**Original Article**

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# BALLOON PULMONARY VALVULOPLASTY IN ISOLATED PULMONARY VALVE STENOSIS VERSUS DYSPLASTIC PULMONARY VALVE IN CHILDREN PRESENTING LATE WITH RV DYSFUNCTION AND ARRYTHMIA

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## ABSTRACT

***Objective:*** To compare the result of balloon pulmonary valvuloplasty (BPV) between dysplastic pulmonary valve (DPVS) and isolated PVS and determine various factors affecting the outcome.

***Study Design:*** Descriptive cross sectional.

***Place and Duration of Study:*** Children Hospital Lahore from 2006 to 2012.

***Material and Methods:*** All patients presenting to single tertiary care hospital from June 2006 to May 2012 with severe PVS undergoing BPV were included in the study excluding patients with critical PS. The patients were divided in dysplastic (Group1) and isolated doming (Group2) pulmonary valves based on echocardiographic appearance of the valves. Immediate percentage reduction in gradient across PV and complications in either group were analyzed along with frequency of RV dysfunction, balloon to annulus ratio, pre dilatation and balloon stabilization.

***Results:*** A total of 162 patients underwent BPV. Patients ranged from 3 months to 14 yrs with mean age + SD was 3.7 + 4.0 yrs. There was a male predominance (M:F; 2.1:1). Mean weight was 13.5 + 10.0 kg. DPV was found in 76 patients (46.9%). Thirty four patients (21%) had RV dysfunction at the time of intervention. There was no significant difference between frequecy of RV dysfunction between both groups ($p$ = 0.4). Nine (5.6%) children were pre dilated with a smaller balloon prior to definitive BPV. (Group 1 vs Group 2, $p$ = 0.4). Balloon stabilization was achieved in 145 (89.5%) children. Balloon stabilization was significantly more difficult in group 1 ($p$= 0.01). Mean balloon to annulus ratio was 1.3 + 0.2 with no significant difference between the two groups ($p$= 0.4). Conclusion: Dysplastic Pulmonary valve shows a suboptimal immediate response to BPV compared to isolated pulmonary valve stenosis. DPV and poor balloon stabilization are most important factor determining the outcome. RV dysfunction is significantly associated with arrythmias during BPV.

**Keywords:** Dysplastic pulmonary valve, RV dysfunction.



## INTRODUCTION

Congenital valvular pulmonary stenosis (PS) remains the most common of the etiology of pulmonary stenosis, and comprises nearly 5 to 10% of all congenital heart defects. Prior to 1947 critical valvular PS used to be managed by surgical valvotomy[1]. Transcatheter therapy of valvar pulmonary stenosis is one of the first catheter interventions for structural congenital heart defects. In 1979, Semb et al. first introduced nonsurgical dilatation of stenotic pulmonary valve by balloon technique in a pediatric patient[2] and in 1982, Pepine et al. started pulmonary valve ballooning in an adult patient[3]. Based on last 20 years data both short- and long-term results of this transcatheter intervention in pediatric age group have been well established[4]. BPV is now the choice of treatment for valvular PS since 1982 reported by Kan et al and method for treating congenital pulmonary valve stenosis[5]. Mostly the patients have thick, conical or dome-shaped pulmonary valve due to fusion of commissures. Occasionally it may be dysplastic, which is related to Noonan's syndrome[6]. While defining the severity, there is general agreement that transvalvular peak systolic pressure gradient <25 mmHg is graded trivial; 25 to 49 mmHg, mild; 50 to 79 mmHg, moderate; > 80 mmHg, severe[7]. The indications for intervention should include patients with

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exertional dyspnea, angina, syncope, or pre syncope[8].

Information about comparative results of ballooning of isolated pulmonary valve stenosis versus dysplastic pulmonary vave is limited. Despite various studies, outcome of ballooning in cases of severe pulmonary stenosis,there is scarce literature on the results of various categories of pulmonary stenosis presenting late with RV dysfunction and arrhythmia.

The purpose of this study was to compare the ballooning of various types of pulmonary stenosis with RV dysfunction with special reference to immediate and late complications of this transcatheter procedure especially in our population.

## METHODOLOGY

The children brought to our tertiary care institute from June 2006 to May 2012 having severe PVS (isolated PVS as well as DPV) undergoing BPV were included in the study excluding patients with critical PS. The patients were divided in dysplastic (Group1) and isolated doming (Group2) pulmonary valves based on echocardiographic appearance of the valves. Immediate percentage reduction in gradient across PV and complications in either group were analysed along with frequency of RV dysfunction, balloon to annulus ratio, pre dilatation and balloon stabilization.

Before the procedure, detailed transthoracic echocardiogram was done in all patients for evaluation of RVOT gradient across the pulmonary valve,estimation of pulmonary valve annulus, ruling out of infundibular and supravalvular stenosis and assesss the shape and leaflets of the valve . During the procedure initially RV angiogram was done for Visualization of RV cavity, pulmonary annulus and infundibular anatomy, simultaneously Preballooning RV pressure was measured, multiple types of balloons (Tyshak II, Z-med, Cordis, Atlas) were used for valvuloplasty. All children were monitored for 24 hours post procedure and detailed echocardiogram was done the next day to evaluate pulmonary Insufficiency, transpulmonary gradient, clot formation, pericardial effusion and function of right Ventricle. The patients were called two weeks after the procedure for follow up.During follow up detailed echocardiogram was done for adequecy of ballooning and any complication.

Informed written consent was taken from parents with expailnation of details of the procedure. Almost all children undergoing balloon valvuloplasty were given general anaesthesia. Pre procedural assessment was done to rule out infection (total leukocyte count), renal function status (urea, electrolytes, creatinine) and estimation of hemoglobin level.

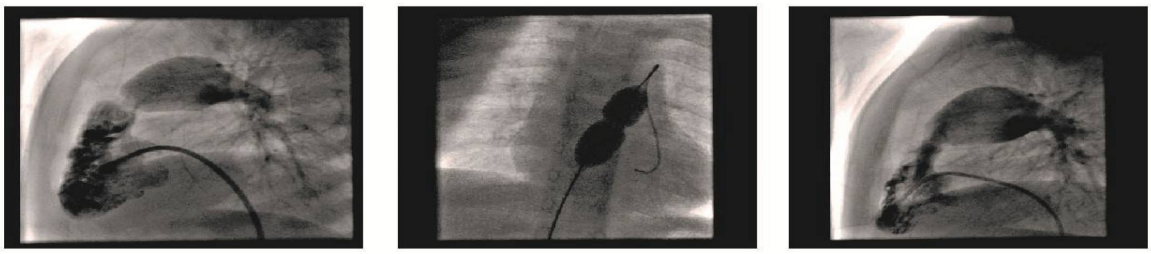

**Figure-1: Transcatheter balloon stabilization.**

During procedure venous access was taken from femoral vein (preferably right) with 6F sheath followed by introduction of Multipurpose catheter to the right ventricle (RV).RV pressure was taken and RV angiogram was done in LAO (left anterior oblique) 90 degree. Based on this angiogram pulmonary valve annulus measured and balloon size 30% more than actual annulus was selected in most of the cases. Subsequently with the introduction of guide wire with in MP catheter pulmonary valve was crossed and pulmonary artery pressure was measured. The guide wire was then exchanged with extra stiff exchange wire in elder children and terumo wire in infants .The wire position was stabilized in left

pulmonary artery (LPA) in most of the cases and right pulmonary artery in few children. The balloon was thoroughly prepared with deairing the system. After stabilization the wire the sheath size was changed compatible with balloon. The contrast used for balloon inflation was diluted (70% contrast 30% saline). The balloon was mounted over the wire carefully while rotating over the wire and depending on the anatomical landmark with two markings on balloon (proximal and distal), the position was verified in same LAO 90 degree position. The balloon was inflated under fluoroscopy till the waist disappeared (fig-1).

During inflation ECG, Oxygen saturation, Pulse and blood pressure was monitored. After deflation the inflation was reinflated to achieve optimal results. After complete deflation the balloon was taken out carefully. Later on MP catheter was reintroduced, LPA pressure and RV pressure was taken. To confirm results of ballooning, RV angiogram was done in the same left lateral position and flow pattern across the pulmonary valve estimated (fig-2).

## RESULTS

A total of 162 patients underwent BPV. The age ranged from 3 months to 14 yrs. with median 2yrs and mean 3.7 + SD 4.0 yrs. There was a male predominance (M:F; 2.1:1). Mean weight was 13.5 + 10.0 kg. DPV was found in 76 patients (46.9%). Thirty four patients (21%) had RV dysfunction at the time of intervention. There was no significant difference between frequency of RV dysfunction between both groups ($p$=0.4). Balloon stabilization was significantly more difficult in group 1 ($p$=0.01) (figure. 1). Mean balloon to annulus ratio was 1.3 + 0.2 with no significant difference between the two groups ($p$=0.4).

Average pre-procedure systolic gradient across PV fell from 93 + 35 mmHg to 29 + 20 mmHg with mean percentage reduction of 67.2 + 19.8%. Percentage reduction in gradient was significantly lower in Group 1 (62.9 + 22.5% vs 70.6 + 16.6%, $p$ = 0.02) (figure.2). Ninety patients (55.6%) had a successful BPV, 67 (41.4%) partially successful BPV with residual gradient while attempt failed in 5 (3.1%) children. DPV and poor balloon stabilization were significantly associated with partial relief or failed attempt ($p$=0.038 and <0.001 respectively).

RV dysfunction was significantly associated with various arrythmias (3.7%, SVT in 3, significant sinus bradycardia in 3) during procedure ($p$=0.001). Thirteen (8%) had RV Muscle bundles causing RVOT obstruction, and 1 having severe pulmonary insufficiency post procedure. There was no significant correlation between balloon to annulus ratio to gradient reduction in either group ($p$=0.78).

## DISCUSSION

Since 1947 surgical valvotomy has been performed for critical valvular PS. Trans catheter therapy of valvar pulmonary stenosis is one of the first catheter interventions for structural congenital heart defects. In 1979, Semb et al. first introduced nonsurgical dilatation of stenotic pulmonary valve by balloon technique in a pediatric patient, and later in 1982, Pepine et al. first described successful balloon valvuloplasty in an adult patient9. During the past 20 years, both short- and long-termbenefits of this non-surgical procedure in children or infants have been well established[10]. BPV has become the choice of treatment for valvular PS since the first series reported by Kan et al, a method for treating congenital pulmonary valve stenosis[11].

The pathologic features of the stenotic pulmonary valve vary; the most commonly observed pathology is what is described as a ‘dome-shaped’ pulmonary valve[12].

Pulmonary valve dysplasia is characterized by thickened, nodular, and redundant valve leaflets with minimal or no commissural fusion, valve ring hypoplasia, and lack of post-stenotic dilatation of the pulmonary artery[13].

Occasionally, the valve may be dysplastic, which is related to Noonan’s syndrome[14]. Changes secondary to pulmonary valve obstruction do occur, and include right ventricular muscle hypertrophy, proportional to the degree and duration of obstruction[15]. Dilatation of the main pulmonary artery, independent of the severity of obstruction,

presumably related to a high velocity jet across the stenotic valve[16]. The majority of children with valvar PS are asymptomatic and are detected because of a cardiac murmur heard on routine examination, although they can present with signs of systemic venous congestion (usually interpreted as congestive heart failure) due to severe right ventricular dysfunction or cyanosis because of right to left shunt across the atrial septum. There are various definitions of severity grading, but there is general agreement that transvalvular peak systolic pressure gradient <25 mmHg is trivial; 25 to 49 mmHg, mild; 50 to 79 mmHg, moderate;_ 80 mmHg, severe[17].It is generally believed that indications for balloon pulmonary valvuloplasty are similar to those used for surgical pulmonary valvotomy, i.e., a moderate degree of pulmonary valve stenosis with a peak to peak gradient ≥ 50 mmHg with normal cardiac index18. It is recommended that the indications for intervention should include the patients with exertional dyspnea, angina, syncope, or presyncope[19].

Natural history studies revealed that trivial and mild stenoses (<50mmHg gradient) are likely to remain mild at follow-up, and an increase in gradient can easily be quantitated by echo Doppler studies at follow-up examination, and if an increase in gradient is documented, the patient could then undergo balloon dilatation[20].

Based on these observations, balloon dilatation should be performed only in patients with a peak to peak gradient > 50mmHg[21]. In a series, 16 (23%) of 71 patients had right ventricular pressure twice that in the left ventricle and these children underwent successful balloon valvuloplasty. Therefore, it is believed that extreme stenosis is not a contraindication for balloon dilatation[22]. Pulmonary valve dysplasia has been considered by some workers as a relative contraindication for balloon dilatation. Based on various experiences, balloon valvuloplasty is the initial treatment of choice[23]. However, based on poor response to exercise and potential for development of myocardial fibrosis, it is prudent to provide catheter-directed relief of the obstruction in all patients, including adults, with moderate to severe stenosis, irrespective of the symptoms[24]. Occasionally surgical intervention may become necessary when there is severe supravalvar stenosis, significant valve annulus hypoplasia, severely dysplastic pulmonary valves, or persistent and severe infundibular narrowing (most of this resolves spontaneously or with beta-blocker therapy) despite successful balloon pulmonary valvuloplasty[25].

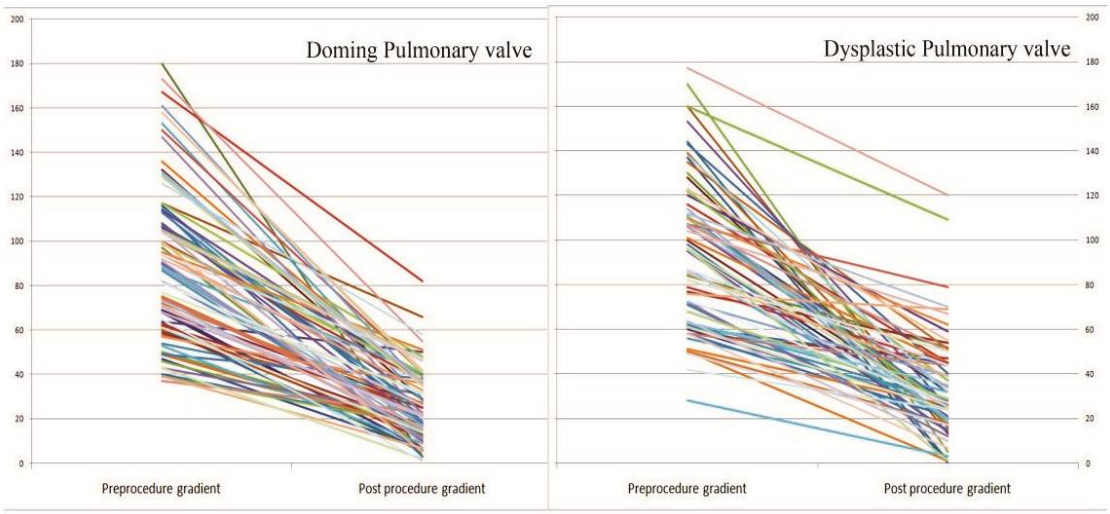


**Figure-2: Fall in gradient across pulmonary valve after balloon valvuloplasty (mmHg).**

The first attempt to relieve pulmonary valve obstruction by transcatheter methodology was in the early 1950s by Rubio-Alverez et al[26]. More recently, Kan and her associates applied the technique of Gruntzig et al to relieve pulmonary valve obstruction by the radial forces of balloon inflation of a balloon catheter positioned across the pulmonic valve[27]. Two-dimensional (2D) echocardiographic pre-cordial short and long axis and sub costal views are most useful in the evaluation of the pulmonary valve leaflets. Thickening and doming of the pulmonary valve leaflets can often be visualized[28].

It was initially thought that the peak instantaneous gradient is reflective of the peak to peak systolic gradient measured during cardiac catheterization; however, the peak instantaneous gradient overestimates the peak to peak gradient, presumably related to a pressure recovery phenomenon[29].

The percutaneous femoral venous route is the most preferred entry site for balloon pulmonary valvuloplasty and should be used routinely. However, other sites such as the axillary, jugular, venous, or transhepatic routes have been successfully used in the absence of femoral venous access[30]. Calculation of the pulmonary valve area by the Gorlin formula has been advocated by some workers, but because of multiple assumptions that must be made during calculation and because of limitations in applying this formula to calculate the pulmonary valve area, it is not routinely calculated. Instead, we utilize peak to peak pulmonary valve gradients to assess the severity of obstruction after ensuring that the cardiac index is within the normal range[31].

The initial recommendations were to use a balloon that is 1.2 to 1.4 times the pulmonary valve Annulus[32]. Most authors suggested that balloon to annulus ratio should not exceed 1.5 due to the higher risk of severe PR or annular laceration, unless there is a residual RV to PA pressure gradient greater than 36 mmHg[33]. Balloons larger than 1.5 times the pulmonary valve annulus should not be used because of the damage to the right ventricular outflow tract such large balloons may produce[34]. While the recommendation to use balloons 1.2 to 1.4 times the annulus is generally followed, recent reports of pulmonary insufficiency at late follow-up raised concerns regarding the balloon size[31,35]. We should strive for a balloon/annulus ratio of 1.2 to 1.25 instead of the previously recommended 1.2 to 1.4. Such smaller balloons are likely to result in good relief of pulmonary valve obstruction while at the same time may help to prevent significant pulmonary insufficiency at late follow-up.

With shorter balloons it is difficult to maintain the balloon center across the pulmonary valve annulus during balloon inflation. Longer balloons may impinge upon the tricuspid valve, causing tricuspid insufficiency, or on the conduction system, causing heart block[36].

The following formula may be used to calculate the effective balloon size: $D1+D2+\pi (D1/2 +D2/2)/ \pi$

Where D1 and D2 are the diameters of the balloons used. This formula has been further simplified[37]. Some cardiologists advocate the use of double balloon valvuloplasty instead of single balloon valvuloplasty especially for adult patients[38]. When equivalent balloon/valve annulus ratios are used, the results of double balloon valvuloplasty, though excellent, are comparable to, but not superior to those observed with single balloon valvuloplasty[39].

The recommendations for balloon inflation pressure (2.0 to 8.5 atm), number of inflations (one to four), and duration of inflation (5 to 60 seconds) varied from one investigator to the other, but without many data to support such contentions. We have examined these parameters from our study subjects[40].

We would recommend balloon inflation at or below the level of balloon burst pressure stated by the manufacturer, and will continue balloon inflation until the waisting of the balloon disappears. One additional balloon inflation is done after disappearance of waisting is demonstrated, to ensure adequate valvuloplasty.

If the balloon is not appropriately centered across the pulmonary valve, the position of the

catheter is re-adjusted and balloon inflation repeated. Once satisfactory balloon inflation is achieved, one more balloon inflation may be performed as per the operator's preference. The balloon catheter is removed, leaving the guide wire in place. Either a multi-track catheter 50 or a Tuohy–Borst is used to record the pressure gradients across the pulmonary valve so that the guide wire is left in place across the pulmonary valve while the results of valvuloplasty are evaluated[41].

**Problems**

The balloon may not be truly across the pulmonary valve during balloon inflation. It is important to ensure that the balloon is indeed across the valve. The waisting of the balloon may be produced by supravalvar stenosis or infundibular constriction. When in doubt, centering the balloon at various locations across the right ventricular outflow region may become necessary.

**Acute Complications**

Complications during and immediately after balloon valvuloplasty have been remarkably minimal; the VACA registry reported a 0.24% death rate and 0.35% major complication rate[51] from the 822 balloon pulmonary valvuloplasty procedures from 26 institutions, attesting to the relative safety of the procedure[42]. Systemic hypotension may be minimal in the presence of a patent foramen ovale52 because of a right to left shunt across it, filling the left ventricle[43]. Use of a short period of balloon inflation may help to reduce the degree and duration of hypotension. Complete right bundle branch block, transient or permanent heart block, cerebrovascular accident, loss of consciousness, cardiac arrest, convulsions, balloon rupture at high balloon inflation pressures, rupture of tricuspid valve papillary muscle, and pulmonary artery tears, though rare, have been reported. Meticulous attention to the technique, use of the appropriate diameter and length of the balloon, avoiding high balloon inflation pressures, and short inflation/deflation cycles may prevent or reduce the complications.

Development of severe infundibular obstruction has been reported. Infundibular gradients occur in nearly 30% of patients; the older the age and the higher the severity of obstruction, the greater is the prevalence of infundibular reaction[44]. When the residual infundibular gradient is ≥50 mmHg, beta-blockade therapy is generally recommended[45]. Transient prolongation of the QTc and the development of premature ventricular contractions following balloon pulmonary valvuloplasty have been reported, causing concern that an R-on-T phenomenon may develop and produce ventricular arrhythmia.

**Complications at Follow-up**

Femoral venous occlusion and development of restenosis and pulmonary insufficiency have been noted. Between 7 and 19% of the patients may develop femoral venous obstruction; the femoral venous obstruction is more likely in small infants[46]. Poor long-term result is observed if the valve is dysplastic or the ratio of balloon to annulus diameter <1.2 or residual transvalvular pressure gradient >36 mmHg[47]. Recurrent pulmonary valve obstruction may occur in about 8% of patients and repeat balloon valvuloplasty may help relieve the residual or recurrent obstruction[48]. If the substrate (dysplastic valves without commissural fusion, supravalvar pulmonary artery stenosis, or severe fixed infundibular obstruction) is the problem, surgical intervention may become necessary. Long term follow-up data of balloon pulmonary valvuloplasty, reviewed in detail elsewhere[32,36,38] indicate development of pulmonary insufficiency (PI); the frequency and severity of PI increase with time[49]. 70 of 80 (88%) had PI at long term follow-up,while only 10% had PI prior to balloon valvuloplasty. Similar experiences documenting a high incidence of PI have been reported by other workers in the field50. Most of the cardiologists did not require pulmonary valve replacement for PI, 6% of patients followed by Berman et al. developed severe PI, requiring (or requiring consideration for) pulmonary valve replacement[51].

### Post-catheter Management

Electrocardiogram and an echocardiogram is performed on the morning following the procedure. Clinical, electrocardiographic, and echo Doppler evaluation at 1, 6 and 12 months after the procedure and yearly thereafter is generally recommended. Regression of right ventricular hypertrophy on the electrocardiogram following balloon dilatation has been well documented and the electrocardiogram is a useful adjunct in the evaluation of follow-up results[52].

However, electrocardiographic evidence for hemodynamic improvement does not become apparent until 6 months after valvuloplasty. The Doppler gradient is generally reflective of the residual obstruction and is a useful and reliable non-invasive monitoring tool.

## CONCLUSION

Severe PVS presents late with 1/3rd having RV dysfunction. DPV and poor balloon stabilization are most important factor determining the outcome of BPV. RV dysfunction is significantly associated with arrythmias during intervention.

## CONFLICT OF INTEREST

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

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