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Balloon valvuloplasty for critical pulmonary valve stenosis in newborn: A single center ten-year experience

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ABSTRACT

Critical pulmonary stenosis (CPS) represents an emergency in neonates. Percutanous balloon pulmonary valvuloplasty (BPV) is now the first therapeutic option. The study present our experience between April 2003 and June 2013. We analyzed 72 patients with CPS and they were followed up from 18 months to 9 years. BPV was accomplished in 68 neonates. Arterial oxygen saturation significantly elevated after the procedure. There were significant reductions in peak-to-peak pressure gradient across the pulmonary valve. 2 patients had hemopericardium. PGE1 was continued because the right ventricle showed a dynamic RV outflow tract obstruction (RVOTO) in 7 patients. Two patients had PDA stent placement. Follow-up revealed a mean transpulmonary systolic gradient of <35 mm Hg. 7 patients required a second balloon dilatation with good results. These findings suggest that BPV is relatively safe and effective in neonates with CPS.

1. Introduction

Critical Pulmonary Valve Stenosis (CPS) is of the life-threatening congenital heart defects (CHDs) present during the neonatal period by cyanosis. It is a duct dependent lesion [1–3]. In CPS, the right ventricular pressure is supra-systemic indicating the requirement for early intervention, otherwise severe RV hypertrophy will eventually develop [4].

Cardiac surgery, particularly in the neonatal period, is associated with high morbidity and mortality [5,6]. Surgical pulmonary valvotomy was the standard line of management of CPS [7,8]. In the past decade, balloon pulmonary valvuloplasty (BPV) became the standard of management for this lesion [1–3]. BPV was first described in 1983 [9,10] and is considered relatively less invasive with a lower risk of complications and death compared to surgery [5,6].

This work aimed to evaluate the immediate, short and medium term results, and follow-up, of percutaneous balloon pulmonary valvuloplasty for critical pulmonary stenosis of neonates in Paediatric Cardiology Unit, Children Hospital, Mansoura University with ten years' experience.

2. Methods

Between April 2003 and June 2013, all consecutive neonates referred to Paediatric Cardiology Unit, Children's Hospital, Mansoura University, with neonatal cyanosis, diagnosed as having critical pulmonary valvular stenosis and underwent percutaneous balloon valvuloplasty were analyzed retrospectively. Patients records, echocardiograms, catheterization data, and angiograms were reviewed. This study was approved by the Institutional Ethical Review Board of the Children's Hospital. Informed written consents were taken from the parents of all patients included in the study.

2.1. Inclusion Criteria

Neonates who were diagnosed as having critical pulmonary valve stenosis with duct dependent pulmonary circulation and RV/systemic pressure > 1 with a right to left shunt across patent foramen ovale.

2.2. Exclusion Criteria

Patients with a large ventricular septal defect (VSD).Patients with significant right ventricular outflow tract (RVOT) obstruction or

Abbreviations: CPS, critical pulmonary stenosis; BPV, balloon pulmonary valvuloplasty; CHDs, congenital heart diseases; PDA, Persistent ductus arteriosus; RV, right ventricle; RVSP, right ventricular systolic pressure; RVOT, right ventricular outflow tract; RVOTO, right ventricular outflow tract obstruction; PI, pulmonary incompetence; PGE1, prostaglandin E1; NICU, neonatal intensive care unit; LPA, left pulmonary artery branch; RPA, right pulmonary artery branch.

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supravalvular pulmonary stenosis. Patients with PFO or a small VSD were not excluded.

All patients were subjected to full history taking, clinical examination, percutaneous pulse oximetry, chest roentgenography, electrocardiography (ECG) and laboratory investigations essential topre-intervention assessment were conducted.

Transthoracic echocardiography was performed by experienced paediatric cardiologists. Standard echocardiographic views and color Doppler were used to assess right ventricular (RV) size, tricuspid annulus diameter, pulmonary valve morphology and flow, in addition to the level of RVOTO, pulmonary annulus diameter, shunt across PFO, PDA patency and dependency, and the presence or absence of associated cardiac lesions. The maximum pressure gradient across the PV was quantified by the modified Bernoulli equation.

All patients had a well developed right ventricle with a tricuspid annulus size ranging from 9 to 14 mm (mean ± SD, 11.6 ± 1.8). Patients with severe desaturation were maintained on Prostaglandin E1 infusion before, during, and shortly after intervention by a dose of 0.05–0.1 μg/kg/min to maintain arterial duct patency.

2.3. Balloon Pulmonary Valvuloplasty

All patients were anesthetized by general anesthesia using Sevoflurane and under biplane fluoroscopic guidance. Invasive arterial blood pressure was monitored in all patients through the femoral artery or umbilical lines. Femoral venous axis was obtained via Seldinger technique, and then a 4 French Terumo (Tokyo, Japan) sheath was percutaneously introduced. Right ventriculography was accomplished using an NIH side holes catheter, which was placed in the RVOT with injection (1 cm^3/kg over one second). Records were taken in both anteroposterior and lateral views. Pulmonary valve annulus diameter was measured and stored as a photo file. Invasive RV pressure was measured and recorded simultaneously with invasive aortic pressure.

Pulmonary valve was crossed by 0.014 (BMW, SHINOBI or ATW) guidewire or 0.18 Terumo guidewire with the aid of the end-hole 4 French Multipurpose (MP) catheter or the 4 French right Judkins catheter (Cordis, Miami, USA). Manipulations were done to adjust the tip of the catheter to face the pinhole of the critically stenotic pulmonary valve till the wire crossed the valve. The guidewire then was positioned via the PDA in the descending aorta in some cases, or placed in the lower right or left lobar branches in others. The catheter was advanced over the guidewire to the main pulmonary artery to measure the pulmonary artery pressure and peak-to-peak pressure gradient across the pulmonary valve.

The dilatation balloon was advanced over the suitable exchange guidewire. In some cases, we used a pre-dilation technique, in which a coronary balloon (PTCA Dilatation catheter-Boston Scientific) was introduced at the beginning to allow the Tayshak mini balloon to cross the valve, but in other patients Tayshak mini balloon was used from the start with a balloon/annulus ratio of 1.3. The balloon was situated across the annulus and inflated rapidly with the in-deflator using diluted contrast material until the waist disappeared then abruptly deflated. End-hole catheter was inserted over the guidewire after removal of the dilation balloon for pressures assessment after intervention.

Right ventriculography was accomplished after dilatation to assess RVOT obstruction, pulmonary flow and regurgitation. Complications which have occurred during or after intervention were reported and analyzed.

2.4. Statistical Analysis

Data were expressed as mean ± SD. Student *t*-test was used to compare variables. Paired *t*-test was used to compare the same patient before and after intervention. Statistical significance was identified as $P < 0.05$. The Analysis was done using SpSS software (version 21.0; SPSS, Chicago, IL, USA).

3. Results

In the period between 2003 and 2013; 72 patients were referred to The Paediatric Cardiology Unit, Children's Hospital, Mansoura University, and diagnosed as having CPS. Their clinical and demographic data are presented in Table 1. Fifty-eight patients (80%) received PGE1 infusion before the procedure to maintain arterial duct patency by a dose of 0.05–0.1 μg/kg/min. Balloon pulmonary valvuloplasty was accomplished in 68 patients (94.4%) of 72 interventions.

3.1. Procedural Details

All patients were generally anesthetized. Four French sheath was inserted through the right femoral artery in 40 patients (55.6%) however, an umbilical catheter was used in 32 patients (44.4%) for invasive arterial pressure monitoring. Four French sheath was introduced into the right femoral vein in 65 patients (90.2%), in the left femoral artery in 7 patients (9.8%). RV pressure before the procedure was measured in all patients as well as aortic pressure (Table 2).

Right ventriculography revealed well developed and average sized RV in all patients with narrowed RVOT. A very small jet was seen during systole through the severely stenotic pulmonary valve (Fig. 1). Post-stenotic pulmonary artery trunk dilatation was reported in 51 patients (70.8%). None reported peripheral pulmonary stenosis.

Four French multipurpose (MP) end-hole catheter (Cordis) was introduced through the femoral vein over 0.018 Terumo guidewire attempting to cannulate the pulmonary valve. Cannulation via the MP catheter was successful in 42 patients (58.3%). Right Judkins catheter was exchanged for the MP catheter for better angulation with the narrowed RVOT. Successful pulmonary valve crossing was achieved in 26 patients (36.1%) by the aid of the right Judkins catheter. The peak-to-peak pressure gradient across the pulmonary valve was measured and documented for the 68 patients. The guidewire crossed the valve and was positioned through the PDA in the descending thoracic aorta in 8 patients (11.1%), in the peripheral LPA in 36 patients (50%), however, the wire was placed in the peripheral RPA in 24 patients (33%).

In 21 patients (29.1%), the valve opening was pin-hole with failure of TayShak mini dilatation balloon to cross the valve while deflated, necessitating the exchange of the guidewire by a 0.014 soft end coronary guidewire (BMW [Abbot Vascular], SHINOBI [Cordis] or ATW [Cordis]), according to availability during the procedure. Pre-dilatation was achieved via Brio coronary balloon in all the 21 patients (Fig. 2), where the TayShak mini dilatation balloon completed the dilatation procedure.

TayShak mini dilatation balloon was introduced over 0.018 Terumo guidewire from the start in 47 patients (65.2%). The balloon was inflated via the in-deflator till the waist disappeared in 47 patients (65.2%). The range of times of inflations was 1–3 inflations (Fig. 3).

Initial good results of BPV were attained in 68 patients (94.4%). Two patients (2.7%) had a difficult crossing of the PV with the guidewire due to severe tricuspid regurgitation and severe RV hypertrophy but with average TV annulus and RV size. Moreover, both patients were premature and couldn't withstand more prolonged procedure with more

Table 1
Demographic and clinical data of patients ($n = 72$).

Gender (M/F, male %)	49/23, 68%		
Urgent need for PGE1 infusion	80%		
	Mean	±SD	Range
Gestational age (weeks)*	37.8	2.6	29–41
Post-natal age (days)	13.8	7.8	4–35
BW	3.15	0.38	2.3–4
Basal O_2 Saturation	67.9	6	52–80
Duration of follow-up (Years)	4.75	2	1.5–9

* Twelve patients (16.6%) were preterm infants.

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