ORIGINAL ARTICLE

OUTCOME OF BALLOON VALVULOPLASTY IN CHILDREN WITH PULMONARY STENOSIS – SINGLE CENTER EXPERIENCE

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Background: Pulmonary valve stenosis (PS) is common congenital heart disease in children and patient can present with cyanosis, chest pain, dyspnea and failure with severe form. The objective of this study was to enlighten the short outcome of balloon pulmonary valvuloplasty in children with severe pulmonary stenosis. **Methods:** This cross sectional observational study was done in paediatric cardiology department of Lady Reading Hosptial, Peshawer form June 2019 to December 2020 over 1.5 years. Children aged 6 months to 16 years of either sex diagnosed as case of severe stenosis with doming pulmonary valve and having symptoms of chest pain and dysnea on exeration and pregradient pressure of 64 mm Hg or more on echocardiography were included. Patients were interviened with ballon-valvuloplasty. Outcome was taken as discharge from hospital with complications after procedure if any. Patients were followed up for 3 months. Data including age, sex, pre cath echocardiography, cath pulmonary valve annulus, post ballooning pulmonary valve (PV) gradient, PV gradient on echocardiography after intervention and follow up gradient on echocardiography at three months was documented. Data was analyzed by SPSS 20. Chi square test and paired T - Test was applied where required. Results were taken as significant with p value <0.05. **Results:** There were 51 patients, 35 (68.6%) male and 16 (31.4%) female. Mean age was 8.35±4.93 years. Mean pre cath gradient across the pulmonary valve on echocardiography was 109.14±31.44 mm Hg. Post intervention mean pressure gradient across PV was 32.41±11.49 mm Hg. Pulmonary valve annulus on echocardiography before intervention ranged from 7 to 25 mm with mean of 14.67±3.79 mm. There was no complication in majority (82.4%) of patients. Mild PR was in 5 (9.8%) patients. There was significant relationship between pre and post intervention pressure gradient across PV valve with p value of <0.001. **Conclusion:** Balloon pulmonary valvuloplasty in one of the safest intervention for PS in children with few complications.

Keywords: Pulmonary valvuloplasty; Pulmonary valve stenosis; Children; Outcome

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INTRODUCTION

Pulmonary valve stenosis (PS) is one of common congenital heart disease in children. Its presenaiton can be asymptomatic with incidental finding of murmur or in severe stenosis with cyanosis, chest pain, dyspnea and failure.[1] The incidence of pulmonary valve stenosis has been reported as 3.1% in one of study by Patel N *et al*.[2] The prevalence of PS is reported to be more in Asian countries as compare to Western countries including USA and Europe.[3–5]

The presentation of PS can be isolated or in association with other CHD including patent foramen ovale, ventricular septal defect, patent ductus arteriosus and atrial septal defect. There are three subtypes of PS including the common most valvular stenosis, sub valvular stenosis and supra valvular stenosis.[6]

In children with moderate, severe, and critical PS, pulmonary balloonvalvuloplasty is the treatment of choice, which issafe and effective treatment.[7]

The first trans-catheter balloon pulmonary valvuloplasty (BPV) was done by Kan et al. in 1982 and since then pulmonary valvuloplasty has become the preferred procedure of choice for simple PS patients with minimally invasive approaches and good outcomes.[8]

Majority of data regarding the outcome and efficacy of pulmonary valve ballooning is from the developed coutnries but data is lacking from developing countries. In Pakistan data is scarce especially in children. The objective of this study is to enlighten the outcome of pulmonary valvuloplasty in children with pulmonary stenosis (PS).

MATERIAL AND METHODS

This cross sectional observational study was done in paediatric cardiology department of Lady Reading Hosptial, Peshawer form June 2019 to December 2020 over 1.5 year. Priror to study, approval for ethical review board was taken. The estimated sample size was 47 patients with taking prevalence of PS as 3.1% as reported by Patel N *et al*.[2] and confidence interval of 95% by open epi smaple size calculator. Inclusion

criteria was patients of either sex diagnosed as case of severe PS stenosis with doming pulmonary valve. Patient having symptoms including chest pain and dysnea on exerationwith pregradient pressure of 64 mm Hg or more across pulmonary valve on echocardiography, aged 6 months to 16 years were included after taking consent from parents. Children who were having haing mild PS requiring no intervention, having syndromic featueres, other associated congenital cardiac anomalies were excluded. Patients were interviened with ballon valvuloplasty and Tyshak II balloon was used. Balloon size used was 1.2–1.4 times larger than the pulmonary valve annulus on cath. Outcome was taken as discharge from hospital with complications after procedure as Optimal BPV (with gradient across Pulmonary valve reduced to more than 50% compared to pre-procedure) mild pulmonary regurgitation, puncture site hematoma, bleed requiring blood transfusion or no complication.Echocardiography was done before discharge and pressure gradient was documented. Patients were followed up for 3 months. Follow up echocardiography was done at three months for pressure gradient. Data including age, sex, pre cathechocardiography, cathpulmonary valve annulus, post ballooning pulmonary valve (PV) gradient, PV gradient on echocardiography after intervention and follow up gradient on echocardiography at three months was documented. Data was analyzed by SPSS 20 and chi square test was applied where required. Results were taken as significant with p value <0.05. Also paired T-Test applied for comparison of pre and post mean.

RESULTS

There were total of 51 patients included in this study. Out of 51 patients, 35 (68.6%) were male and 16 (31.4%) were female. Age of patients ranged from 6 months to 16 years with mean age of 8.35±4.93 years. Pre cath gradient across the pulmonary valve on echocardiography ranged from 65–180 mm Hg before intervention with mean of 109.14±31.44 mm Hg. PV annulus on echocardiography before intervention ranged from 7–25 mm withmean of 14.67±3.79 mm. Other findings of pre and post cath and echocardiography are given in table-1. There was no complication in majority (82.4%) of patients. Puncture site hematoma was there in 3 (5.9%) patients, mild PR in 5 (9.8%) patients and bleed requiring transfusion was in one (2%) patient. All observed complications were in age group less than 5 years as shown in table-2.

Paired T-test was applied for pre and post intervention PV gradient on echocardiography. Post intervention mean pressure gradient across PV was 32.41±11.49 mm Hg. There was significant relationship with pre and post invetervtion pressure gradient across PV on echocardiograpy with p value of <0.001 as shown in table-3. Mean pressure gradient across PV on cath prior to intervention was 104.33±37.41 mm Hg. And mean pressure post intervention was 24.61±12.55 mm Hg. There was significant relationship between pre and post intervention pressure gradient across PV valve with p value of <0.001. (Table 4 and 5).

Table-1: Pulmonary gradients before and after BPV

	Minimum	Maximum	Mean	SD
Precath echo gradient (mm Hg) before intervention	65.00	180.00	109.1373	31.44011
Cath PS gradient (mm Hg)	47.00	182.00	104.3333	37.40945
Post Balloning PV Gradient (mm Hg)	2	45	24.69	12.548
Echo PV Gradient (mm Hg) before discharge	8.00	58.00	32.4118	11.48943
Follow Up echo Gradient (mm Hg) at 3 months	11.00	63.00	33.7843	12.05208

Table-2: Age category vs complications cross table

Age category	Complications				Total
	Nil	Puncture Site Hematoma	Mild PR	Bleed requiring transfusion	
5 years and less	9	3	2	1	15
5.01 to 10.0 years	20	0	0	0	20
10.01 and above	13	0	3	0	16
Total	42	3	5	1	51

Table-3: Paired samples test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	SD	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	pre cath echo gradient mm Hg before intervention - Echo PV Gradient mm Hg before discharge	76.72549	31.25001	4.37588	67.93628	85.51470	17.534	50	.000

Table-4: Paired samples statistics

		Mean	n	Std. Deviation	Std. Error Mean
Pair 1	cath PS gradient mm Hg	104.3333	51	37.40945	5.23837
	Post Balloning PV Gradient mm Hg	24.69	51	12.548	1.757

Table-5: Paired samples test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	SD	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	cath PS gradient mm Hg - Post Balloning PV Gradient mm Hg	79.64706	37.42557	5.24063	69.12095	90.17317	15.198	50	.000

DISCUSSION

Severe pulmonary stenosis with pressure gradient 65 mm Hg or more requires intervention. Balloon valvuloplasty is one of the safe approach in since practice since 182 when first trans-catheter balloon pulmonary valvuloplasty was done by Kan *et al*.[8]

The objective of this study was to enlighten the outcome in children in whom intervention was done and short term out come assessed.

Among congenital malformations, congenital heart diseases represent important proportion in 2–3% neonates. In one of study by Rizvi *et al*[9] in rural community of Pakistan the most congential heart disease was ASD and VSD. Whereas one study done in one of tertiary care center of Karachi by Patel N *et al*[2] showed tetralogy of fallot the most common congenital heart disease followed by VSD and ASD. In Patel N *et al* study the frequency of PS was 3.1%.

Surgical pulmonary valvuloplasty has been replaced by BPV as procedure of choice for moderate to severe PS in children as well as inadults patients.[10]

Due to minimal trauma and minimal complications, BPV has excellent outcome.[11] In literature we could not find any study describing the outcome of intervention including ballonvalvuloplasty in children with PS in Pakistan. There are various reasons regarding delay in diagnosis and management of congential heart diseases in children in Pakistan including socieoecnomical factors and inadequate trained health system.[12]

One study done by Mughal AR *et al*[13] included both children aged more than 10 years and adults wth mean age of 22.2±10.5 years with male to female ratio of 1:1.05. In their study mild PR was observed in 48.8% on post intervention and no other major complication. While in our study mean age of patietns were 8.35±4.93 years. In majority (82.4%) of patients, there was no complcation. Mild PR was there in 9.8% patients.

In one of study by Candrasatria RM *et al*[14] done in Indonesia, efficacy of BPV was evaluated in short term. However in their study apart from children, adults upto 40 years were also included as there were total of 61 patients. There was significant relationship between pre and post catheterization systolic pressure gradient. In their study 33.9% patients developed mild PR an 6.5% patients developed moderate pulmonary regurgitation. In our study all 51 patients were chidren upto 16 years of age. In our study only 9.8% got mild PR.

Hong D *et al*[15] did one retrospective study in one of paediatric cardiology center in China in infants with PS and it was concluded in their study that on basis of safety and effectiveness, BPV is one of the definitive therapy for children with PS.

Amoozgar H *et al*[16] in their study in Iran concluded that PS decreased significantly along with right ventricular pressure after the procedure and on follow the pressure gradient remain in acceptable limits. In our study there were significant reduction of pressure gradient across pulmonary valve both on cath and echocardiography and on follow up after 3 months.

Maostafa BA *et al*[11] did one study in children with PS which included 33 females and 27 males. BPV was successful in 88.3% patients, while in our study there was no complication in 82.4% patients.

In one of retrospective longitudinal cohort study done by Adhikari CM *et al*[17], there were 62 patients with severe PS. After BPV the preintervention peak pressure across pulmonary valve was 76.5±25.1 mm Hg and post procedure pressure was 32.0±20.9 with p value of <0.001. In our study,proior to intervention, mean pressure was 104.33±37.41 mm Hg and mean pressure post intervention was 24.61±12.55 mm Hg.

Complications with BPV are more when balloon size to valve annulus size ratio exceeds 30%.[18] However, in our study study there were no complications in majority of patients.

CONCLUSION

BPV in one of the safest intervention for PS in children with few complications.

AUTHORS' CONTRIBUTION

TA: Manuscript wrting, data collection. IH: review of statistics and overall supervision. SI: SPSS analysis.

SSHS: manuscript writing and SPSS analysis. YR: getting consent from the patients data collection. AK: Data collection. MZH: Final review before submission

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