic Int. Tolothenaz, Switzerland) in tricuspid position in a 1-year-old infant. Technical problems and their solution are discussed in detail.

## CASE AND PROCEDURAL DESCRIPTION

The patient presented as fetus at 25 weeks gestation with massive tricuspid valve regurgitation due to a flail tricuspid valve. Because of persistent heart failure, a surgical plasty on the tricuspid valve was performed on day 15. However because of persistent tricuspid valve dysfunction a bioprosthetic valve (inverted 19 mm Epic™ aortic valve, St Jude) was placed in the tricuspid position

at the age of 1 month. One year after implant, the leaflet function of the bioprosthesis had dramatically decreased with again massive tricuspid regurgitation (3–4/4) and moderate stenosis. (Fig. 1A)

The goal was to avoid re-redo surgery by implanting percutaneously a valved stent. The inner diameter of the Epic 19 mm is 16 mm; in September 2014, the only valved stent, which would fit and function within

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Conflict of interest: Marc Gewillig is proctor for Numed and Medtronic.

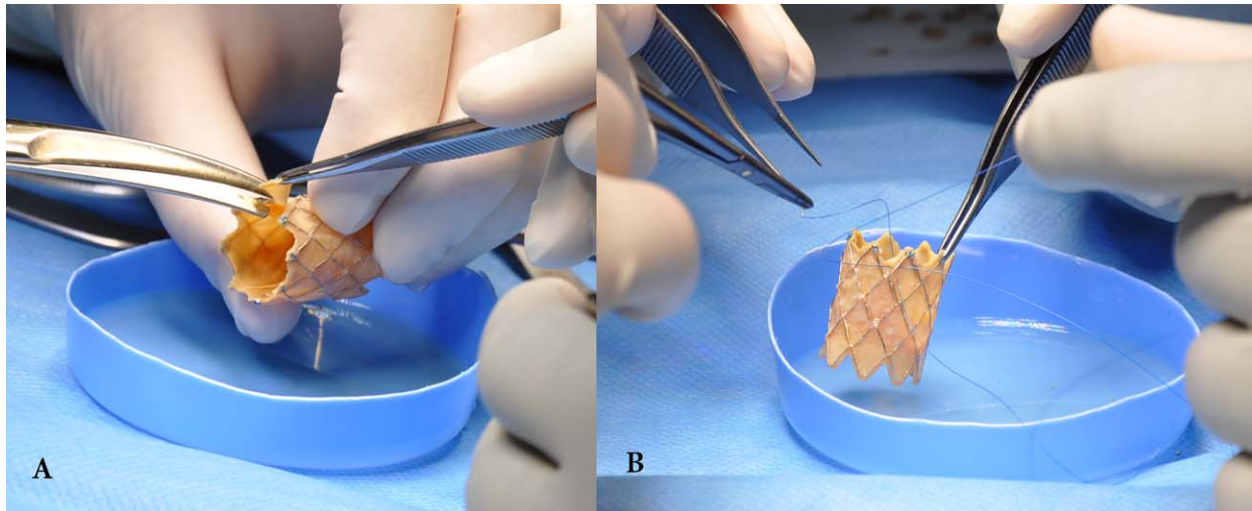
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**Fig. 1. Trimming of Melody valved stent: A: resection of distal zigs at both ends; B: Suturing the valve at the new distal zigs with prolene 7/0. [Color figure can be viewed in the online issue, which is available at [wileyonlinelibrary.com](http://wileyonlinelibrary.com).]**

such ring, is the Melody™ (off label indication). Some technical issues needed to be addressed: the classic delivery system is too big (outer diameter 22 Fr) for classic vascular access in a 1-year-old child; the delivery system is too long and bulky in order to deploy the stent into the tricuspid position; the stent itself when deployed at 16 mm diameter is too long (28 mm). In order to use the Melody™ system, these technical issues such as vascular access, delivery system, and stent length after deployment needed to be addressed.

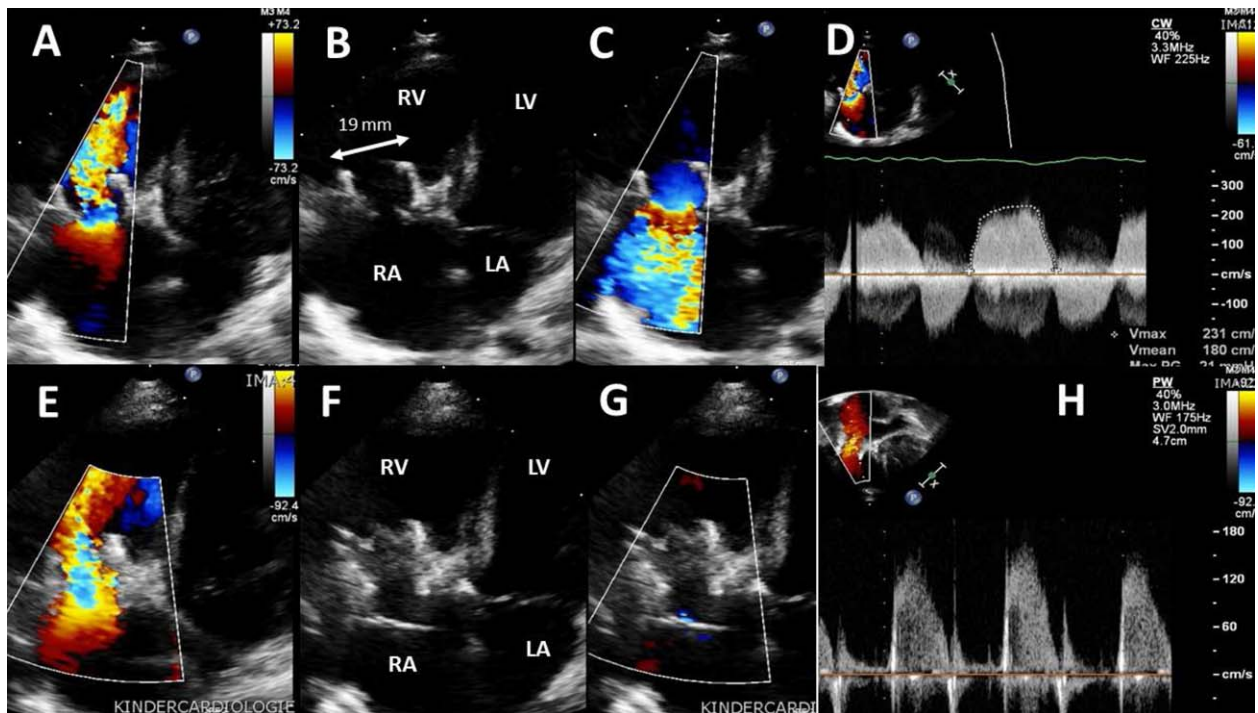
Bench testing was performed to miniaturize the system but keeping a 0.035" wire as guide wire. Because of the inner diameter of the epic valve, we chose a 16 mm balloon with a small 7 Fr profile, in casu a Tyshak balloon (Numed, NY; off label indication). We know from personal experience that a Tyshak balloon can open in safety a Cheatham-Platinum stent which is incorporated in the Melody™ system, provided the balloon is not significantly longer than the stent and slow inflation limited to 3.5 atmospheres is provided. The final profile of the crimped valve on the Tyshak balloon is 16 Fr; however, the shaft of the balloon on a 0.035" wire has insufficient pushability to advance the complex through such sheath; a 7 Fr sheath over the shaft behind the balloon was used to provide this support.

It is known that the distal Zigs from the stent are not required for adequate valve function [9,10]. The Melody™ valve was therefore trimmed by cutting the distal zigs (off-label), after which the ends of the graft were resutured to the stent with a 7.0 prolene wire. Care was taken to cover all the sharp edges of the stent with the graft to avoid puncture of the Tyshak balloon during inflation. The valved stent shortened from 28 mm to 20 mm. We

now had a trimmed Melody™ valve of 20 mm which can be delivered with margin through an 18 Fr (inner diameter) sheath over a 0.035" wire by a single balloon up to 16 mm, stiff zone of about 22 mm, instead of the standard 28 mm Melody™ valved stent delivered by a 22F (outer diameter) Ensemble system with a stiff end of 110 mm (measured from blue tip – end of balloon) (60 mm from blue tip – begin of balloon). (Fig. 2) The drawback of this setup is that once the trimmed valve has left the sheath, one is committed to delivery of the stent or go for surgical removal.

Informed consent was obtained from the parents. The procedure was conform the guidelines of the local ethical committee; a cardiac surgical team was in stand-by.

The procedure was performed in the cathlab with biplane X-ray modality under general anesthesia; the patient was lined up as for cardiac surgery. The right hepatic vein was punctured under echo guidance with a Chiba Echotip™ Biopsy Needle (Cook® Medical Europe, Limerick, Ireland), a 0.014" wire was placed into the right atrium. An 8 Fr introducer sheath (Terumo® Europe NV, Leuven, Belgium) was advanced into the inferior caval vein. With a guide wire in the superior caval vein, the hepatic route was enlarged with hydrophilic dilators with increasing size until an 18 Fr sheath (Edwards Lifescience® Europe, Dilbeek, Belgium) was inserted. A 0.035" pre-bended Amplatzer Super Stiff wire (Cook Int, Bloomington) was positioned in the right pulmonary artery. The orifice of the 19 mm Epic valve was interrogated with a 16/20 mm Tyshak balloon; it was estimated to measure 14.5 mm. The balloon remained very stable in the tricuspid orifice, which made us not use fast pacing during valve deployment.



**Fig. 2.** Echocardiography of the dysfunctional bioprosthetic valve in tricuspid position **A:** diastolic frame showing turbulent jet much more narrow than valve annulus; **B:** Epic valve in tricuspid position outer diameter 19 mm; **C:** systolic frame showing broad regurgitant jet; **D:** continuous Doppler across Epic valve with peak gradient of 21 mm Hg. **E–F:** 1 day after implantation of Melody: **E:** broad laminar diastolic flow **F:**

trimmed Melody valve with leaflet bulging at the atrial end; **G:** competent valve, trivial regurgitation on color Doppler; and **H:** pulsed Doppler on different scale: no significant gradient, and trivial protosystolic regurgitation. [Color figure can be viewed in the online issue, which is available at [wileyonlinelibrary.com](http://wileyonlinelibrary.com).]

The trimmed Melody<sup>TM</sup> valved stent was mounted on the same 16/20 mm Tyshak balloon (Numed, Hopkinton NY) with support of a 7 Fr Mullins<sup>TM</sup> sheath (Cook Int, Bloomington) as pusher. The Tyshak balloon was mildly inflated in order to get small shoulders at both ends of the stent; the distal shoulder at the tip serves like a tulip to help the stent pass ridges such as the Epic valve; the proximal shoulder prohibits the stent to slide from the balloon while progressing through the sheath. The mild inflation of the balloon also allows a more symmetric inflation and expansion of the balloon, with both shoulders impeding the stent to slide off the balloon during inflation. The balloon-Melody<sup>TM</sup> unit was passed through the valve of the 18F sheath while covered by a short cut-off 18F sheath. The balloon-Melody<sup>TM</sup> complex exited the sheath into the right atrium; with minimal manipulation, the distal tip of the stent crossed two ridges: the annulus of the Epic valve and the distal tips of the Epic leaflets. The Melody<sup>TM</sup> valved stent could then easily be deployed in the tricuspid bioprosthesis by gentle inflation. (Fig. 3) Good valvular function was confirmed.

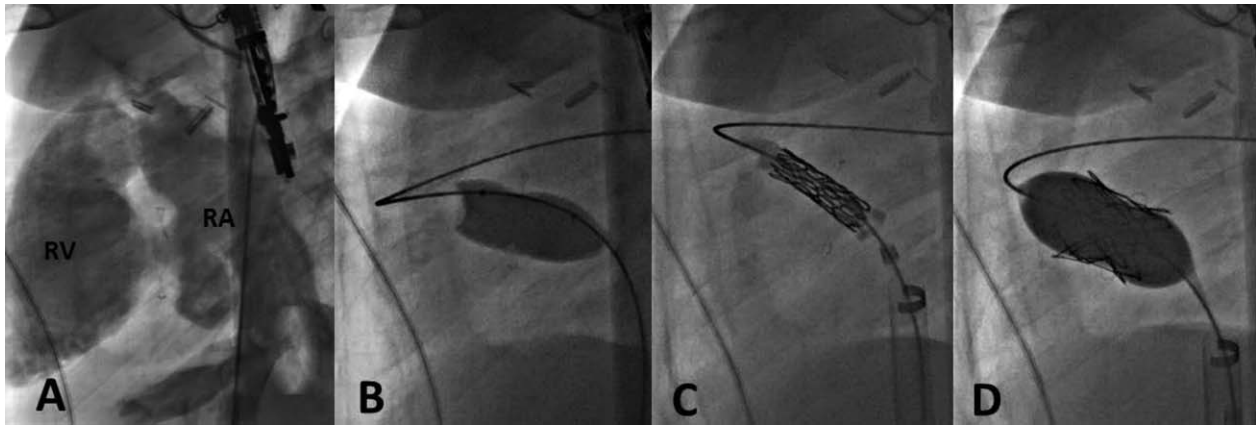
The hepatic route of about 7 mm diameter was then closed. A 0.035" Terumo wire was put in the superior caval vein as safety line. The heparin was neutralized

with protamine. The 18 Fr sheath was pulled back into the hepatic vein under flushes with contrast (Iomeron<sup>TM</sup>) until the border of liver parenchyma was reached (Fig. 4). Two vascular plugs 8 and 10 mm Amplatzer Vascular Occluder were deployed in tandem position through a 7F Cook sheath next to the safety line. With intervals of 5 minutes, small contrast injections were performed to check for occlusion. Only after confirmation of full stop of blood flow, the safety line and the 18F sheath were completely withdrawn. The scar at the skin was sutured with 1 Donati stitch. The abdomen was checked with echo for 1 hour to confirm absence of bleeding.

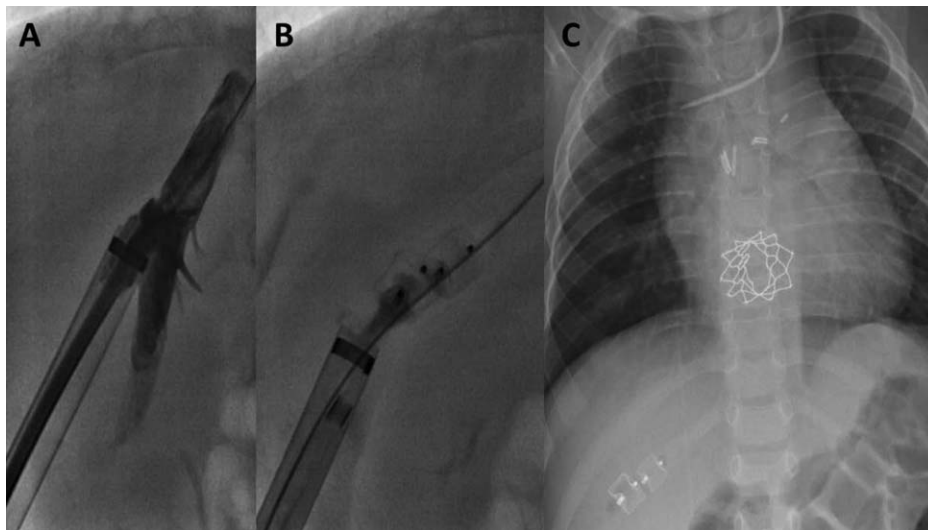
Echocardiography showed perfect function of the Melody<sup>TM</sup> leaflets immediately after the procedure (Fig. 1B) and repeatedly up to 18 months after implantation (Fig. 1C). Radiographic examination showed no change of stent configuration nor fracture.

## DISCUSSION

An infant presented at the age of less than 1 year with a dysfunctional bioprosthetic valve in tricuspid position. A surgical replacement would be a third bypass operation within the first year of life with a very high risk for total



**Fig. 3.** A: right atrial angiogram perpendicular on the Epic™ annulus B: balloon interrogation with 16 mm Tyshak balloon; C: Trimmed Melody™ valve on 16 mm Tyshak balloon (with shoulders at both ends) through 18 Fr Edwards sheath with 7 Fr Mullins sheath as ‘pusher’; D: after pull-back of 7 Fr pusher sheath, deployed trimmed Melody™ valve in tricuspid position.



**Fig. 4.** A: Pullback of the 18 Fr sheath over the 0.035” wire into the hepatic route; B: two vascular plugs (8 and 10 mm) are placed in the hepatic route to seal the exit; C: X-ray showing the trimmed Melody™™ in the tricuspid position and vascular plugs in hepatic parenchyma.

AV block; a percutaneous implantation of Melody™ valved stent was therefore preferred. The Melody™ valved stent has already been used with success in low-pressure tricuspid position with good early and medium term results [4–6,8].

Placing a Melody™ valve in tricuspid position in an infant weighing 9.7 kg is however technical challenging: the valved stent is too long, the delivery system too big and bulky, and a classic venous access is not possible.

First, we tackled the length of the valved stent. When the Melody™ valved stent is deployed at a diameter of 16 mm the total length is 28 mm, which is considered very long for the tricuspid position in such small infant. Different techniques can be used to overcome this prob-

lem. One can use the “Folded valve technique” as described by Jalal *et al.*: folding back one row of zigs at each end, however this makes the stent thicker in crimped position and will need a 19–20 Fr sheath [11]. We choose to downsize the stent by cutting one row of zigs at both ends of the stent, then suturing the valve again to the stent to avoid a hammock effect [9,10,12]. The total length could be downsized from 28 mm to 20 mm. The shorter stent should allow easier maneuverability through the right atrium across the tricuspid valve annulus; with 18 months of follow-up the valve function and stent integrity remained preserved at this diameter.

The classic delivery system Ensemble of the Melody™ is too big and too long to maneuver safely in the

right heart. We therefore choose a thin profiled balloon to deliver the valved stent uncovered; we thereby decreased the safety margin, but this technique is “standard” in other valved stents such as the Sapien valve. The stiff zone hereby decreased from 110 mm down to about 20 mm, which significantly added to the maneuverability and safety in this small patient. However, this set-up still requires a sheath of minimum 16F, which makes a classic venous access still impossible.

Options that allow such sheath size are limited thoracotomy and purse string on the atrium or ventricle, or a percutaneous transhepatic approach. A percutaneous transhepatic approach has become routine in diagnostic and interventional catheterizations in children and adults, but usually through sheaths less than 8–12F [13]. Relatively big sheaths have been used in infants up to 9 Fr [1–3]. The upper size limit of hepatic sheaths has not been explored, but hepatologists frequently use sheaths up to 18F for cholangioscopic procedures; they allow the intraparenchymatous route to collapse spontaneously over 48 hours [14]. The reported complication rates are relatively low (<0.5%), and major complications include bleeding, infection, thrombosis, embolization of closure device or foam, bile leakage, intraperitoneal bleeding, and pneumothorax [15–17]. Hepatic surgeons confirm that the liver is a forgiving organ, provided no bile fistula is created and that bleeding or bile leakage into the peritoneum is controlled. After puncture under echo guidance, we progressively dilated the intrahepatic route with hydrophilic dilators up to 20 Fr (= outer diameter of 18F sheath). The main issue is however to avoid bleeding from the hepatic vein into the abdomen after removal of the sheath. It is our standard to close hepatic parenchymatous routes with Surgicel® (Ethicon), a surgical absorbable hemostatic gauze delivered through the sheath. However, with this big sheath we chose to close the route in the hepatic parenchyma with two vascular plugs. We were impressed by the characteristic of the hepatic tissue to recoil and obliterate most of the lumen within minutes; in a future patient we would consider to place a thin safety line, over which a soft compliant balloon can be positioned at the capsula of the liver; mild inflation could impede blood loss but allow liver recoil for at least 20–30 minutes; the residual lumen should be able to be obliterated safely with hemostatic gauze.

At last, follow-up evaluation 18 months after implantation the trimmed Melody™ valved stent is still functioning perfectly. This is promising: the jugular bovine leaflets perform better between age 12–30 months than the Epic leaflets between 1–12 months.

The inner diameter of tricuspid prosthetic valve is currently 12.5 mm. When tricuspid valve dysfunction occurs, reinsertion of a new valve can be possible but first the frame of the Epic valve has to be cracked in

order to increase the inner diameter prior implantation of a new bioprosthetic valve percutaneously. Cracking the frame is possible as described by Brown *et al* [18].

## CONCLUSIONS

Transhepatic approach opens options to perform complex cardiac catheterizations with big sheaths in small infants. The upper limit of sheaths in hepatic access still needs to be defined. This report confirms the ability of the Melody™ valve to be trimmed and still function well in low-pressure tricuspid position at medium term follow-up at a diameter of 16 mm.

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