

## Immediate and Intermediate Term Outcome of Percutaneous Balloon Pulmonary Valvuloplasty

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### Abstract

**Background:** Pulmonary stenosis (PS) is one of the common congenital heart diseases (CHD) with the incidence of 8-10% of all CHD. Percutaneous balloon pulmonary valvuloplasty (PBPV) is considered as the treatment of choice for these purposes. It is a safe, effective and less time-consuming procedure. But in Bangladesh, we have very limited research-based data regarding the effectiveness of percutaneous balloon pulmonary valvuloplasty in treating pulmonary stenosis. **Aim of the Study:** The aim of this study was to evaluate the immediate and intermediate term outcome of percutaneous balloon pulmonary valvuloplasty in treating pulmonary stenosis. **Methods:** This was a hospital based prospective observational study conducted from January 2021 to December 2021 at Combined Military Hospital (CMH) Dhaka, Bangladesh. Interventional work was completed during the first 06 months and follow up was completed during the remaining 06months. A total of 50 patients were evaluated who had undergone PBPV by detailed clinical history, thorough physical examination and relevant investigations, like- CXR, ECG and Echocardiography. All data were processed, analyzed and disseminated by using MS Excel and SPSS version 24 program as per necessity. **Results:** In this study, two cases were undergone double intervention. During the procedure all cases developed bradycardia and 5(10%) developed cardiac arrest. Immediately after the procedure RV pressure was reduced and PA pressure was increased and PS gradient was reduced dramatically. The peak-to-peak pressure gradient across pulmonary valve reduced from pre-procedure value of  $76.8 \pm 5.41$  mmHg to post procedure value of  $18.14 \pm 6.88$  mmHg which is statistically significant ( $P < .00001$ ). On D1 Echocardiographic follow up, 13 cases developed trivial pulmonary regurgitation (PR) and after that at D30 follow up, 1 patient developed mild PR out of these 13. In our study 46(92%) cases were successful and 4(8%) and procedure failed; out of these 04 procedures failed cases 3(6%) cases developed restenosis, one patient on D30 Echo and two cases on D90 Echo, D180 Echo do not develop any complications. Other than 3 restenosed cases all 47(94%) cases were leading healthy life without any unwanted events. All the restenosed cases had dysplastic pulmonary valve (PV). RV function of 50(100%) cases was good both in pre and post procedure as evidenced by normal TAPSE ranges from 15-22. Chest X- Ray (CXR) and Electrocardiography was found normal in 180 days follow up. **Conclusion:** Percutaneous balloon pulmonary valvuloplasty (PBPV) is already considered as the gold standard in the treatment of valvular pulmonary stenosis. This patient friendly procedure should be taken as a first line interventional treatment for congenital as well as post-operative valvular pulmonary stenosis. This study showed excellent outcome among study population without major complications and mortality and recommend PBPV as the first-choice therapy in our setup.

**Keywords:** Immediate, Intermediate term outcome, Percutaneous, Balloon pulmonary valvuloplasty.

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## 1. INTRODUCTION

Pulmonary stenosis is not an uncommon congenital heart disease in our population. Pulmonary valve restenosis is a condition that occurs when the pulmonary valve becomes narrow or blocked. This condition can occur after surgery to repair or replace the pulmonary valve. In some cases, pulmonary valve restenosis can lead to heart failure. Various age groups present with severe pulmonary stenosis require intervention either surgical or percutaneous catheter-based. Often lifesaving surgical intervention is not feasible considering procedural risk, the patient's physical condition, and young age. Percutaneous balloon pulmonary valvuloplasty is safe, effective, almost painless, economical and less hospital stay in any age group with immediate and long-term success. A fair number of studies on outcomes following pulmonary balloon valvuloplasty have been done in western and developed countries. Very few studies were carried out on the result following balloon pulmonary valvuloplasty in our country. In Bangladesh, it was first performed in 1999 at CMH Dhaka 6 [1]. Now a day, it is performed under echo guidance [2]. But in our lab, we are practicing under fluoroscopy. The main disadvantage of fluoroscopy is radiation injury. Surgery is indicated if balloon valvuloplasty is unsuccessful, or contraindicated and associated with infundibular stenosis and right ventricular outflow tract (RVOT) muscle bundle. The balloon procedure carries an extremely low risk, is painless, less costly than surgery, and shorter hospital stay. The outcome is good in 85% of cases. Restenosis after balloon dilatation is extremely rare but PR is common, occurring in 10% to 40% of patients. PR is usually well tolerated, although rarely some of these patients may become candidates for pulmonary valve implantation [3]. Recently recommended balloon/annulus ratio is 1.2 to 1.25. Restenosis means gradient across PV >50mm of Hg at follow-up echo. Significant predictors of restenosis include the balloon/annulus ratio. So, the immediate and intermediate-term complications are not so much revealed in the context of our country. If immediate and intermediate-term complications are being found in the context of our country then the unfortunate complications and the treatment cost can be reduced significantly. For that, we have chosen the topic of immediate and intermediate-term outcomes of balloon pulmonary valvuloplasty for moderate and severe pulmonary stenosis. We believe the result of our study compared with other study series will help a physician to take a better decision considering the risk-benefit ratio concerning balloon pulmonary valvuloplasty in different age groups in our population.

## 2. METHODOLOGY

This was a hospital based prospective observational study conducted from January 2021 to December 2021 at Combined Military Hospital (CMH) Dhaka, Bangladesh. The whole intervention was

conducted in accordance with the principles of human research specified in the Helsinki Declaration [4] and executed in compliance with currently applicable regulations and the provisions of the General Data Protection Regulation (GDPR) [5]. Interventional work was completed during the first 06 months and follow up was completed during the remaining 06 months. After careful history taking, examination and appropriate investigations, total 782 children were diagnosed with congenital heart diseases (CHD) during study period. Among these 782 children with CHD, total 50 children with isolated Valvular Pulmonary Stenosis cases were included as study sample after fulfilling inclusion and exclusion criteria. All study children were given interventional treatment, Percutaneous balloon pulmonary valvuloplasty (PBPV) after initial medical management as per their clinical status, none of the patient required surgical interventions.

### Inclusion Criteria

- 0-18 years old patient with Valvular Pulmonary Stenosis.
- Echocardiographic gradient of PS >50 mm of Hg.

### Exclusion Criteria

- Child, who had any surgical or medical procedure.
- Pulmonary stenosis associated with other complex CHD, tetralogy of fallot (TOF), transposition of great arteries (TGA), tricuspid atresia (TA), single ventricle etcetera, but not associated with simple CHD like-ASD, PDA which are amendable to intervention.

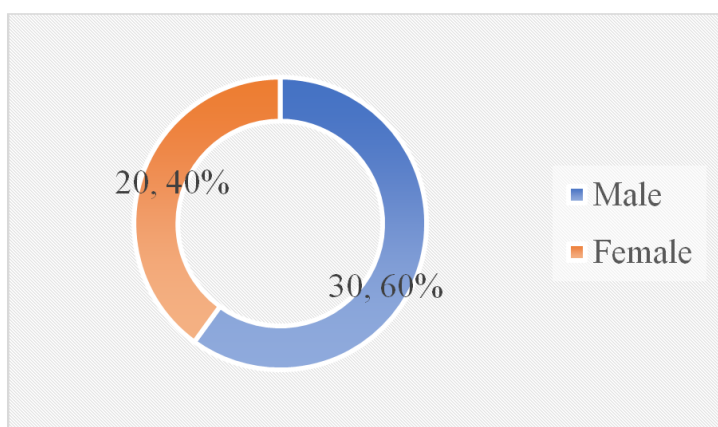
Before the beginning of the study ethical clearance was obtained from the ERC of Combined Military Hospital (CMH) Dhaka. Total 782 children with CHD admitted during study period in study place. Among them, 50 children had isolated valvular PS with moderate to severe grade those were included as study sample following informed written consent from parents. Valvular PS was confirmed by echocardiography. Data were collected with a predesigned standard data collection sheet. Collected data were analyzed using SPSS Version 24. Statistical significance was set as 95% confidence level at 5% acceptable error level. Categorical variables were expressed as frequency and percentages. Mean, standard deviation, and/or medians with interquartile ranges were used to express the continuous variables. Paired t- test was performed in categorical comparison. A p value of <0.05 was considered statistically significant.

## 3. RESULT

During the study period, 782 children were admitted with different varieties of CHD in the mentioned hospital. Out of them, 50(6.39%) were isolated valvular who were selected as the study

population. Among the participant, 30(60%) were male and the rest 20(40%) were female. In our study, we have found male predominance with a male- female ratio of 3:2 though there is no gender dominance found in other studies. Among total participant, 3 (6%) were neonates, 7 (14%) were infants, 27 (54%) were 1-5 years aged, and the rest 13 (26%) were more than 5 years aged. Out of 50 cases, 26 (52%) were incidentally diagnosed, 15 (30%) presented with exertional dyspnea, 3 (6%) presented with chest pain and 6 (12%) presented with cyanosis as critical PS. Among total participants, 40 (80%) were presented with doming PV, 8 (16%) were with dysplastic PV and 2 (4%) were with normal PV. All 03 restenosis cases were in dysplastic PV. Among the RV function cases, all the patient's RV function was good as evidenced by TAPSE within the normal range. On diagnosis, severe PS was found in 27 (54%) cases (PS grdt more than 70 mm of Hg) and moderate PS was found in 23 (46%) cases with PS grdt more than 50 mm of Hg but less than 70 mm of Hg. Among the cases, RV pressure was more than 100 mm of Hg in 22 (44%) cases and RV pressure was less than 100 mm of Hg in 28 (56%) cases. Among total cases, in the procedure, all 50 (100%) cases developed bradycardia. Out of them, 5 (10%) cases have undergone cardiac arrest. None of the patients reported

hematoma, femoral venous obstruction, pericardial effusion, or cerebrovascular accident. Among all the participant, 46 patient's PS grdt came down below 30 mm of Hg which indicated the successful procedure rate was 92% and in 4 cases, PS grdt remained more than 30 mm of Hg which indicated the procedure's failure rate was 8%.Among the Balloon and PV annulus ratio cases, all the patients have kept balloon and pulmonary valve annulus ratios was between 1.2 to 1.25. The balloon-to-pulmonary valve annulus ratio which was  $1.23 \pm 0.013$ .Among the restenosis cases, out of 50 cases, 46 (92%) were successful and in 4 cases procedure was failed. None of the successful cases developed restenosis. Out of 4 procedures failed cases, in 1 patient developed restenosis on D30 follow up and in 2 patients developed restenosis on the D90 follow-up. At D180 follow up, among none of the patients, developed restenosis. All the restenosis cases had dysplastic pulmonary valves. One patient's PS grdt persisted at 30-50 mm of Hg throughout the follow-up period. Overall restenosis in 180-day follow-up was found in 3 (6%) and the remaining 47 (94%) cases lead a healthy life in 6 months follow-up. Reblooming was done immediately after diagnosis of restenosis in restenosis cases.



**Figure1: Gender distribution of participants (N=50)**

**Table 1: Age distribution of the participants (N=50)**

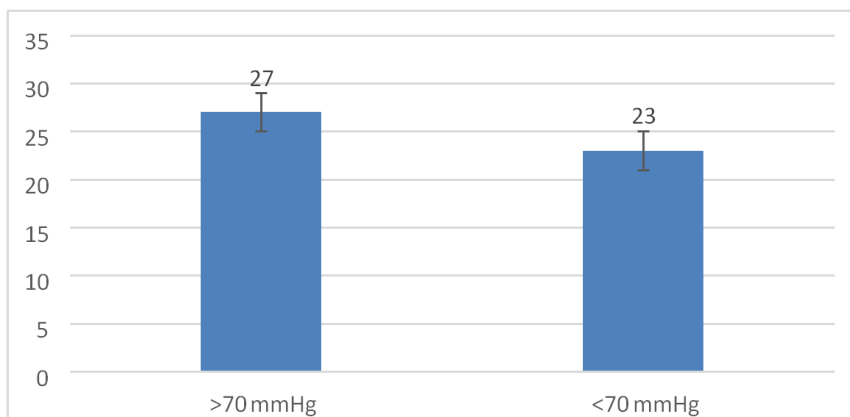
Age	n	%
Neonate (0-1 month)	3	6
Infant (1 month- 1 year)	7	14
Child (1-5 years)	27	54
> 5 years	13	26
<b>Total(n)</b>	<b>50</b>	<b>100</b>

**Table 2: Mode of presentation (N=50)**

Modes	n	%
Incidental/Screening	26	52
Dyspnea	15	30
Chest pain	03	06
Critical PS	06	12

**Table 3: Valve morphology among participants (N=50)**

Valve morphology	n	%
Dysplastic	08	16%
Doming	40	80%
Normal	02	04%
<b>Total</b>	<b>50</b>	<b>100%</b>



**Figure 2: PS grdt on diagnosis (N=50)**

**Table 4: RV Pressure on Cath (N=50)**

RV pressure	n	%
<100 mmHg	28	56%
>100 mmHg	22	44%
<b>Total (n)</b>	<b>50</b>	<b>100%</b>

**Table 5: Immediate consequences among participants (N=50)**

Immediate Consequences	n	%
Bradycardia	50	100%
Arrest	5	10%
<b>Total (n)</b>	<b>50</b>	<b>100%</b>

**Table 6: Immediate reduction of PS grdt (N=50)**

PS gradient (<30mmHg) on D <sub>1</sub>	n	%
PS gradient <30mmHg	46	92%
PS gradient >30mmHg	4	8%
<b>Total (n)</b>	<b>50</b>	<b>100%</b>

**Table 7: Balloon size and balloon and PV annulus ratio (N=50)**

Serial	Pulmonary valve Annulus (mm)	Balloon size (mm)	Balloon Annulus ratio
1	6.6	8X3	1.21
2	6.1	8X3	1.25
3	11.2	14X4	1.25
4	8	10X3	1.25
5	6.4	8X3	1.25
6	6.6	8X3	1.21
7	8.06	10X3	1.24
8	9.6	12X3	1.25
9	8.13	10X3	1.23
10	11.2	14X3	1.25
11	9.6	12X3	1.25
12	12.93	16X3	1.24
13	6.45	8X4	1.24
14	6.45	8X3	1.24
15	8	10X3	1.25

Serial	Pulmonary valve Annulus (mm)	Balloon size (mm)	Balloon Annulus ratio
16	8	10X3	1.25
17	6.4	8X4	1.25
18	9.91	12X3	1.21
19	11.29	14X3	1.24
20	8.13	10X3	1.23
21	6.61	8X3	1.21
22	6.55	8X3	1.22
23	11.24	14X3	1.24
24	6.4	8X3	1.25
25	8.13	10X3	1.23
26	6.44	8X3	1.25
27	12.8	16X3	1.25
28	11.57	14X3	1.21
29	11.2	14X3	1.25
30	8.06	10X3	1.24
31	9.67	12X3	1.24
32	12.8	16X3	1.25
33	6.4	8X3	1.25
34	6.34	8X3	1.24
35	9.64	12X3	1.24
36	6.5	8X4	1.23
37	9.67	12X3	1.24
38	9.67	12X3	1.24
39	11.2	14X3	1.25
40	11.38	14X3	1.23
41	9.91	12X3	1.21
42	6.4	8X3	1.25
43	6.50	8X4	1.23
44	12.9	16X4	1.24
45	8.06	10X3	1.24
46	8.13	10X3	1.23
47	11.2	14X3	1.25
48	6.5	8X3	1.23
49	8.06	10X3	1.24
50	8	10X3	1.25

**Table 8: Follow-up data by Echocardiography (N=50)**

Events		D-1 Follow up	D-30 Follow up	D-90 Follow up	D-180 Follow up
PS gradient	<30 mm of Hg	46	46	46	46
	30-50 mm of Hg	4	3	1	1
	>50 mm of Hg	0	1	2+1	2+1
PR	Trivial	13	12	12	12
	Mild	0	1	1	1
	Moderate	0	0	0	0
	Free	0	0	0	0

#### 4. DISCUSSION

Balloon pulmonary valvuloplasty is a commonly performed procedure in many centers around the world as well as in Bangladesh. This study was performed to analyze the early and intermediate-term outcomes of balloon pulmonary valvuloplasty. The PBPV is a very safe procedure with a low incidence of complications. Stanger P *et al.*, [6] in the VACA registry of 26 institutions reported only a 0.35 % major complications rate while a 0.24 % death rate from a total of 822 cases of balloon pulmonary valvuloplasty.

There has been a high incidence of complications of the procedure in neonates, infants, and children 51 [7] while most of the studies describe no major complications of PBPV in children, adolescents, or adult population [8]. In our study, self-limited vasovagal syncope as a minor complication was not recorded but our total study subjects were only 50. There was not a single case of arrhythmia, pericardial effusion, significant residual PS, venous injury, thromboembolic phenomenon, or death. Sievert H *et al.*, [9] in the early era of interventions, reported that



post-PBPV significant pulmonary valve regurgitation is rare and more commonly seen in surgical pulmonary valvotomy. A study from Iran [10] showed 57 % of patients had mild pulmonary regurgitation in the immediate post-PBPV period. Similarly, mild PR was noted in 55% of patients in Idrizi S *et al.*, study [11] while 34% of patients developed mild PR in Qian X *et al.*, study [12]. The incidence of trivial and mild pulmonary valve regurgitation in the immediate post-PBPV period was 13(26%) in our study while there was not a single case of moderate or free pulmonary regurgitation. This study showed that, the incidence of PR after PBPV is variable and depends on different factors like age, balloon annulus ratio, and morphology of the pulmonary valve. The success of the procedure in our case is due to the use of an appropriate size balloon with an adequate balloon annulus ratio which is following other studies in the available literature. The outcome of balloon valvuloplasty for critical PS in newborn babies was also excellent. One study conducted in Taiwan showed 79% definitive success of balloon valvuloplasty in neonates with critical PS [13]. In our study, we had 06 patients with critical PS. In 1 critical case developed restenosis and our success rate was 83.34% in respect of critical PS which was very much nearer to a study of Taiwan. The sex distribution of patients was about equal, but in our study, male was predominant. Growth and development in a patient with pulmonary stenosis were usually normal [14]. Although immediate and intermediate-term results after balloon dilatation of congenital stenotic lesions of the heart in children were well studied, long-term results have not been documented [15]. In our study, follow-up echocardiography revealed 92 % procedural success and only 6 % restenosis. One study conducted in Osaka, Japan showed a decrease in mean pressure gradient immediately after balloon valvuloplasty (BVP) from  $61 \pm 27$  mmHg to  $28 \pm 20$  mmHg and the reduced gradient continued at follow-up in most cases [16]. In a study in Bangladesh, Fatema NN showed the success of multiple interventions in single setting, good medium-term result [17].

#### Limitation of the Study

In this study, all samples were collected from single tertiary care center; therefore it may not reflect the regional variations of the country. Sample size was too small to infer the findings as a general rule. Follow up period was short. Chance of biasedness present as there was no randomization because of many logistic and ethical reasons. Due to Covid Pandemic movement of both operator and observer were restricted.

#### 5. CONCLUSION & RECOMMENDATION

Undoubtedly, PBPV is the best and gold standard therapy for obstructive PV diseases, while several worldwide recognized studies prove the feasibility, safety, and effectiveness. However, recent studies recommend to use conservative sized balloon catheter to reduce immediate and intermediate term

complications. It will take time to get long-term result on our patients. Immediate and intermediate term follow up with Doppler echocardiography showed excellent outcome in all cases except three restenosis cases and 13 insignificant PR cases. The baby who all had restenosis, had the risk factor, like- dysplastic PV. It may be concluded that balloon valvuloplasty is the procedure of choice for moderate, severe and critical pulmonary valve stenosis. Surgery should be reserved for those with unsuccessful balloon valvuloplasty. Notwithstanding, new technological improvement will certainly increase the number of patients who can be successfully treated with this minimally invasive intervention in the future.

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