

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

Massimo Chessa, Gianfranco Butera, Luca Giugno, Angelo Micheletti, Diana G Negura, Mario Carminati

Massimo Chessa, Gianfranco Butera, Luca Giugno, Angelo Micheletti, Diana G Negura, Mario Carminati, Pediatric and Adult Congenital Heart Centre, IRCCS-Policlinico San Donato-University Hospital, San Donato Milanese, 20097 Milan, Italy

Author contributions: Chessa M, Butera G and Carminati M designed research; Giugno L, Micheletti A and Negura DG performed research; Giugno L, Micheletti A and Negura DG analyzed data; Chessa M wrote the paper.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment, according with the National Law.

Conflict-of-interest statement: The authors have no conflicts of interest to declare.

Open-Access: This article is an open-access article which was selected by an in-house editor and fully peer-reviewed by external reviewers. It is distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

Correspondence to: Dr. Massimo Chessa, MD, PhD, FSCAI, FESC, Pediatric and Adult Congenital Heart Centre, IRCCS-Policlinico San Donato-University Hospital, via Morandi 30, San Donato Milanese, 20097 Milan, Italy. massimo.chessa@grupposandonato.it
Telephone: +39-2-52774531
Fax: +39-2-52774459

Received: January 29, 2015
Peer-review started: January 30, 2015
First decision: April 27, 2015
Revised: May 29, 2015
Accepted: September 7, 2015
Article in press: September 9, 2015
Published online: October 26, 2015

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

© The Author(s) 2015. Published by Baishideng Publishing Group Inc. All rights reserved.

Core tip: Today MelodyVR valve (Medtronic, Minneapolis, MN) and the SAPIENTM transcatheter heart valve 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; 7(10): 695-699 Available from: URL: <http://www.wjgnet.com/1949-8462/full/v7/i10/695.htm> DOI: <http://dx.doi.org/10.4330/wjc.v7.i10.695>

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 (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 + 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, 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 pre-stenting 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 and B). A pre-stenting of the conduit was made using 2

pre-mounted 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 where 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 angiography (CTA) and the final diagnosis was micro pulmonary embolism 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 transannular 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 pre-stenting) 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

Table 1 Patients' characteristics

Patient	DoB	Weight (kg)	Diagnosis	Surgery	L/R PAB	PVR (yes/no)	RVOTO (yes/no)	Previous Caths (year)	CMR/CT scan	Valve	Prestening	Complications	Follow-up
1 st (male)	June-2000	43	ToF	TAP	RPAB	Yes	No	2006	CMR	Sapien 26	Yes	No	12-mo
2 nd (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

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; PVR: Pulmonary valve regurgitation.

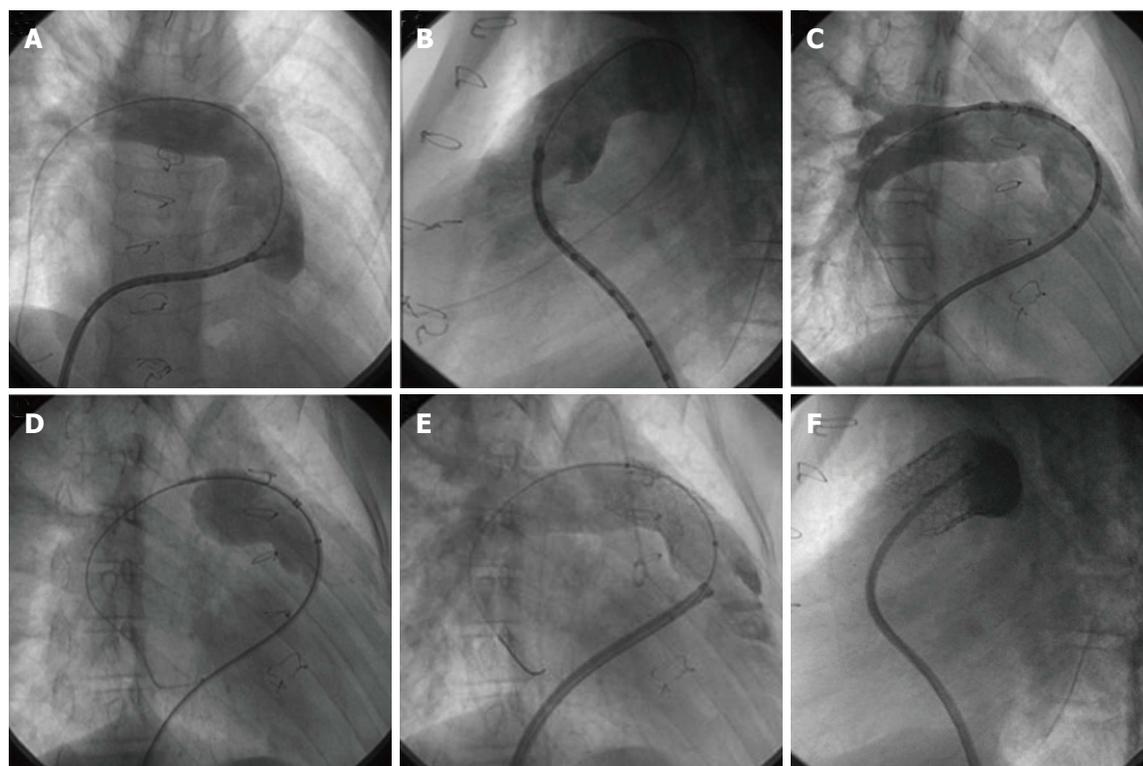


Figure 1 Angiograms in anterior-posterior, LL, right anterior oblique projections of the percutaneous pulmonary valve implantation using a Melody valve. A-C: Injections in the RV and origin of the RPA showing a dilated RVOT and stenosis at the origin of the RPA; D: Evidence at the balloon sizing of a 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; AP: Anterior-posterior.

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.

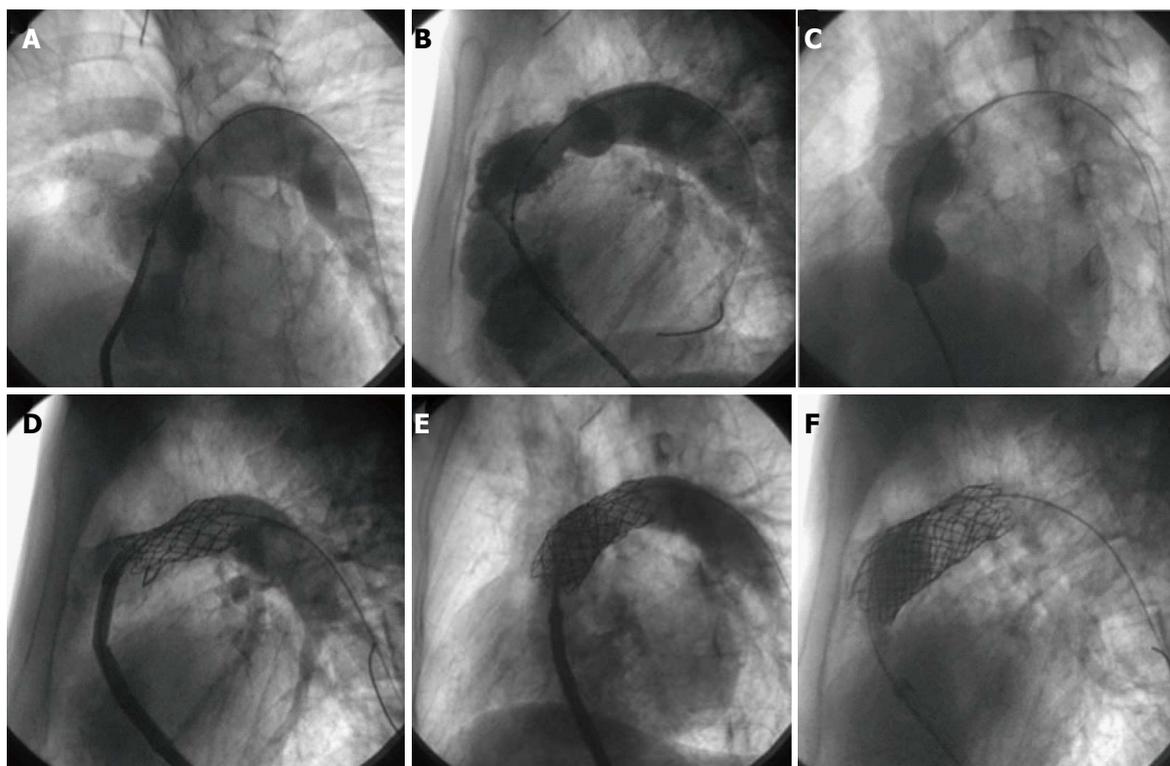


Figure 2 Angiograms in anterior-posterior, LL, projections of the percutaneous pulmonary valve implantation using a Sapien valve. A, B: Injections in the RV showing a dilated and calcified conduit with some degree of stenosis at the PA edge; C: A compliant AGA 34 mm ASD sizing balloon was inserted into the Freestyle conduit showing the stenotic area; D: Pre-dilation of the conduit using a pre-mounted 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.

Clinical diagnosis

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

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 with a diameter of 32 mm and at the origin of right pulmonary artery 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.

REFERENCES

- 1 **Bonhoeffer P**, Boudjemline Y, Saliba Z, Merckx J, Aggoun Y, Bonnet D, Acar P, Le Bidois J, Sidi D, Kachaner J. Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction. *Lancet* 2000; **356**: 1403-1405 [PMID: 11052583 DOI: 10.1016/S0140-6736(00)02844-0]
- 2 **Momenah TS**, El Oakley R, Al Najashi K, Khoshhal S, Al Qethamy H, Bonhoeffer P. Extended application of percutaneous pulmonary valve implantation. *J Am Coll Cardiol* 2009; **53**: 1859-1863 [PMID: 194428865 DOI: 10.1016/J.JACC.2008.08.061]
- 3 **Boudjemline Y**, Agnoletti G, Bonnet D, Sidi D, Bonhoeffer P. Percutaneous pulmonary valve replacement in a large right ventricular outflow tract: an experimental study. *J Am Coll Cardiol* 2004; **43**:

- 1082-1087 [PMID: 15028370 DOI: 10.1016/j.jacc.2003.10.037]
- 4 **Boshoff DE**, Cools BL, Heying R, Troost E, Kefer J, Budts W, Gewillig M. Off-label use of percutaneous pulmonary valved stents in the right ventricular outflow tract: time to rewrite the label? *Catheter Cardiovasc Interv* 2013; **81**: 987-995 [PMID: 22887796]
- 5 **Robb JD**, Harris MA, Minakawa M, Rodriguez E, Koomalsingh KJ, Shuto T, Shin DC, Dori Y, Glatz AC, Rome JJ, Gorman RC, Gorman JH, Gillespie MJ. Melody valve implantation into the branch

- pulmonary arteries for treatment of pulmonary insufficiency in an ovine model of right ventricular outflow tract dysfunction following tetralogy of Fallot repair. *Circ Cardiovasc Interv* 2011; **4**: 80-87 [PMID: 21205938]
- 6 **Qureshi AM**, Krasuski RA, Prieto LR. Percutaneous pulmonary valve implantation in left pulmonary artery branch in a patient with a functional single lung. *J Invasive Cardiol* 2012; **24**: E202-E204 [PMID: 22954578]

P- Reviewer: Kettering K, Landesberg G **S- Editor:** Tian YL
L- Editor: A **E- Editor:** Lu YJ





Published by **Baishideng Publishing Group Inc**

8226 Regency Drive, Pleasanton, CA 94588, USA

Telephone: +1-925-223-8242

Fax: +1-925-223-8243

E-mail: bpgoffice@wjgnet.com

Help Desk: <http://www.wjgnet.com/esps/helpdesk.aspx>

<http://www.wjgnet.com>

