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**Percutaneous pulmonary valve implantation in a single artery branch: A preliminary experience**

Chessa M *et al*. PPVI in a single Artery branch

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**Abstract**

To describe preliminary experience of percutaneous pulmonary valve implantation, in a single pulmonary branch position. Two procedures in 2 patients from a single center are described, where implantation of percutaneous valves within a single pulmonary artery branch was technically successful. The procedural indication was pulmonary valve regurgitation and/or residual stenosis. The 2 patients were symptomatic. An Edwards Sapien™ valve (Patient 1), and a Medtronic Melody™ valve (Patient 2) were implanted. Both pts were discharged with an excellent valve function. In this report it is underlined that this modality is technically feasible and may be considered an option in patients with Congenital Heart Defect under special circumstances.

**Key words:** Congenital heart disease; Tetralogy of fallot; Pulmonary atresia; Percutaneous pulmonary valve; Grown-ups with congenital heart diseases

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**Core tip:** Today MelodyVR valve (Medtronic, Minneapolis, MN) and the SAPIENTM THV valve (Edwards Lifesciences LLC, Irvine, CA) are available to use in patients with a conduit connecting the right ventricle to the main pulmonary arteries (PA). However, given the anatomic variability of the right ventricular outflow tract and the concomitant occurrence of branch PA disease frequently encountered in this patient population, alternative approaches to valve replacement needs to be explored. In order to solve this problem we use a different approach implementing percutaneous pulmonary valve implantation, in a single pulmonary branch position.

Chessa M*,* Butera G, Giugno L, Micheletti A, Negura DG, Carminati M. Percutaneous pulmonary valve implantation in a single artery branch: A preliminary experience. *World J Cardiol* 2015; In press

**INTRODUCTION**

The first successful percutaneous pulmonary valve implantation (PPVI) was described by Bonhoeffer *et al*[1], Currently two balloon expandable transcatheter valves are available for PPVI: the MelodyVR valve (Medtronic, Minneapolis, MN) and the SAPIENTM transcatheter heart valve (THV) (Edwards Lifesciences LLC, Irvine, CA).

Both valves are indicated in patients with a conduit connecting the right ventricle to the main pulmonary arteries (PA). However, given the anatomic variability of the right ventricular outflow tract (RVOT) and the concomitant occurrence of branch PA disease frequently encountered in this patient population, alternative approaches to valve replacement have been explored[2-4]. We report our preliminary experience of PPVI in a single pulmonary branch.

**CASE REPORT**

Two patients (Table 1) underwent PPVI in a single branch between 2013 and 2014.

Patient 1 had a complete repair of tetralogy of Fallot in 2001, followed by a re-operation in August 2003 for residual ventricular septal defect (VSD) + right ventricular outflow tract obstruction (RVOTO). During the second intervention a trans-annular patch (TAP) + VSD closure + Tricuspid Valve plasty and patch enlargement of a hypoplastic left pulmonary artery (LPA) were performed. In 2006, the patient underwent a cardiac catheterization that showed absence of the LPA, confirmed in 2013 with a cardiac magnetic resonance (CMR) patient 2 had a left modified Blalock-Taussig Shunt (MBTS), and then at age 1 year, underwent a complete correction of her PA-VSD + MAPCAs unifocalization and Freestyle 14 mm RV-PA conduit implantation. The conduit was changed when she was 5-year-old using a 23 mm FreeStyle conduit associated with PA bifurcation plasty.

A CMR showed a dilated RV (EDVI = 157 mL/m2) with severe pulmonary valve regurgitation (PVR) (RF = 43%), moderate RVOTO (peak gradient 40 mmHg), preserved RV systolic function, and absence of the right pulmonary artery (RPA) branch.

Informed consent was obtained for both two patients. Femoral venous and arterial accesses were obtained under general anesthesia. A complete left and right heart catheterization was done in both pts.

The RV angiography in patient 1 showed a dilated RVOT with a diameter of 32 mm (Figure 1A-C), too large for classical PPVI. At the origin of the RPA, there was the evidence of a waist (Figure 1D) with a diameter of 24 mm; a prestenting of the PA branch was made with a 43 mm ANDRA XXL stent mounted on 25 mm × 50 mm Crystal Balt balloon (Figure 1E).

The RV angiography in patient 2 showed a dilated, calcified, and moderate stenotic conduit (Figure 2A-B). A prestenting of the conduit was made using 2 premounted covered CP stents (45 mm length, 8 zigs and dilated with a BiB balloon 22 mm × 55 mm) (Figure 2C-E). The final stented conduit had a proximal angle which was considered not perfectly suitable (Figure 2F) for a traditional implant of the percutaneous valve. The valve was implanted at the origin of the LPA were the landing zone was better.

After a standard valve preparation including a thorough washing protocol and crimping protocol, a 26 mm Edwards Sapien valve in patient 1, and a 22 mm MelodyVR valve in patient 2 were deployed.

There were no immediate procedure-related complications. The trans-thoracic echo (TTE) performed the day after showed excellent valve function with no regurgitation and no stenosis. Therefore the patient 2 complained, 48 h later, about an abrupt onset of chest pain, shortness of breath, and hypoxia. She immediately underwent a computed tomography angiograpy (CTA) and the final diagnosis was micro pulmonary embolismi with evidence of filling defects in the distal pulmonary branches in the latero-basal segment of the lower lobe + in the inferior segment of the lingula.

She was immediately transferred to the ICU and she was started on Eparine.

The patient recovered immediately, the saturation became normal and she was discharged at home 10 d after.

At the last follow-up (range 6-12 mo) both pts were asymptomatic, with neither pulmonary valve regurgitation nor residual stenosis.

Patient 1 repeated the CMR 1 year after and the EDVI was 123 mL/m2.

**DISCUSSION**

Robb *et al*[5], reported an animal study, with a Melody valve implantation in the pulmonary artery branches. The Authors demonstrated that RVOT dilation and distortion consistent with transanular patch repair of ToF could be reliably mimicked with an animal model. Secondly, it was shown that PPVI into the right and left branch PAs resulted in a significant reduction in pulmonary regurgitation, with preserved biventricular function demonstrated by MRI and catheterization.

Qureshi *et al*[6], reported a case of a transcatheter placement of the Melody valve in the proximal left pulmonary artery of a patient with acquired right pulmonary artery occlusion.

In our patients the valve was inserted in the only pulmonary artery branch available either because the RVOT was judged to be too large to allow a PPVI in a regular position, or the previous implanted conduit had a better angle (after prestenting) in the distal part, in the area in which there was a conjunction with the left pulmonary artery.

The complication experienced by Patient 2 could have occurred to the fact that some microemboli originate in the lower part of the conduit just under the pulmonary valve. Since this zone in which there is a flow is not contractile, it could have favored a slowing down of the flow, creating a favorable condition for the formation of microemboli. It is difficult to support the idea that these emboli were related to the large sheaths used, because the episode was 48 h later. The pt was anticoagulated with a Heparine bolus of 100 IU/kg and the ACT was > 200 during all the procedure-time: She was just on antiplatelet therapy (ASA: 100 mg as in our protocol), after the procedure. Anticoagulation prophylaxis *vs* standard platelet antiaggregation should be take into consideration for these specific pts.

This brief report shows that PPVI can be performed in Pts with a congenital heart defect, and with a single pulmonary artery branch.

The use of a percutaneous valve in a branch pulmonary artery is not to be proposed for all the pts with a large or with a complex RVOT anatomy; what can be underlined with this report is that this modality is technically feasible and it may be considered as an option in high-risk patients under special circumstances.

**COMMENTS**

***Case characteristics***

Patient 1: Dyspnea and low stress tolerance; and Patient 2: Chest pain, shortness of breath, and hypoxia.

***Clinical diagnosis***

Patient 1: Hypoplasia of left pulmonary branch; and Patient 2: Occlusion of right pulmonary branch.

***Differential diagnosis***

Two patients had no differential diagnosis was possible.

***Laboratory diagnosis***

Patient 1: WBC: 7650/mm3 (N: 66%; L: 18%; M: 10%). Hb: 13.3 g/dL, Hct: 38.4%; PLT 216000/mm3; PCR: 2.8 mg/dL; PCT: 0.05 ng/mL; Patient 2: Hb: 10.2 g/dL, Hct: 31.1%; RBC: 3.78 × 106 U/L; INR: 2.12.

***Imaging diagnosis***

Patient 1: Cardiac magnetic resonance (MR), chest X-ray, echocardiography; Patient 2: Cardiac TC multi-slide, cardiac MR, chest X-ray, echocardiography.

***Pathological diagnosis***

Patient 1: The right ventricular angiography showed a dilated right ventricular outflow tract (RVOT) with a diameter of 32 mm and at the origin of right pulmonary artery (RPA) there was an evidence of a waist with a diameter of 24 mm; Patient 2: A cardiac RM show a dilated right ventricle (EDVI = 157 mL/m2) with severe pulmonary valve regurgitation (PVR) (RF = 43%), moderate **right ventricular outflow tract obstruction** (RVOTO) (peak gradient: 40 mmHg), preserved RVC systolic function.

***Treatment***

Patient 1: 26 mm Edward Sapien Valve implantation in left pulmonary branch; Patient 2: 22 mm MelodyVR valve implantation.

***Related reports***

Patient 1: TOF s/p complete surgical repair and following surgical treatment of residual Ventricular septal defect + RVOTO with trans annular patch (TAP) + VSD closure + Tricuspid valve plasty and patch enlargement of hypoplastic left pulmonary artery (LPA). In 2006 a cardiac catheterization showed the absence of LPA, confirmed in 2013 with a cardiac MR that show hypoplasia of left pulmonary branch; Patient 2: pulmonary atresia + VSD and MAPCAs s/p a left modified Blalock-Taussing shunt (MBTS) and following complete correction with unifocalization and 14 mm RV-PA conduit implantation that five years later was change with a 23 mm FreeStyle conduit + PA bifurcation plasty.

***Term explanation***

PPVI is the Percutaneous Pulmonary Valve Implantation that can be done in case of congenital heart disease in a GUCH population (Grown Ups with Congenital Heart Diseases) with RVOTO and/or PVR.

***Experiences and lessons***

Valve implantation in pulmonary branches could be a useful approach in high-risk patients under special circumstances.

***Peer-review***

This article provided the innovative approach to a particular kind of diseases in critical patients and gave the good results at the last follow up.

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| **Patient** | **DoB** | **Weight**  **(kg)** | **Diagnosis** | **Surgery** | **L/R PAB** | **PVR**  **(yes/no)** | **RVOTO**  **(yes/no)** | **Previous Caths**  **year** | **CMR/CTscan** | **Valve** | **prestening** | **Complications** | **F-Up** |
| 1st(male) | June 2000 | 43 | ToF | TAP | RPAB | yes | No | 2006 | CMR | Sapien 26 | Yes | No | 12-mo |
| 2nd(female) | July 1994 | 56 | PA-VSD-MAPCAs | RV-PA conduit Freestyle 14 mm and  23 mm (1999) | LPAB | yes | Yes (moderate) | 2012 | CMR | Melody 22 | Yes | Yes | 6-mo |

**Table 1 Patients’ characteristics**

PA-VSD-MAPCAs: Pulmonary arteries-ventricular septal defect-major aortopulmonary collateral arteries; TAP: Trans-annular patch; RVOTO: Right ventricular outflow tract obstruction. CMR: Cardiac magnetic resonance.

  

  

**Figure 1 Angiograms in anterior-posterior, LL, right anterior oblique projections of the percutaneous pulmonary valve implantation using a Melody valve.** A-C: Injections in the RV and origin of the RPA showing a dilated RVOT and stenosis at the origin of the RPA; D: Evidence at the balloon sizing of a waist at the origin of the RPA; E: Pre-stenting of the PA branch with a 43 mm ANDRA XXL; F: Good final result after Valve implantation with no evidence of PVR. PPVI: Percutaneous pulmonary valve implantation; RVOT: Right ventricular outflow tract; PA: Pulmonary arteries; RPA: Right pulmonary artery; RAO: Right anterior oblique; AP: Anterior-posterior.

  

  

**Figure 2 Angiograms in anterior-posterior, LL, projections of the percutaneous pulmonary valve implantation using a Sapien valve.** A, B: Injections in the RV showing a dilated and calcified conduit with some degree of stenosis at the PA edge; C: A compliant AGA 34 mm ASD sizing balloon was inserted into the Freestyle conduit showing the stenotic area; D: Prestenting of the conduit using a premounted covered CP stent 45 mm; E: Second covered CP stent was implantation; F: After a re-dilation by utilizing an ATLAS 22 × 40 balloon dilatated at 14 Atm a final stented conduit was obtained with a proximal angle nor suitable for a PPVI in a regular position. PPVI: Percutaneous pulmonary valve implantation; RV: Right ventricular; PA: Pulmonary arteries; AP: Anterior-posterior.