

IMMEDIATE THERAPEUTIC OUTCOMES OF TRANS CATHETER PULMONARY BALLOON VALVULOPLASTY FOR CRITICAL PULMONARY STENOSIS

Syed Asif Akbar Shah, Mehboob Sultan, Khurram Akhtar, Aziz Ahmed, Nadeem Sadiq, Amjad Mahmood, Ali Nawaz, Kamal Saleem

Armed Forces Institute of Cardiology/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

ABSTRACT

Objective: To share a single centre experience of percutaneous balloon valvuloplasty for critical pulmonary valve stenosis.

Study Design: A retrospective cross sectional study.

Place and Duration of study: This study was conducted at AFIC/NIHD Rawalpindi, from Aug 2010 to Dec 2015.

Materials and Methods: In this study a retrospective analysis of all consecutive infants who underwent BVP for critical PVS was carried out to assess its immediate efficacy and safety.

Results: A total of 28 infants diagnosed with critical PVS were enrolled. Male to female ratio was 1.5:1. Pulmonary valve (PV) annulus mean diameter was 12 ± 4.2 . Mean age of pulmonary BVP was 6 ± 8 years and average balloon to PV annulus ratio was 1.35. Immediate success was achieved in 100% by significant reduction of trans-pulmonary valve peak pressure gradient ($p < 0.001$). One death occurred 5 days after the procedure, 21.4 % had complications and none of our patient needed re-intervention in the immediate post procedure period or before discharge.

Conclusion: Percutaneous BVP was found very effective and safe intervention for critical narrowing of pulmonary valve in order to gain time for further intervention needed in a high risk age group for surgery. Balloon pulmonary valvuloplasty is equally successful in neonates as well as in adult subjects and is the treatment of choice for relief of pulmonary valve stenosis. Surgery should be reserved for unsuccessful BVP. Life-long follow-up to identify the significance of residual pulmonary insufficiency is indicated.

Keywords: Critical pulmonary valve stenosis, Percutaneous balloon valvuloplasty, Patent ductus arteriosus

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INTRODUCTION

PVS has a reported incidence of 0.6 to 0.8 per 1000 live births, and occurs in 50% of all patients with congenital heart disease in association with other CHD's^{1,2}. Critical pulmonary stenosis with an intact ventricular septum is relatively uncommon but demands urgent intervention because of high risk of mortality. It is defined as very severe pulmonary valve narrowing with some flow across the valve resulting in duct dependant pulmonary circulation and cyanosis or RV dysfunction with supra systemic RV pressures³⁻⁷. Cyanosis is because of right to left shunting at atrial level secondary to decrease RV compliance because of RV hypoplasia or hypertrophy. BPV is a preferred therapeutic alternative to surgical valvotomy in patients with

isolated congenital pulmonary valve stenosis³⁻⁶. It results in immediate reduction of the valvular obstruction, it is safe and provides equivalent or better sustained gradient relief when compared to surgical valvotomy^{4,5,12}. Since the first description of balloon pulmonary valvuloplasty in 1982 by Kan⁸, several have applied this technique with great success in all age groups⁹⁻¹¹. Recommended use of a balloon/annulus ratio of 1.2 to 1.5, should give better results¹⁰. In neonates gradational BVP and balloon annulus ratio not greater than 1.3 can significantly reduce incidence of PR in long term¹²⁻¹⁷. Success rates of balloon pulmonary valvuloplasty in infants with critical PS have been reported to be 55% to 94%¹⁸⁻²⁰. Five to ten percent might need surgery to relieve any residual valvular or sub valvular stenosis and 25-30% will need a percutaneous re-intervention in the longterm^{17,21,22}. Previous surgery and pulmonary valve dysplasia are not contra-

Correspondence: Dr Syed Asif Akbar Shah, Department of PAEDS Cardiology, Armed Forces Institute of Cardiology/NHID Rawalpindi Pakistan (Email:Saashah16@hotmail.com)

indications for balloon valvuloplasty^{10,23}. Complication can be higher in infants and neonates but are rare in children and adults²⁴⁻²⁶ and also relatively less as compared to other treatment options like PDA stenting²⁵⁻²⁷, surgical valvotomy and systemic to PA shunt. Neonatal mortality is approx 3% and morbidity is on average 10%^{25,26}. Venous injury, myocardial dissection and necrotising enterocolitis (NEC) are leading causes of mortality. RVOT perforation, cardiac tamponade, PV and TV regurgitation, stroke, seizures, endocarditis, septic shock and abrupt closure of ductus are some important complications during BPVP²⁶. The aim of this study was to assess the immediate results of percutaneous balloon valvuloplasty in all age groups diagnosed with critical pulmonary valve stenosis in a tertiary-care setting.

MATERIAL AND METHODS

A retrospective cross sectional analysis of all consecutive patients from neonatal to adult age group who underwent percutaneous balloon valvuloplasty for critical pulmonary valve stenosis from Aug 2010 to Dec 2015 at AFIC/NIHD was done. We identified 28 patients who fulfilled the following criteria for critical pulmonary valve stenosis: Severe narrowing of pulmonary valve with some antegrade flow across it resulting in duct dependant pulmonary circulation, cyanosis and RV dysfunction or hypoplastic RV or supra systemic RV pressures as well as those who have undergone percutaneous balloon valvuloplasty within 8 weeks of age. Patients with predominantly subvalvular, supra valvular or branch PS, pulmonary atresia, severe tricuspid annulus hypoplasia (<-4 Z score), coronary circulation dependent on the right ventricle, post surgery critical pulmonary stenosis, patients with any other CHD that needed treatment in the neonatal period and patients with large ASD or VSD (but not PFO or small VSD) were excluded from the study.

Clinical records of the selected patients were retrospectively analysed in pre-intervention,

intervention, and immediate post intervention period. In the pre-intervention period age, sex, height, weight, symptoms, oxygen saturation in room air and TTE assessment by an experienced cardiologist for existence and direction of shunt across atrial septal defect/patent foramen ovale, PDA patency and dependancy, tricuspid annulus diameter, right ventricle size, morphology and contraction, pulmonary valve morphology and flow, largest pulmonary annulus diameter measured in systole, maximum peak instantaneous systolic PG across the PV quantified by the modified Bernoulli equation, presence or absence of sub valvular, supra valvular and branch PA's stenosis or any associated cardiac lesions was done. All patients had a well developed right ventricle with a tricuspid annulus size ranging from 9-25 mm (mean \pm SD, 11.6 \pm 1.8). Patients with severe desaturation were maintained on oral Prostaglandin E2 1 to 2 hrly before, during, and shortly after intervention by a dose of 25 microgram/kg/dose to maintain arterial duct patency. During intervention we recorded age, pre and post percutaneous balloon valvuloplasty pulmonary variables such as trans valvular peak pulmonary gradient, right ventricle pressure, procedural details such as diameter of the largest balloon and ratio of the largest balloon/diameter of the pulmonary annulus, and complications during cardiac catheterisation. Patients were analysed 24 hr after the procedure and on discharge from hospital for oxygen dependance, maximum peak instantaneous systolic PG across the PV, degree of PR, RVF reversal of shunt across PFO and need for percutaneous or surgical intervention.

Procedures were performed under general anaesthesia according to the previously described technique^{4,5}. Venous and arterial accesses were placed by cannulation of the femoral vessels. After cannulation of the femoral vein, right cardiac catheterisation was performed. Pressure gradients were measured, followed by right ventricular angiography in lateral projection to measure the diameter of the pulmonary valve

annulus in systole. The valvuloplasty balloon was centred on the annulus valve and inflated until complete resolution of the waist. Finally, pressure measurements were obtained, and a final angiography was performed. Safety of the procedure was assessed by mortality and major complications; success of the procedure was determined by the reduction in pulmonary trans-valvular peak gradient after percutaneous balloon valvuloplasty for values $\leq 50\%$ of pre ballooning gradient and by the need for percutaneous re-intervention or surgical intervention before hospital discharge.

Data Analysis

Continuous variables were expressed as

pulmonary BVP for critical PVS at our institute. sixteen patients (57.1%) were below 1 year of age. Age of the patients ranged from 1 day to 30 years with a mean age of 6 ± 8 years. There were 17 males (60.7%) and 11 females (39.2%). Weight of the patients ranged from 2.5 to 55 kg with a mean of 17 ± 16 kg. Height of the patients ranged from 51 to 165 cm with a mean of 93 ± 41 cm. Calculated body surface area (BSA) ranged from 0.18 to 1.6. The PV annulus measured from the left lateral angiogram had a mean of 12 ± 4.2 (fig-1). The balloon sizes used had a mean of 14 ± 5.7 mm with balloon/ annulus ratio ranging from 1.2 to 1.5. Progressive dilatation or gradational BVP of the critical stenosed pulmonary valve was



Figure-1: Contrast injection via Judkins right catheter at RVOT in LAO 90 degree (Left lateral view) showing a very narrow jet of contrast going across the critically stenosed pulmonary valve.

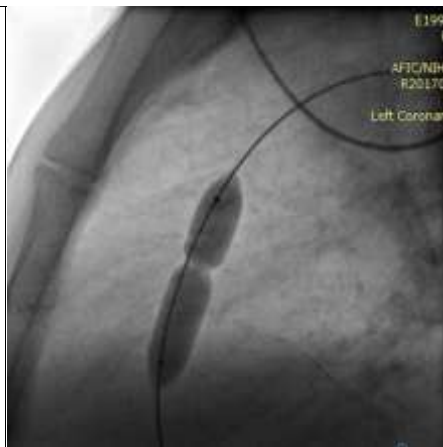


Figure-2: Pre dilatation being done with 12 x 40mm VACS-II balloon over Amplatzer super stiff wire across the critically stenosed pulmonary valve.

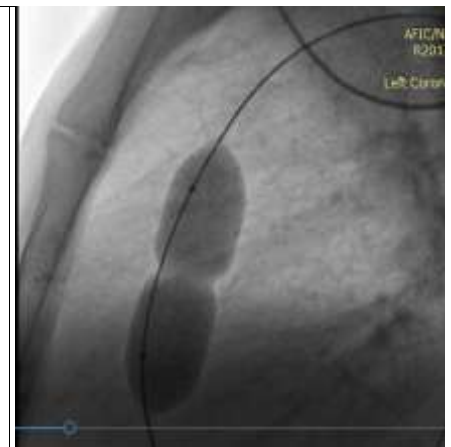


Figure-3: Final dilatation with a bigger balloon (22 x 40 mm VACS-II) over Amplatzer super stiff wire across critically stenosed pulmonary valve.

ranges and Mean \pm Standard deviation. Qualitative variables were expressed as percentages. A paired Student t test was used for the comparison of different variables before versus immediately after BVP. All statistical analyses were performed using SPSS (v 20.0; IBM SPSS Software for Predictive Analytics; SPSS, Chicago, IL, United States of America). A p -value < 0.05 was considered statistically significant.

RESULTS

Over the span of 6 years and 5 months from Aug 2010 to Dec 2015, 28pt's underwent

done in 5 pt's (17.8%) of neonatal age group by using low profile coronary angioplasty balloons over coronary wires deployed across the pulmonary valve and was also done in one 30 years old by using 12 x 40 mm balloon for pre dilatation (fig-2 & 3) to facilitate passage of catheters and guide wires for definitive BVP. The peak to peak trans valvular PG measured during the procedure dropped significantly from a mean of 98 ± 38 mm Hg before performing the BPV to a mean of 29 ± 14 mmHg after the procedure (p -value <0.001). The immediate

success rate defined as the drop in the trans valvular peak to peak PG to more than or equal to 50% of the baseline measurement was achieved in 93% of the cases. Procedural time ranged from 28-180 min with a mean of 62 ± 42 min's and mean fluoroscopy time was 20 ± 18 min's. There was a highly significant drop in trans valvular pulmonary gradient on trans thoracic echocardiogram from a mean of 116.3 ± 41 mmHg to a mean of 30.6 ± 15.4 mm Hg 24 hrs after BPV (p -value <0.001), this drop in the PG was maintained at discharge.

Although incidence of PR significantly increased immediately after the BPV in some of patients ($<30\%$), severity of PR correlated with the increase in balloon/annulus ratio. Regarding complication during BPV, one (3.5%) patient had VT responding to medical treatment, 4 (14.2%) had non fatal cardiac arrest responding to CPR and 2 patients had suboptimal results ($<50\%$ reduction in trans valvular peak PG. The intra-procedure mortality rate was zero but one patient died later due to sepsis and DIC needing mechanical ventilation.

DISCUSSION

Congenital isolated pulmonary valve stenosis is one of the first congenital cardiac defect for which balloon valvuloplasty has become the treatment of choice and preferred therapeutic alternative³⁻⁶ in all age groups regardless of valve morphology²⁸. Since 1984 when Tynan et al²⁹ described the results of percutaneous balloon valvuloplasty in neonates with critical pulmonary valve stenosis many have shown its efficacy and success as first-line treatment for critical PS^{3,5,6,12,14-17,28}. In the present study successful immediate outcome of BPV was reported in 93% of the cases. These results are in close agreement with Loureiro et al³, Alsawah⁷ as well as Luo and his colleagues³⁰ who have studied BPV in neonates with CPS with immediate success rates of 91.7%, 94.4% and 100% respectively. The significant immediate reduction of pulmonary trans valvular PG, RVSP and the PG across the RVOT in the current study

was consistent with data published by Karagoz et al³¹, Saad et al³², zeevi et al³³ and Loureiro et al³. Achieving an immediate gradient reduction by using oversized balloons (20 to 40% larger than the annulus) was consistent with results achieved by Benjamin zeevi et al³³. Hundred percent success was achieved by gradational BVP of the critical stenosed pulmonary valve in 5 pts (17.8%) of neonatal age group in contrast to 75% reported by Janusz et al³⁴ Pre dilatation was necessary in 29.1% cases reported by Alsawah et al⁷ and also described by Li and colleagues³⁵. Contrary to other studies data published by Saad et al³² who reported immediate post procedure PR in 64% and Werynski et al³⁶ in 39.5% of children with critical PS, in our patients significant PR (moderate to severe) was observed in less than $<30\%$ of cases in the immediate post procedure period and at discharge which is in agreement with the recent findings of Loureiro et al³ who found moderate PR in 25% and severe in 4.2% post BVP. None of our patients required any additional percutaneous or surgical intervention during or after BVP before discharge contrary to 2.7% requiring PDA stent implantation during the BVP procedure reported by Alsawah et al and also in some by Mortera and assistants³⁷, Schneider and colleagues³⁸.

Following successful BPV some of our patients were still oxygen or oral PGE2 dependent, to maintain adequate arterial oxygen saturation. This has been reported before by many authors^{6,7,39,40} and thought to be secondary to reactive infundibular stenosis as well as impaired RV compliance resulting in right to left shunt across PFO. These patients were treated with propranolol while on oxygen and oral PGE2 with gradual reduction of PGE2 or propranolol only in mild cases. Our experience in that situation was consistent with that of Alsawah et al⁷, Buheitel and coworkers⁴¹, Freund and colleagues⁴². In our study major complications were observed in 21.4% of patients and only one pt died of complications (3.5%) in the post BVP period, which are almost similar results to what has been reported by Loureiro et al (14 and 31%)

(3), Karagoz et al (2.7 to 25%)³¹ and Alsawah et al⁷ respectively. Relatively low mortality rate is because of inclusion of older age groups in our study like reported with almost no mortality by Rao PS⁵.

CONCLUSION

BVP for critical PS was found relatively safe and effective procedure which can be successfully used as primary procedure for critical PS at all ages and a high success rate with low mortality and morbidity can be achieved by careful and sensible attention to various procedural details. Miniaturization of balloon/catheter systems and refinement of technique can further reduced the complication rate.

LIMITATION OF STUDY

Our study limitations are primarily related to its retrospective nature, sample size and reporting only the immediate post procedure or pre discharge results which limited evaluation of right ventricular function and dimensions after percutaneous balloon valvuloplasty over a longer period of time and also neither the consequences of pulmonary valve regurgitation on the right ventricle. In addition this is a single center data. Multi center studies with longer follow-up periods are needed to analyze the important predictors of successful BPV in patients with critical PS.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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