# **Original Research Article**

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# Pattern of transcatheter interventional procedure have done in Cath lab and their immediate outcome: one year experience at Bangladesh Shishu hospital and institute

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#### **ABSTRACT**

**Background:** Congenital heart disease (CHD) is defined by structural and functional malformations of the heart. If CHD not managed through appropriate interventions, it affects quality of life of the individual and potential premature death. Objectives were assessing the frequency and pattern of interventional procedure done in Cath lab of paediatric cardiology department, Bangladesh Shishu Hospital and Institute and their immediate outcome.

**Methods:** It was a cross sectional retrospective study. Total 56 patients of ventricular septal defect (VSD), atrial septal defect (ASD), patent ductus arteriosus (PDA), pulmonary stenosis (PS), aortic stenosis (AS), coarctation of aorta, pulmonary atresia, TGA from January 2019 to December 2019 who underwent trans-catheter interventional procedure by author at Cath lab of paediatric cardiology department, Bangladesh Shishu Hospital and Institute were enrolled in this study.

**Results:** Among 56 patients, PDA device closure done in 19, balloon pulmonary valvuloplasty (BPV) in 13 patients, device closure of ASD in 3 patients, device closure of VSD in 2 patients and balloon aortic valvuloplasty (BAV) in 1 patient. Two patients died; one is pulmonary atresia with PDA dependent pulmonary circulation following ductal stenting another is d-TGA intact IVS with PFO following BAS. One PDA device embolized and retrieved surgically from main and right pulmonary artery. Mean fluoroscopy time=17.29 and mean total procedure time=38.52 min.

**Conclusions:** Trans-catheter interventional procedure for PS, coarctation of aorta, PDA, ASD, VSD, AS, d-TGA, Pulmonary atresia is a safe and some procedure such as BAS for d- TGA, BPV for critical PS, Ductal stenting for pulmonary atresia, Balloon angioplasty for severe coarctation of aorta with LV dysfunction is lifesaving with a low adverse event rate.

Keywords: VSD, ASD, PAD

# INTRODUCTION

Congenital heart disease (CHD) is defined by structural and functional malformations of the heart which if not managed through appropriate interventions affects quality of life of the individual and potential premature death. CHD is significantly decreased of morbidity and mortality by early detection, diagnosis and prompt interventions result.<sup>1,2</sup>Congenital heart defect (CHD) is

the most common defect among all birth defects representing a major global health problem. 28% of all major congenital anomalies consist of heart defects.<sup>3</sup> The worldwide prevalence of CHD is estimated to be eight to ten per 1000 live births.<sup>4</sup> but the prevalence greatly varies between regions. Prevalence of CHD in India is reported to be between 2.5 to 5/1000 live births but the prevalence to be between 8.5 and 13.6 recent studies by Bhat et al.<sup>5</sup> Recently in Bangladesh, a birth prevalence of CHD is 8.3

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per 1000 live.<sup>6</sup> The reported prevalence of CHD in our country seems to have dramatically increased in recent decades, but this is most likely because of better diagnostic procedures, especially echocardiography. In combination with other heart defects CHD malformations occur as single lesions or.7 In most of the studies, it has been found that VSD is the most common lesion followed by PDA, ASD, PS, coarctation of aorta and AS. Commonly diagnosed cyanotic lesions include tetralogy of Fallot (TOF), Pulmonary atresia with PDA dependent pulmonary circulation and d-transposition of the great arteries (d-TGA).<sup>7-9</sup> Transcatheter or surgical closure of VSD was indicated in the following conditions: (1) significant left-to-right shunt affecting the child clinically (2) Chest x-ray showing lung plethora or cardiomegaly (3) Increased left atrial and left ventricular end diastolic diameters above upper normal limits according to the child body weight in TTE evidence of significant shunt. 10 TGA with intact IVS required urgent atrial septostomy with following criteria that are suggestive of inadequate mixing (inadequate Qp/Qs): severe hypoxemia, metabolic acidosis, marked cyanosis, interatrial defect diameter <4 mm and maximum interatrial gradient >5 mm Hg, or mean interatrial gradient > 3 mm Hg. 11 Pulmonary atresia PDA dependent pulmonary circulation. Prostaglandin E1 (PGE1) treatment is begun with the aim of maintain the patency of duct. Historically, the palliative procedure of choice was the surgical modified Blalock-Taussig aorto-pulmonary shunt (BTS) for pulmonary atresia with PDA dependent pulmonary circulation. 12 This procedure has significant morbidity and mortality (10%-20%) that has not decreased with time. 13 Transcatheter PDA stenting has emerged as an attractive alternative. 14 Most of the ASD patient became asymptomatic, the closure of ASD is indicated in 2-4 year's age with failure to thrive, or significantly elevated pulmonary arterial pressure, or significant left to right evidence by dilated RA, RV Echocardiography. 15,16 BAV was first suggested in 1986 by Cribier as an alternative to surgical aortic valve replacement in patients with severe AS.<sup>17</sup> The introduction of transcatheter aortic valve replacement (TAVR) led to restarted interest in BAV especially in the United States.<sup>18</sup> But still BAV is the first treatment of choice in Bangladesh like developing country until 18 years of age followed by Valve replacement. Isolated pulmonary valve stenosis (PVS) is detected in 0.33/1000 newborns and makes up 6-9% of all congenital heart defects among children. 19 Percutaneous transcatheter BPV is the treatment of choice for pulmonary valve stenosis since the introduction of this procedure in 1982 by Kan.<sup>20</sup> BPV is the treatment of choice for moderate to severe valvular PS in all age groups.<sup>21</sup> PDA, a communication between the aorta and pulmonary artery, is a commonly encountered CHD in any age group.<sup>22</sup> Incidence is about 6 to 11%. Closing PDA by percutaneous transcatheter device is now becoming the first choice of therapy. Balloon angioplasty for native coarctation of aorta is a well-established treatment in children and adults with efficacy comparable to surgery

and low complication rates.<sup>23</sup> If peak to peak pressure gradient ≥20 mm of Hg, there is indication for angioplasty of coarctation of aorta. The aim of this study to assess the frequency and pattern of transcatheter interventional procedure for CHD done in Cath lab of paediatric cardiology department, Bangladesh Shishu Hospital and Institute and their immediate outcome.

#### **METHODS**

This retrospective study was conducted at the Bangladesh Shishu hospital and Institute from January 2019 to December 2019. The data for all consecutive children who underwent transcatheter interventional procedure during the study period were retrieved and included in the study. A complete evaluation including clinical examination, chest X-rays, electrocardiograms (ECG), transthoracic echocardiogram (TTE) and specific laboratory investigations to rule out any bleeding disorders. Patients with following CHD with following indication were included in the study. In case of PDA, weighing  $\geq 4.5$  kg and age  $\geq 6$  months hemodynamically significant PDA was included in the study. Patients were excluded from the study if small, silent PDA and patients with irreversible pulmonary artery hypertension. BPV is indicated for isolated pulmonary valve stenosis with gradient across pulmonary valve ≥64 mm of Hg. Balloon angioplasty for native coarctation of a rta If peak to peak pressure gradient  $\geq 20$ mm of Hg. BAV for AS if mean aortic valve gradient > 40 mm of Hg. Ductal stenting for Pulmonary atresia with PDA dependent pulmonary circulation if SPO<sub>2</sub> <60%. TGA with intact IVS required urgent atrial septostomy if there is severe hypoxemia, metabolic acidosis, marked cyanosis. Transcatheter or surgical closure of VSD was indicated in the following conditions: (1) significant leftto-right shunt affecting the child clinically failure to thrive, and recurrent chest infections in spite of adequate medications. (2) Chest x-ray showing cardiomegaly and lung plethora. The closure of ASD is indicated in 2-4 year's age with failure to thrive, or significantly elevated pulmonary arterial pressure, or significant left to right shunt evidence by dilated RA, RV in echocardiography. Data were analyzed by using the SPSS version 22.0 software. The result was presented in tables in mean, standard deviation and percentage. The study was approved by the institutional review board in Bangladesh Shishu Hospital and Institute, Dhaka, Bangladesh.

### **RESULTS**

Among 56 cases there was male predominance as 37 (66.1%) were male patient and 19 (33.9%) were female patient. The male female ratio is 1.94:1.

Most of the patient in 1 month to 1-year age group that is 27 (48.2%) patients followed by >1 year to 5 year's age group 14 (25%), >5 year's age group 10 (17.9%), 0 day-1 month 5 (8.9%).

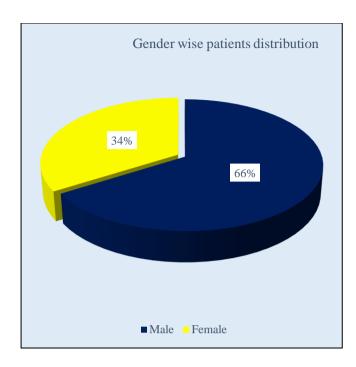


Figure 1: The gender wise patient's distribution, (n=56).

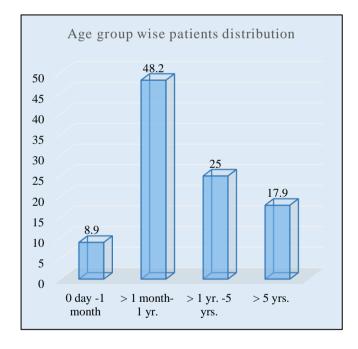


Figure 2: Colum chart showed age group wise patients' distribution, (n=56).

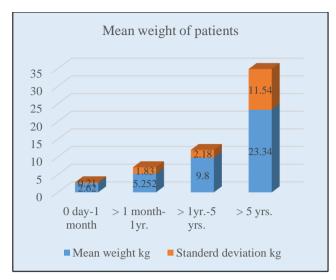


Figure 3: Patients group wise age distribution in kg, (n=56).

Out of 56 patients, 19 patients were PDA, 13 patients were PS, 7 patients were coarctation of aorta (CoA), 7 patients were d-TGA, 4 patients were pulmonary atresia, 3 patients were ASD, 2 patients were VSD and 1 patient was AS.

Among 56 patients, 19 patients underwent PDA device closure, BPV done in 13 patients, Balloon angioplasty in 7 patients, balloon atrial sept ostomy (BAS) in 7 patients, Ductal stenting in 4 patients, Device closure of ASD in 3 patients, Device closure of VSD in 2 patients and BAV in 1 patient.

After BPV, there was a significant reduction in peak-to-peak pressure gradient across pulmonary valve from 84.03±26.31 mm of Hg to 22.76±10.42 mm of Hg (p=0.000).

Mean fluoroscopy time was 17.29 min, mean total procedure time was 38.52 min, highest mean fluoroscopy time and mean total procedure time was in ductal stenting for pulmonary atresia.

Among 56 interventional procedures, 2 patients died, one is pulmonary atresia with PDA dependent pulmonary circulation following ductal stenting another is d-TGA intact IVS with PFO following BAS and one device embolized following PDA device closure.

Table 1: Patient on the basis of CHD. (N-56).

Patients age group (In years)	PDA	VSD	ASD	PS	COA	D - TGA	Pulmonary atresia	AS	Total
0 days-1 month	0	0	0	0	2	3	0	0	5
>1 month-1	8	0	0	6	4	4	4	1	27
> 1-5	7	0	1	6	0	0	0	0	14
>5	4	2	2	1	1	0	0	0	10
Total	19	2	3	13	7	7	4	1	56

Table 2: Frequency and percentage of the trans catheter interventional procedure in the CHD, (n=56).

Diagnosis	Name of procedure	N	Percentage (%)
PDA	PDA device closure	19	33.9
PS	BPV	13	23.2
Coarctation of aorta	Balloon angioplasty	7	12.5
d-TGA	Balloon atrial sept ostomy (BAS)	7	12.5
Pulmonary atresia	Ductal stenting	4	7.1
ASD	Device closure of ASD	3	5.4
VSD	Device closure of VSD	2	3.6
AS	BAV	1	1.8

Table 3: Comparison of peak to peak pressures before and immediately after BPV, (n=56).

Paired samples	Mean ± SD	T value	P value
Peak to peak pressure across pulmonary valve before procedure	84.03±26.31	16.065	0.000
Peak to peak pressure across pulmonary valve after procedure	22.76±10.42	16.065	

Significance p≤0.05.

Table 4: Procedure wise mean fluroscopy and total procedure time in min, (n=56).

Name of procedure	Mean fluoroscopy time (min)	Mean total procedure time (min)
PDA device closure, (n=19)	10.1286	33.30
BPV, (n=13)	24.4978	45.09
BAS, (n=7)	27.7568	40.00
<b>Ductal stenting, (n=4)</b>	38.7576	66.00
Balloon angioplasty of coarctation of aorta, (n=7)	7.0838	25.17
VSD device closure, (n=2)	20.5871	47.50
<b>BAV</b> , (n= 1)	15.0362	37.00
ASD device closure, (n=3)	8.0556	40.00
Total, (n=56)	17.2907	38.52

Table 5: Outcome of the interventional procedure, (n=56).

Outcomes	N	Percentage (%)
Successful	53	94.6
Died	2	3.6
Embolization of PDA device	1	1.8

#### DISCUSSION

In Bangladesh, there are only few centers where pediatric cardiac surgery is being practiced. In view of this, cardiac surgery virtually cannot be offered to every patient with CHD and trans catheter interventions remains the only viable option for large majority of cases which are suitable for interventional procedure. In 2019, total 160 therapeutic interventions have done in Bangladesh Shishu hospital and institute Cath lab by 3 operators, among 160 patients, 56 therapeutic interventions have done by author. Male were 37 (66.1) and female were 19 (33.9) with male female ratio 1.94:1. Among 56 patients, 19 patients were PDA and they were attempted for device closure with an overall 94.7% of success. Since first PDA device closure by Porstmann et al.<sup>24</sup> Percutaneous PDA device closure is safe and effective option in the experienced hands, and is now widely accepted as an attractive alternative to surgery by avoiding thoracotomy scar, shorter hospital stays, minimal discomfort or pain.<sup>25</sup> One PDA device embolized that retrieved surgically from MPA and RPA. The 13 patients underwent BPV with significant reduction of peak-to-peak pressure difference before and after procedure (p=0.000). our study showed 100% success rate but one study from Iran found 77% of their patient has residual catheter gradient <36 mm Hg in.26 Seven patient underwent BAS for d-TGA. The average saturation at the beginning of the procedure was 58% with a final saturation of 86%. Procedures were carried out using Z5 atrioseptostomy balloons and the Rashkind technique. Six patients improved and referred to cardiac surgery, 1 patient died due to septicemia. Seven patients underwent balloon angioplasty of coarctation of aorta. In 6 (85.7%) patients, there is significant reduction of peak-to-peak pressure gradient immediately after balloon angioplasty of coarctation of aorta. But in one patient (14.3%), there is no reduction of peak-to-peak pressure gradient across coarctation. This is due to hypoplasia of the arch of the aorta. Parra-Bravo et al found similar result in their study.<sup>27</sup> Ductal stenting for pulmonary atresia was done among four patients. Three (75%) patients improved and discharged; 1 patient died on 5<sup>rd</sup> post-operative day due to septicemia. The average saturation at the beginning of the procedure was 62% with a final saturation of 85%. Only 1 BAV, 2 VSD device and 3 ASD device have done successful in 1 year. This is due to author started interventional procedure in 2017 at Bangladesh Shishu Hospital and Institute individually and started with simple cases.

#### Limitations

The study was conducted in a single hospital with small sample size. So, the results may not represent the whole community.

#### **CONCLUSION**

Transcatheter interventional procedure is a safe, effective and reliable treatment for patients with PS, Coarctation of aorta, PDA, ASD, VSD and AS. Transcatheter interventional procedure is lifesaving in d-TGA with intact IVS, Pulmonary atresia with PDA dependent pulmonary circulation.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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