# Percutaneous Melody<sup>™</sup> Valve Implantation in Patients with Dysfunctional Right Ventricular Outflow Tract

Implante percutáneo de la válvula Melody® en pacientes con disfunción del conducto del tracto de salida del ventrículo derecho

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## ABSTRACT

**Background:** Percutaneous pulmonary valve implantation is currently considered the treatment of choice in selected cases with previous history of congenital heart disease that present with symptoms of right ventricular outflow tract (RVOT) obstruction and/ or pulmonary regurgitation.

**Objective:** The aim of this study was to describe the initial experience with the Melody<sup>™</sup> pulmonary valve in a tertiary care center of Argentina.

Methods: All patients treated with the Melody<sup>™</sup> valve from August 2013 to May 2016 (n=8) were included in the study.

**Results:** Mean age was  $25\pm18$  years (range: 13-69), and weight was  $56.9\pm9.3$  kg (range: 45-73). Baseline heart diseases were aortic stenosis corrected with the Ross procedure (n=3), truncus arteriosus (n=2), tetralogy of Fallot (n=2) and transposition of the great vessels (n=1). Two patients had severe pulmonary regurgitation, 2 severe stenosis, and 4 double lesion. The number of stents prior to implantation was  $2.1\pm0.64$ . The overall success rate was 100%. The right ventricular outflow tract gradient and the ratio between right ventricular pressure and systemic pressure diminished significantly (from  $57.3\pm30$  to  $15\pm4.2$  mmHg, and from  $0.67\pm0.22$  to  $0.32\pm0.04$ , respectively) (p <0.001) with only trace or absent pulmonary regurgitation. No complications were observed. At a mean follow up of  $14.3\pm10.3$  months (range 34-1), all patients remained asymptomatic and free from significant pulmonary regurgitation. **Conclusion:** In our preliminary experience, the Melody<sup>™</sup> pulmonary valve was found to be safe and effective, showing drastic right ventricular outflow tract gradient reduction, absence of significant regurgitation and marked clinical improvement. These findings confirm the excellent performance of this valve in patients with dysfunctional right ventricular outflow tract.

Key words: Pulmonary Valve - Heart Valve Diseases - Endovascular Procedures - Melody Prosthetic Valve

# RESUMEN

**Introducción:** El implante percutáneo de una válvula pulmonar se considera el tratamiento de elección en casos seleccionados portadores de cardiopatías congénitas que presentan obstrucción del tracto de salida del ventrículo derecho y/o reflujo pulmonar. **Objetivo:** Describir la experiencia inicial de un centro terciario argentino con la válvula pulmonar Melody®.

Material y métodos: Se incluyeron todos los pacientes tratados con una válvula Melody® desde agosto de 2013 hasta mayo de 2016 (n = 8).

**Resultados:** La edad promedio fue de  $25 \pm 18$  años (rango: 13-69) y el peso, de  $56,9 \pm 9,3$  kg (rango: 45-73). Las cardiopatías de base fueron enfermedad o estenosis aórtica corregida con cirugía de Ross (n = 3), tronco arterioso (n = 2), tetralogía de Fallot (n = 2) y transposición de los grandes vasos (n = 1). Dos pacientes presentaban insuficiencia pulmonar grave, 2 tenían estenosis grave y 4, doble lesión. El número de *stents* previo al implante fue de  $2,1 \pm 0,64$ . La tasa de éxito fue del 100%. El gradiente del tracto de salida del ventrículo derecho y la relación entre las presiones del ventrículo derecho y sistémica disminuyeron significativamente (de 57,3  $\pm$  30 a  $15 \pm 4,2$  mm Hg y de  $0,67 \pm 0,22$  a  $0,32 \pm 0,04$ , respectivamente) (p < 0,001), con ausencia o mínimo reflujo pulmonar. No se observaron complicaciones. En un seguimiento medio de 14,3  $\pm$  10,3 meses (rango 34-1 meses), todos los pacientes se mantuvieron asintomáticos y libres de insuficiencia significativa.

**Conclusión:** En nuestra experiencia preliminar, el implante de la válvula Melody® resultó seguro y eficaz, demostrando una drástica reducción del gradiente, ausencia de reflujo significativo y una marcada mejoría clínica. Estos hallazgos confirman el excelente desempeño de la válvula en pacientes con disfunción del tracto de salida del ventrículo derecho.

Palabras clave: Válvula pulmonar - Enfermedad de válvulas cardíacas - Procedimientos endovasculares - Prótesis valvular Melody

#### Abbreviations

PA	Pulmonary artery	RV	Right ventricle
RVOT	Right ventricular outflow tract		

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# INTRODUCTION

Development of right ventricular outflow tract (RVOT) regurgitation and/or stenosis is a common complication in patients with congenital heart disease, undergoing angioplasty with or without implantation of non-valved stent, (1) although this strategy is a transient solution since it does not correct the associated severe pulmonary regurgitation. For several decades, the development of severe symptomatic regurgitation in patients with previously corrected congenital heart disease has required surgical repair. (2) However, the risk of cardiac reoperation (2) has prompted less invasive approaches.

Percutaneous Melody<sup>TM</sup> valve implantation (Medtronic Inc.) restores pulmonary valve function. In this report, we describe our initial experience with this prosthesis for the treatment of dysfunctional RVOT in a tertiary care university medical center.

## **METHODS**

#### **Patient inclusion**

All patients treated with the Melody<sup>TM</sup> valve from August 2013 to May 2016 (n=8) were included in the study. Intervention was indicated in case of dysfunctional 16-22 mm diameter RVOT conduit due to mild to moderate regurgitation and/or significant stenosis with gradient >45 mmHg, or right ventricular pressure >2/3 of systemic pressure, who were symptomatic or presented with severe right ventricular enlargement.

## **Procedure description**

Selective angiography of the right ventricle (RV) and pulmonary artery (PA) (trunk and pulmonary branches, Figure 1 A and B) was performed, and chamber pressures were measured, paying attention to the conduit gradient and the association between right ventricular pressure and systemic pressure. Then, coronary arteries were selectively injected, simultaneously occluding the conduit with a balloon to determine if there was coronary compression. The anchor site was then expanded with a balloon <110% the diameter of the original homograft, followed by implantation of one or two covered stents until the conduit gradient was  $\leq 10 \text{ mm Hg}$ .

On a second step, under general anesthesia, the absence of gradient was confirmed (by expanding the balloon within the conduit if necessary), and an extra-rigid super stiff guidewire was advanced into the left pulmonary artery. The Melody<sup>TM</sup> valve was mounted on a 18-22 mm BiB (balloon-in-balloon) balloon, according to the diameter of the conduit. The delivery system was then advanced with the mounted valve up to the anchor site and implanted (Figures 1 C and D). The following criteria determined a successful procedure:

- 1. RVOT gradient  $\leq 10 \text{ mm Hg.}$
- 2. Pulmonary  $\leq$  mild regurgitation.
- 3. Absence of lesions in the RVOT.

Venous access closure (22 Fr) was performed with percutaneous suture (Prostar  $10F^{\,\rm \tiny TM}$  , Abbott Vascular).

Patient follow-up was clinical, and included echocardiographic, X-ray, and ECG controls every 3 months initially, and after the first year, every 6 months for the first 3 years.

Fig. 1. Angiography of the right ventricular outflow tract conduit (anteroposterior and lateral views). A-B. Severe homograft regurgitation. C-D. Regurgitation resolution after Melody<sup>™</sup> valve implantation.



## **Statistical analysis**

Data are expressed as mean  $\pm$  standard deviation for continuous variables, and as number (percentage) in case of categorical variables. Data were analyzed with SPSS, version 10 statistical software package (Chicago, IL, USA).

## **Ethical considerations**

All the patients or legally authorized responsible persons signed a consent form for this type of procedures.

# RESULTS

A total of 8 patients were treated between August 2013 and May 2016. Mean age was  $25\pm18$  years (range: 13-69), and weight was  $56.9\pm9.3$  kg (range: 45-73). Three patients presented with aortic stenosis, and the rest had truncus arteriosus, tetralogy of Fallot, or transposition of the great vessels. Mean correction time was 11.2 years (range: 1 month-16 years), and the number of surgeries per patient was 2.6 (range: 5-1).

The indication was severe pulmonary regurgitation in 2 patients, severe stenosis in 2 patients, and double lesion in 4. All patients had previous stent implantation, with an average of  $2.1\pm0.64$  stents/patient. The implantation was successfully performed on the RV-PA surgical conduit in all the cases (Table 1), with reduction of the RV-PA peak gradient from  $57.3\pm30$  to  $15\pm4.2$  mmHg (p <0.001), and of the RV/aortic pressure ratio from  $0.67\pm0.22$  to  $0.32\pm0.04$  (p <0.001, Table), with absence of or minimum pulmonary regurgitation (Figure 2). No complications were observed.

At mean follow-up of  $14.3\pm5.7$  months (range 34-1), all patients remained asymptomatic with an acceptable right ventricular function (Table 1). In 2 cases, prosthetic regurgitation was not observed, being mild in the remaining 6 patients.

# DISCUSSION

Palliative or corrective valve bioprosthesis implantation, either homografts or valved conduits, invariably develops progressive dysfunction with resultant stenosis and/or regurgitation. (3) Initially, the course of

#### Table 1. Details of the procedure

					Baseline measurements			Post-implant measurements			Follow-up measurements		
Case	Conduit diameter (mm)	Stent	Number of stents	Valve diameter (mm)	Systemic cardiac output (L/min/m2)	RV-PA gradient (mmHg)	RVSP (mmHg)	Systemic cardiac output (L/min/m2)	RV-PA gradient (mmHg)	RVSP (mmHg)	TAPSE	RVSF (%)	Peak trans- valvular gradient (mmHg)
1	20	Palmaz	2	18	5.44	41	64	5.2	15	35	24	48	38
2	18	СР	2	16	5.2	65	72	5.1	15	39	22	45	40
3	18	Palmaz, CP	2	16	4.8	46	69	4.5	10	32	24	47	14
4	18	СР	3	16	4.2	110	145	4.3	15	35	14	32	30
5	18	CP	3	16	5.2	95	131	5.2	14	32	16	35	25
6	20	СР	1	16	4.6	35	48	4.9	15	32	19	49	16
7	22	СР	2	18	4.7	29	48	4.6	24	46	22	38	26
8	20	Andrastent	2	18	4.4	38	56	4.7	12	34	-	-	-

RV-PA: Right ventricle - Pulmonary artery. RVSP: Right ventricular systolic pressure. CP (Cheetah Platinum, Numed Inc), Palmaz (Cordis Corp), Andrastent (Andramed). TAPSE: Tricuspid annular plane systolic excursion. RVSF: Right ventricular shortening fraction.

**Fig. 2.** Coronary angiography during right ventricular outflow tract compression showing bilateral coronary artery patency.



such dysfunction is oligosymptomatic, but the pathologic left ventricular remodeling brings about arrhythmia and reduced functional capacity. (3, 4) Further interventions increase morbidity and mortality of these subjects as a result of adhesions enhancing perioperative bleeding risk. (2) Furthermore, cardiac reoperation in adult patients is associated with a significant risk of heart failure, arrhythmia, myocardial

ischemia, and multi-organ dysfunction.(5) Luckily, since the introduction of the first balloonexpandable valve (1), the advances in percutaneous valve technology have revolutionized the management of these patients. This study presents the preliminary experience with Melody<sup>™</sup> valve implantation in an Argentine tertiary care university medical center with a multi-disciplinary team dedicated to structural heart disease in children and adults. The use of the percutaneous Melody<sup>™</sup> valve approach for dysfunctional RVOT conduit arises from several studies that demonstrated symptomatic improvement and reduction of right ventricular volume, particularly in patients treated for conduit obstruction with or without regurgitation, while this phenomenon is less common in cases of pure regurgitation. In the US Melody Valve Trial (n=148), the rate for reintervention and surgery at 5 years was 26% and 8%, respectively, the main reasons for reintervention being valve fracture and endocarditis. (6-9) Fracture is due to repetitive stress on the device. In this regard, the preparation of the anchor site with a stent developing sufficient radial force has significantly reduced this complication.

The Melody<sup>TM</sup> valve can also be an attractive therapeutic option for patients with bioprosthetic pulmonary valve dysfunction. In our experience, all cases were successful with significant gradient reduction, which led to symptomatic improvement in the midterm follow-up. The absence of complications was also encouraging, taking into account: 1) the average age of the population since the first surgery (13.2 years); 2) the number of previous interventions ( $2.6 \pm 1.4$ ); 3) the high index of RV/systemic pressure ratio ( $0.67 \pm 0.22$ ) and the high baseline gradient ( $57.3 \pm 30$  mmHg).

A current disadvantage of the device is that it can only be used in 15% of the patients with dysfunctional conduit. This is due to conduit size ( $\geq 22$  mm), absence of venous access admitting a 22-Fr introducer, compression of the coronary arteries during conduit occlusion, or recoil limiting the proper diameter needed for valve implantation. The transapical approach can be an effective option in patients with limited venous access, whereas in cases of conduits with larger caliber, the Edwards Sapien valve (up to 29 mm) can be used. We look forward to a self-expandable valve in the near future, so that we can include more cases.

Non-invasive assessment is important to define the anatomy and dimensions of the RVOT and its relation with the aorta. Transthoracic echocardiography is mandatory in these patients, though it can be supplemented with CT scan or cardiac magnetic resonance imaging. Cardiac multislice computed tomography offers improved resolution and detailed information on RVOT abnormalities and its relationship with the coronary arteries, whereas cardiac magnetic resonance imaging estimates right ventricular involvement with greater accuracy, avoiding contrast and radiation exposure. Diagnostic catheterization is the preferred tool in our setting, because it estimates not only the degree of regurgitation but also the severity of the stenosis, which can be treated during the procedure as a previous step to percutaneous valve implantation.

# CONCLUSION

Percutaneous implantation of a prosthesis especially designed to replace the function of the pulmonary valve is a major advance for the treatment of patients with congenital heart diseases, immediately restoring function with minimum risk, and avoiding the danger of a new surgery.

#### **Conflicts of interest**

None declared. (See authors' conflicts of interest forms in the website/Supplementary material).

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