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ORIGINAL ARTICLE

Relationship of Balloon Size in Pulmonary Valvuloplasty Outcome

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ABSTRACT

Objective: To evaluate the relation between balloon size and outcome of patients undergoing pulmonary valvuloplasty.
Study Design: A quasi-experimental study.
Place and Duration: Pediatric Cardiology Department of Chaudhary Pervaiz Elahi Institute of Cardiology, Multan, Pakistan from January 2021 to June 2022.
Methodology: Children of both genders aged less than 15 years having severe pulmonary stenosis and who underwent pulmonary valvuloplasty during the study period were analyzed. After 24 hours post procedure, echocardiography was done to see echo gradient across pulmonary valve, tricuspid regurgitation, pulmonary regurgitation, right ventricular dysfunction or pericardial effusion. Procedure was considered successful if the residual gradient across pulmonary valve was < 40 mmHg, pulmonary regurgitation < moderate and patients had no major complications.
Results: In a total of 75 children, 42 (56.3%) were male. The mean age was 6.24 ± 4.81 years. Cyanosis was observed in 10 (13.3%) children while there was right ventricular dysfunction in 6 (8.0%) children. The pulmonary valvuloplasty procedure was successful in 53 (70.6%) cases while in remaining 22 (29.4%) cases, the procedure was partially successful because of infundibular obstruction. We observed that the degree of pulmonary regurgitation was greater when annulus- balloon ratio was 1.3 or more than that ($p<0.0001$).
Practical Implications: Large balloons do not impart advantages beyond that produced by balloons between 1.2-1.4 times of the annular size but further research is required to ascertain these findings
Conclusion: Signification relation exists regarding balloon size and outcome of children undergoing pulmonary valvuloplasty as the degree of pulmonary regurgitation was greater when annulus- balloon ratio was 1.3 or more.
Keywords: Cyanosis, pulmonary regurgitation, pulmonary valvuloplasty, right ventricular dysfunction.

INTRODUCTION

The prevalence of congenital pulmonary stenosis is estimated to range between 8-10% among patients with congenital heart disease (CHD). In classical form of pulmonary stenosis, the valve is dome shaped. Other form is pulmonary valve dysplasia which occurs in 10-12% of patients of pulmonary stenosis.[1,2] Patients having severe stenosis are usually planned to undergo treatment even if the disease is tolerable and is without any symptoms as there is a fair possibility that major complications might exhibit if underlying disease is not addressed and treated timely.[3]

The 1st catheter attempted to relieve the gradient were done by "Rubio and Limon" in 1954[4] while later attempts have been reported by Semb and colleagues in 1979.[5] Percutaneous balloon valvuloplasty was initially introduced by Kan et al in 1982.[6] In the next four years, 680 cases of pulmonary valvuloplasty had been performed successfully.[6] The reported short-term, intermediate as well as long-term outcomes following pulmonary balloon valvuloplasty have been very good and this approach is taken as the best choice for the resolution of pulmonary valve stenosis in the pediatric population.[7]

Recent data elaborates that pulmonary valvuloplasty is a beneficial percutaneous intervention for infants with critical pulmonary stenosis or a membranous form of pulmonary atresia.[8,9] As no real data exists from Pakistan regarding outcomes of patients undergoing pulmonary valvuloplasty, we planned this study. The main aim of our study was to evaluate the relation between balloon size and outcome of patients undergoing pulmonary valvuloplasty.

METHODOLOGY

This quasi experimental study was conducted during January 2021 to June 2022 at Pediatric Cardiology Department of Chaudhary Pervaiz Elahi Institute of Cardiology, Multan, Pakistan. Approval from Institutional Ethical Committee was acquired (letter number: 150, dated 07-12-2021). Informed and written consents were taken from parents/guardians of all study participants. Inclusion criteria were children of both genders aged less than 15 years having severe pulmonary stenosis and who underwent pulmonary valvuloplasty. Exclusion criteria were children with moderate pulmonary stenosis (echo gradient less than 60 mm Hg), severe infundibular or significant supravalvular stenosis, dysplastic pulmonary valve or any additional cardiac lesion needing surgery like large atrial septal defect (ASD) or ventricular septal defect (VSD). Severe pulmonary stenosis was defined as patients having echo gradient > 60 mm Hg.

Regarding procedure, a 5-6 French MP catheter according to age of the patient was used to cross the pulmonary valve. Gradient across pulmonary valve was measured. Extra stiff exchange wire was anchored either in right or left branch pulmonary artery. Balloon was taken after measuring the pulmonary valve annulus. Balloon was advanced over the guide wire and placed across the pulmonary valve. Two to three inflations were given under fluoroscopy. Balloon was removed and MP catheter was again advanced over guide wire and pressure gradient was measured across valve after the procedure. Right ventricular (RV) angiogram was also done to see the post procedure flow through valve and degree of pulmonary regurgitation. Hemostasis was maintained and patient was observed for 24 hours in angiography ward.

After 24 hours post procedure, echocardiography was done to see echo gradient across pulmonary valve, tricuspid regurgitation, pulmonary regurgitation, RV dysfunction or pericardial effusion. After 24 hours, patients were discharge. In outcome, we studied residual gradient across pulmonary valve, degree of pulmonary regurgitation and any major complication occurred during the procedure. Procedure was considered successful if the residual gradient across pulmonary valve was < 40 mm Hg; pulmonary regurgitation was less than moderate and patient had no major complications.

All the data was entered in "Statistical Package for Social Sciences" (SPSS) program version 26. Qualitative data were shown as frequency and percentages while numeric variables were represented as mean±standard deviation (SD). Chi-square test was used to analyze relationship of balloon size and outcome pulmonary valvuloplasty considering p-value < 0.05 as significant.

RESULTS

In a total of 75 children who underwent pulmonary valvuloplasty, 42 (56.3%) were male. The mean age was 6.24 ± 4.81 years (ranging one month to 15 year). The mean body weight was 20.34±10.84 kg (range 3.3 to 45.0 Kg). Cyanosis was observed in 10 (13.3%) children. There was RV dysfunction in 6 (8.0%) children associated with severe PS.

There was no associated congenital heart disease in 53 (70.7%) children but 22 (29.3%) had PFO/small ASD. Seventy two (96%) patients were having classical pulmonary valvular stenosis while 3 (4%) patients were having dysplastic pulmonary valve. Table-1 shows baseline characteristics of all studied children.

The pulmonary valvuloplasty procedure was successful in 53 (70.6%) cases while in remaining 22 (29.4%) cases, the procedure was partially successful because of infundibular obstruction. When we determined the degree of PR in relation to annulus - balloon ratio, we observed that the degree of PR was greater when annulus- balloon ratio was 1.3 or more than that. In 31 (41.3%) children, the annulus-balloon ratio was 1.3 and the degree of PR was moderate in 7 children which is 22.5% of these 31 patients. Total of 4 (0.5%) patients had annulus-balloon ratio of 1.4, out of which 1 patient had mild PR while 1 patient had moderate to severe PR. Two (2.6%) patients had annulus-balloon ratio of 1.5, out of which one patient had moderate PR after the procedure while other patient had moderate to severe PR after pulmonary valvuloplasty. Majority of the patients, (total of 60 out of 75 patients which is 80% of the total patients) had annulus-balloon ratio of 1.2-1.3 and the degree of PR in these patients was not more than moderate. Table-2 is showing details of association of annulus balloon ratio and degree of PR on echo after the procedure and there was noted to be a signification association (p<0.0001).

Table-1: Baseline characteristics of Children with Severe Pulmonary Stenosis (n=75)

Baseline Characteristics		Number (%) / Mean±Sd
Gender	Male	42 (56.0%)
	Female	33 (44.0%)
Age (years)	<1	6 (8.0%)
	1-5	35 (46.7%)
	6-10	14 (18.7%)
	11-15	20 (26.7%)
Pre Valve Saturation (%)		91.39±6.53
Post Valve Saturation (%)		97.07±2.67
Cyanosis		10 (13.3%)
RV Dysfunction		6 (8.0%)
Association CHDs	PFO/ASD Shunting L to R	12 (16.0%)
	PFO/ASD Shunting R to L	10 (13.3%)
Pre RV Pressure (mmHg)		134.32±41.96
Pre PAP Peak (mmHg)		26.07±7.65
Echo Gradient (mmHg)		114.95±41.68
Gradient on Catheter (mmHg)		104.53±43.29

Table-2: Annulus Balloon ratio and degree of PR on Echo after procedure (N=75)

Annulus Balloon ratio	PR on Echo after procedure					Total
	No PR (n=26)	Mild PR (n=6)	Moderate PR (n=9)	Moderate to severe PR (n=1)	Severe PR (n=1)	
1.1	3 (11.5%)	6 (15.8%)	-	-	-	9 (12.0%)
1.2	9 (34.6%)	19 (50.0%)	1 (11.1%)	-	-	29 (38.7%)
1.3	12 (46.2%)	12 (31.6%)	7 (77.8%)	-	-	31 (41.3%)
1.4	2 (7.7%)	1 (2.6%)	-		1 (100%)	4 (5.3%)
1.5	-	-	1 (11.1%)	1 (100%)	-	2 (2.7%)

Chi-square value = 66.23; p-value <0.0001
PR: Pulmonary regurgitation

Regarding complications six, 6 (8.0%) children had post-procedural arrhythmias (Supraventricular tachycardia [SVT]). Out of these 6 children, 2 had SVT resolved spontaneously while other 4 needed medication (verapamil / adenosine). Three patients developed bradycardia, out of which, one improved spontaneously while other two required oxygen.

DISCUSSION

Pulmonary valvuloplasty is a procedure of choice for valvular pulmonary stenosis since 1982 when it was first described by Kan et al.[6] Pulmonary valvuloplasty has somewhat replaced surgical valvotomy in most of the pediatric patients.[10] In our study, pulmonary valvuloplasty yielded successful results in 70.6% cases. We also observed that the degree of pulmonary regurgitation was greater when balloon- annulus ratio was 1.3 or more. Most interventional pediatric cardiologists advocate that balloon to annulus ratio should not be exceeding 1.5 because of the increased chances of severe pulmonary regurgitation or annular laceration.[11-13] Moderate to severe pulmonary regurgitation can be tolerated hemodynamically.[14] In another study, it was observed that annulus to balloon ratio was not predictive of acute results.[15]

Although, undersize balloons have been reported to be linked with poor acute results especially in neonates and infants, the use of oversized balloons have been shown to have no clear benefit in long-term outcomes and might be increasing the chances of valve disruption, outflow tract damage and related vascular complications.[16] It was also observed that PR after BPV was trivial to mild in severity. Patients with moderate to severe PR have had reduced exercise capacity and abnormal hemodynamic response while these patients may require close follow-ups.[6] The literature reports best outcomes following conventional balloons when the balloon diameter is relatively large in comparison to PV annulus, and generally, best rations are between 1.2-1.3.[17] Berman et al observed that large balloon to annulus ratio was associated with significant PR at late follow-ups.[18]

Abu Haweleh and Hakim reported results of BPV performed between 1995 and 2002 and detected post procedural PR to be mild in 29% and moderate in 12%.[19] It was also suggested that a balloon annulus ratio between 1.2-1.25 may be most appropriate for BPV but annulus to balloon ratio 1.2 to 1.4 times the PV annulus in effectively relieving PS is also well recognized. Large balloons do not impart advantages beyond that produced by balloons between 1.2-1.4 times of the annular size.[20]

This is one of the very first studies from Pakistan aimed at analyzing the relation between balloon size and outcome of patients undergoing pulmonary valvuloplasty. Relatively small sample size and single study center were some of the limitations of this study. We were also able to only note immediate outcomes of patients undergoing balloon pulmonary valvuloplasty. Further studies should be conducted evaluating mid-term and long term outcomes of these patients.

CONCLUSION

Signification relation exists regarding balloon size and outcome of children undergoing pulmonary valvuloplasty as the degree of pulmonary regurgitation was greater when annulus- balloon ratio was 1.3 or more.

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