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Percutaneous pulmonary valve implantation in small conduits: A multicenter experience

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ABSTRACT

Background: Guidelines allow percutaneous pulmonary valve implantation (PPVI) in conduits above 16 mm diameter. Balloon dilatation of a conduit to a diameter > 110% of the original implant size is also not recommended. We analyzed patients undergoing PPVI in such conditions.

Methods and results: Nine patients (May 2008–July 2016) from 8 institutions underwent PPVI in conduits <16 mm diameter. Five patients with 16–18 mm conduit diameter underwent PPVI after over-expansion of the conduit > 110%. Mean age and weight of the 14 patients was 12.1 (7.7 to 16) years and 44.9 (19 to 83) kg. Median conduit diameter at PPVI was 12 (10 to 17) mm. Median systolic right ventricular pressure was 70 (40 to 94) mm Hg. Procedure was successful in all cases. A confined conduit rupture occurred in 7 patients (50%) and was treated with covered stent in 6. One patient experienced dislocation of 2 pulmonary artery stents that were parked distally. The post-implantation median systolic right ventricular pressure was 36 (28 to 51) mm Hg. A fistula between right-ventricle outflow and aorta was found in one patient, secondary to undiagnosed conduit rupture. This was closed surgically. After a median follow-up of 20.16 (6.95 to 103.61) months, all the patients are asymptomatic with no significant RVOT stenosis.

Conclusions: PPVI is feasible in small conduits but rate of ruptures is high. Although such ruptures remain contained and can be managed with covered stents in our experience, careful selection of patients and high level of expertise are necessary. More studies are needed to better assess the risk of PPVI in this population.

1. Introduction

Percutaneous pulmonary valve implantation (PPVI) has emerged as an alternative to surgery for reconstruction of the right ventricle outflow tract (RVOT). Since the first PPVI in 2000 [1], multiple studies have confirmed its safety and efficacy [2–9]. The Melody valve (Medtronic Inc., Minneapolis, MN, USA) has been the first valve inserted percutaneously in humans and obtained European certification (CE) in 2006 as well as approval for use in the USA in 2010. Mid-term outcome is good with regards to hemodynamic evolution, functional status and device durability [2–4,7,10]. Nevertheless guidelines recommend its use in conduits with nominal diameter equal to or above 16 mm [7,11]. Moreover, overdilation of the conduit diameter > 110% of the nominal diameter (original implant size) prior to PPVI is not recommended (www.medtronic.com/safety-info-html). PPVI in children with small weight has previously been performed [8,12,13]. But little is known about PPVI efficiency in small and/or over-expanded conduits. A-priori issues were raised with regards to conduit rupture risk [14] and residual gradient across the valve [15]. Thus we analyzed outcome of patients with off-label PPVI in small and over-expanded conduits.

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2. Methods

2.1. Study design

Between November 2008 and July 2016, 14 patients who underwent off-label PPVI in conduits below 16 mm and/or in conduits below or equal to 18 mm with a final Melody valve to tube diameter ratio above 110% were retrospectively analyzed. Procedures were performed in 8 centers (Royal Brompton hospital, England, n = 4; CHU La Timone, Marseille, France, n = 3; Lisbon, Portugal, n = 2; CHU Toulouse, France, n = 1; Astana, Kazakhstan, n = 1; Amman, Jordan, n = 1; Jeddah, Saudi Arabia, n = 1; Beirut, Lebanon, n = 1).

Patients were considered for PPVI if they had congenital heart disease requiring previous RVOT surgery, with an indication for pulmonary valve replacement according to current indications and practices [11]. Patients were discussed and approved for off-label PPVI after a joint cardiac surgical conference. Only patients with "expandable" conduits such as Contegra conduit or homograft or native outflow tract were considered suitable for off-label PPVI. Otherwise, patients with "non-expandable" conduits such as Hancock conduits below 16 mm were not suitable for off-label PPVI and surgical PV replacement was considered. PPVI was contra-indicated in case of active infection or coronary artery compression during balloon testing. Patients with failure attempt of PPVI were not included in this study. The study protocol conforms to the ethical guidelines of the 1975 declaration of Helsinki. Written informed consent for the procedure was obtained from all patients and/or parents before PPVI. The off-label indication of PPVI was explained to the family together with the alternative possibility of surgical valve replacement. The risk of conduit rupture and the potential for emergency surgery were also clearly stated.

2.2. Procedure

Melody valves were used for PPVI. The Melody valve is made of a bovine jugular valved vein (Contegra Pulmonary Valved conduit, Medtronic Inc., Minneapolis, MN, USA) sutured within a Cheatham-Platinium stent (CP stent, NuMED Inc., Hopkinton, NY). The valve was manually crimped and implanted through a dedicated delivery system (Ensemble Transcatheter Delivery System, Medtronic Inc., Minneapolis, MN, USA). It consists of a balloon-in-balloon (BiB, NuMED Inc., Hopkinton, NY) catheter delivery system with a retractable sheath that covers the Melody valve once it is crimped over the balloon. The outer balloon is available in 3 sizes: 18, 20 and 22 mm in diameter.

In view of a potential unconfined conduit rupture requiring covered stent implantation in emergency, all the patients had a pre-procedure computerized tomodensitometry to assess proximity of the coronary arteries from the conduit. RVOT calcification was estimated on pre-procedure CT scan in each patient, using the following descriptive, semi-quantitative approach: Grade 0 = no calcification, 1 = mild calcification, 2 = moderate calcification that is not circumferential, 3 = moderate calcification that is circumferential or heavy calcification that is not circumferential, and 4 = heavy calcification that is circumferential. All procedures were achieved under general anesthesia. Regarding the risk for conduit rupture during staged balloon dilation of the conduit, surgical back-up was organized on a systematic basis. PPVI was performed by a local specialist assisted by the primary investigator (A.F.) in 13 of the 14 cases. Percutaneous trans-femoral access was used in 13 patients. PPVI was done on a one-stage procedure in all cases. Direct invasive hemodynamic measurements and angiographic assessment were made in all patients before and after valve deployment. Minimal internal tube diameter was measured. Progressive balloon dilation of the conduit with high (Mullins, NuMED Inc., Hopkinton, New-York, USA) or ultra-high (Atlas or Atlas Gold, Bard, Tempe, AZ, USA) pressure balloons was performed, through a 14 French long Mullins sheath that was advanced immediately below the conduit. A balloon 2 to 4 mm larger than the conduit diameter was initially used. RVOT angiography was performed after every balloon dilation, to rule-out any conduit rupture. In the absence of rupture, step-by step balloon dilation of the conduit was performed using 2 mm diameter increment until the diameter of the intended pre-stent was reached. Aortic root angiogram was then performed during this latest balloon dilation to exclude coronary compression in lateral and either right-anterior or left-anterior and cranial projection. In case a confined conduit rupture was diagnosed during progressive balloon dilation of the conduit, a covered stent was immediately crimped on a BIB balloon (NuMED Inc., Hopkinton, New-York, USA) of the same diameter or 2 mm larger than the last balloon used for RVOT dilation. If coronary artery testing was already performed, the covered stent was implanted in the RVOT to treat the conduit rupture. If coronary testing was not yet performed, subsequent balloon dilation of the RVOT was performed with the same or a slightly (2 mm) larger balloon than the last one used for RVOT dilation, with concomitant aortic root angiogram. Covered stent was immediately implanted after coronary compression testing. After pre-stenting of the landing zone, Melody valve was implanted through the Ensemble delivery system using the standardized method [11].

At the time of the procedure, no patient presented ongoing infection on either clinical or biological exams. All patients received antibiotics bolus (25 mg/kg intravenous cefazolin) and anticoagulation (100 UI/kg intravenous heparin) at the beginning of the procedure. Prophylaxis and heparin were repeated if the procedure was prolonged, to maintain the ACT > 250. After PPVI, oral aspirin (100–250 mg once a day) was prescribed life-long. Antibiotic prophylaxis and non-specific prevention measures were recommended following guidelines [16].

2.3. Follow-up

Outcome was assessed in September 2017 in all patients. All local investigators were contacted to obtain clinical and echo data at last visit.

2.4. Statistical analysis

For each patient, we collected demographic characteristics, procedural hemodynamic data, technical details, results and follow-up. Statistical analyses were performed using Stata 11.2 software (Statacorp, Texas, USA). Data are summarized as mean (Standard Deviation), minimal and maximal values. The Shapiro-Wilks test did not reject normality of distribution of continuous variables. Categorical variables were summarized as number and percentages. Pre and post procedural hemodynamic data were compared using a Wilcoxon matched-pairs signed rank test. Fischer Exact and Mann-Whitney tests were used to compare variables of interest among patients with versus without conduit rupture after balloon predilation. Reported P-values are two sided. Values of $P < 0.05$ were considered statistically significant.

3. Results (Tables 1–3, Fig. 1)

A total of 14 patients were included at a mean age of 12.1 ± 3.0 years old between November 2008 and July 2016.

Congenital heart defects were cono-truncal defects in 10 cases (71.4%), congenital aortic valve disease with Ross surgery in 2 cases (14.3%), transposition of the great arteries in 1 case (7.1%) and pulmonary valve stenosis in 1 case (7.1%). All patients had a right ventricle to pulmonary artery conduit. A homograft had been used in 10 cases (71.4%), a Contegra (Contegra Pulmonary Valved conduit, Medtronic Inc., Minneapolis, MN, USA) in 3 cases (21.4%) and a non valved tube in 1 case (7.1%). Patient demographics data are presented in Table 1.

Procedural data are displayed in Table 2. PPVI was performed in a one-stage procedure in all cases. A trans-femoral approach was used in 13 cases whereas a left internal jugular vein approach was required in one patient. Predilation of the conduit was performed in all cases with simultaneous coronary artery angiogram. Pre-stenting of the conduit was performed in 13 cases (92.9%). Only one patient with a 15 mm homograft had no prestenting at the beginning of the experience. Two stents were implanted in the RVOT conduit in 4 cases (28.6%). Two

Table 1
Demographics and Diagnostic in patients undergoing percutaneous pulmonary valve implantation in small or overdilated conduits.

Patients	(n = 14)
Age, years	12.1 (3.0) 7.7–16
Weight, kg	44.9 (18.3) 19–83
Congenital heart diseases	
Commun arterial trunk	5 (35.7%)
Tetralogy of fallot with pulmonary atresia	3 (21.4%)
Tetralogy of fallot with pulmonary stenosis	1 (7.1%)
Pulmonary valve agenesis	1 (7.1%)
Ross procedure	2 (14.3%)
Transposition of the great arteries	1 (7.1%)
Pulmonary valve stenosis	1 (7.1%)
Number of surgery	
1	10 (71.4%)
2	4 (28.6%)
Right ventricle outflow tract	
Homograft	10 (71.4%)
Valved conduit (Contegra)	3 (21.4%)
Non valved conduit	1 (7.1%)
Conduit diameter at implantation, mm	
12	1 (7.1%)
13	1 (7.1%)
14	4 (28.6%)
15	3 (21.4%)
16	2 (14.3%)
17	2 (14.3%)
18	1 (7.1%)
Conduit diameter at catheterization, mm	
10	2 (14.3%)
11	4 (28.6%)
12	2 (14.3%)
13	2 (14.3%)
14	3 (21.4%)
16	1 (7.1%)

Data are presented as frequency (% of total patients in the column) or mean (Standard Deviation) minimum-maximum.

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