

# Melody Pulmonary Valve Implantation Through the Periventricular Way

Chozas Agustín<sup>1\*</sup>, Augusto Gutierrez<sup>2</sup>, Mariana Lopez Daneri<sup>2</sup>, Christian Kreutzer<sup>3</sup>, Daniel Klinger<sup>3</sup>, Benjamin Chiostrì<sup>3</sup> and Marcelo Rivarola<sup>1</sup>

<sup>1</sup>*Pediatric Hemodynamics, Hospital Universitario Austral, Argentina.*

<sup>2</sup>*Pediatric Cardiology department, Hospital Universitario Austral, Argentina.*

<sup>3</sup>*Pediatric Cardiovascular surgery, Hospital Universitario Austral, Argentina.*

**\*Corresponding Author:** Dr. Chozas Agustín, Pediatric Hemodynamics, Hospital Universitario Austral, Argentina.

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## Abstract

**Introduction:** Percutaneous pulmonary valve implantation (PPVI) initiated a new era in the intervention of congenital heart disease. The Melody valve has the greatest experience around the world with more than 10,000 implants, mostly in the pulmonary position, recommended for patients over 5 years of age and 30kg. There are reports of hybrid implants through a small subxiphoid incision for those patients who do not meet the requirements for a traditional implant.

**Material and method:** Retrospective observational analysis with demographic and procedural evaluation, and medium-term follow-up of two cases of IVP through the periventricular route, in a tertiary care University Hospital.

**Results:** Both patients had multiple sternotomies and had presented severe neurological complications secondary to corrective surgery, which is why they were rejected for surgical valve replacement; weighed less than 30 kg; They met criteria for pulmonary valve replacement and were proposed for periventricular IVP. In a hybrid catheterization laboratory with support from pediatric cardiovascular surgery, a minimal sternotomy (lower third of the sternum) was performed; Extra support guidewire was stabilized in the left pulmonary branch through a hemostatic purse string and Landing Zone was performed with a CP stent. Subsequently, the Melody valve was implanted on an 18 and 22 mm balloon (case 1 and case 2, respectively). Control angiographies were performed without observing pulmonary insufficiency or paravalvular leak. Both were discharged from the hospital in excellent hemodynamic condition at 72 hours, maintaining periodic check-ups.

**Conclusion:** Percutaneous pulmonary valve implantation emerges as an alternative to valve replacement surgery; Periventricular access is a novel technique that allows for effective valve implantation by entering through a small surgical incision, avoiding the complications of major surgery, with excellent results and prompt recovery.

**Keywords:** Pulmonary Valve, Periventricular Way, Pediatric cardiovascular surgery

## Introduction

Since the first percutaneous pulmonary valve implantation in the year 2000 described by Phillippe Bonhoeffer [1 2 3 4], a new era began in the intervention of congenital heart disease. The valve demonstrated satisfactory clinical results and was purchased by the Medtronic company calling it the Melody Valve (Medtronic Inc., Minneapolis, MN). It is currently the valve with the most experience around the world, with more than 10,000 implantations, mostly in the pulmonary position, on right ventricle (RV) conduits to the pulmonary artery or native RV outflow tracts [5 6 7]. The valve is delivered usually through a 22Fr femoral sheath and is recommended for patients > 5 years and > 30kg [8]. Several reports of hybrid implants have been described through a small subxiphoid incision for those patients who do not meet the criteria for a traditional implant, either due to their age, weight or inadequate vascular access, as well as their comorbidities [9 10 11 12].

We report our experience of two Melody valve implants through the periventricular approach in patients who were not candidates for traditional implantation through the femoral approach [13].

## Material and method

It is a retrospective study with demographic and procedural analysis and medium-term follow-up. Table 1 describes the demographic data. Both patients had multiple sternotomies and had presented severe neurological complications secondary to corrective surgery, for which reason they were rejected for surgical valve replacement. Both patients weighed less than 30 kg, so a periventricular valve implantation was proposed.

**Table 1:** Demography.

|        | Diagnosis  | Age (years) | Weight (kg) | Sternotomy (n) | Complication POP  | Intervention in the TSVD | Stent (landing zone) + balloon       |
|--------|--|-------------|-------------|----------------|-------------------|--------------------------|--------------------------------------|
| Case 1 | TOF (Tetralogy of Fallot) + absence of sigmoids                | 4           | 15          | 2              | Seizure syndrome  | Homograft 17             | CP stent 8 Zigs of 34mm in B&B 16×35 |
| Case 2 | PA with VSD (Pulmonary Atresia with Ventricular Septal Defect) | 12          | 26          | 3              | Cerebral ischemia | Homograft 20             | CP stent 8 Zigs of 39mm in B&B 22×40 |

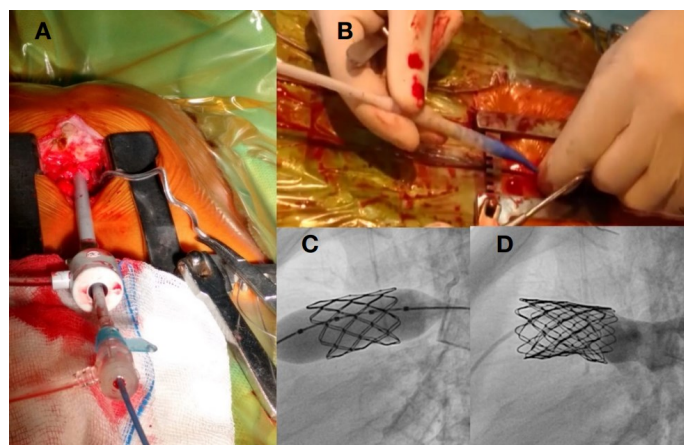
Both were in NYHA Functional Class II, presented moderate cardiomegaly and complete right bundle branch block with a QRS duration of 120 and 160 mS, respectively. They were studied by Cardiac Magnetic Resonance and presented increased RV end-diastolic volumes (EDV); decreased RV ejection fraction; Severe Pulmonary Insufficiency (PI) in both cases. Regarding the echocardiographic study, severe IP was demonstrated; RVOT, Ring and Trunk measurements were performed; both presented pulmonary branches of adequate caliber. They were studied by right and left catheterization in order to measure pressures, perform angiography and rule out the possibility of coronary compression with angioplasty balloon located in RVOT, which was negative. Table 2 describes the measurements.

## Description of the implant technique

Both procedures were carried out in the hybrid catheterization laboratory with support from pediatric cardiovascular surgery, anesthesia and perfusionist (standby). Under general anesthesia, orotracheal intubation, antibiotic prophylaxis according to the infectious disease scheme of our institution, heparin to maintain ACT (activated clotting time) > 250 seconds with time control, peripheral vascular access and right femoral arterial access for monitoring.

**Table 2:** Measurements.

|        | VFDVD (RMN) | VD EF (RMN) | Pulmonary trunk (RMN) | TSVD (ECHO) | Pulmonary ring (ECHO) | Pulmonary trunk diameter (ECHO) | Coronary compression test (CATH) |
|--------|-------------|-------------|-----------------------|-------------|-----------------------|---------------------------------|----------------------------------|
| Case 1 | 178ml/32    | 42%         | 11mm                  | 22mm        | 16mm                  | 11mm                            | Negative                         |
| Case 2 | 170ml/32    | 51%         | 20mm                  | 27mm        | 17mm                  | 20mm                            | Negative                         |



**Figure 1:** A) shows mini sternotomy with sternal retractor, hemostatic purse-string and introducer; B) shows Melody valve delivery system entering RV; C) Landing Zone; D) Melody valve implantation with resolution of pulmonary insufficiency.

Using a surgical technique, a minimal sternotomy (lower third of the sternum) 4 cm long was performed by pediatric cardiovascular surgery, a sternal separator was placed, and a hemostatic purse-string was made through which a 14Fr introducer was positioned to perform new pressure monitoring and angiograms. A Lunderquist (Cook Medical, Bloomington, IN) extra-support guidewire was stabilized in the left pulmonary branch and LandingZone was performed with a CP stent pre-mounted on a B&B balloon (NuMed inc., Hopkinton, NY) under radioscopic guidance. Subsequently, the 22Fr delivery system of the Melody valve pre-assembled in the 18 and 22 mm B&B balloon was advanced (case 1 and case 2, respectively). Its position was correctly located within the CP Stent by means of fluoroscopy and it was implanted without complications, performing a second dilation with an external balloon at maximum pressure. Control angiographies were performed without observing pulmonary insufficiency or paravalvular leak. The delivery system was removed and a hemostatic cuff was adjusted with minimal blood loss. The chest was closed and the hemodynamic situation was controlled. Extubation was achieved without complications. Table 3 details the data of the procedure.

**Table 3:** Procedure.

| Duration (min) | Rx time (min) | Contrast (ml) | Pulmonary ring (mm) | Pulmonary trunk (mm) | Stent (landing zone) + balloon       | Valve diameter |
|----------------|---------------|---------------|---------------------|----------------------|--------------------------------------|----------------|
| 114            | 20            | 230           | 16                  | 11                   | CP stent 8 Zigs of 34mm in B&B 16×35 | 18mm           |
| 143            | 22            | 278           | 17                  | 20                   | CP stent 8 Zigs of 39mm in B&B 22×40 | 22mm           |

Both patients remained in pediatric intensive care for 24 hours and were discharged from the hospital in excellent hemodynamic condition 72 hours later, maintaining periodic check-ups. Case 1 has been in outpatient follow-up for more than 4 years, CF I, decreased VFDVD, does not present pulmonary insufficiency or stenosis. Case 2 has been followed up for two years, CF I, good growth and improvement in cardiac resonance parameters, without stenosis or valvular insufficiency.

## Discussion

Advances in percutaneous valve implantation techniques have revolutionized the world of congenital heart disease [14 15]. Patients who required multiple surgeries using extracorporeal circulation (ECC) currently require less since the valves can be implanted percutaneously. However, when small patients develop dysfunction of their RV-AP conduit or their native tract, therapeutic options are limited. The valves available on the market today to treat dysfunction for both conduits (Melody valve or Edwards Sapien valve) or for native and dilated outflow tracts (Venus valve or Harmony valve), require large introducers which can be potentially traumatic in the veins. Vascular structures of young children.

Based on the experience described in the literature about the different procedures that achieve optimal results through a hybrid periventricular access (ventricular septal defect closure; stage I palliation of hypoplasia of the left cavities, etc.) [16 17], we decided to carry out this procedure using the periventricular access thus avoiding a new surgery and reducing the risks on vascular structures due to the small size of the patient.

Although the volume of cases described is limited, we believe that sharing our experience may contribute to conducting multicenter studies and may encourage other centers to develop this technique.

## Conclusion

In those situations, in which traditional percutaneous valve implantation is not recommended, periventricular access can be used and the delivery system can be entered through a small subxiphoid surgical incision or with minimal sternotomy, avoiding the complications of major surgery, the use extracorporeal circulation and markedly improving patient recovery times and hospital stay.

## Conflict of Interest

The authors declare no conflict of interest.

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