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Transcatheter Cardiac Intervention in Neonates: Experience From a Tertiary Care Centre in Bangladesh

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ABSTRACT

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Background: Critical congenital heart disease (cCHD) is the most common reason requiring surgery or catheter- based intervention in the neonatal period. Transcatheter interventions in neonates present unique challenges in Bangladesh due to limited resources, unavailability of hardware, cost of procedure, low birth weight, sepsis, and delayed diagnosis. Careful technique, proper planning & safety measures reduces the incidence of complications.

Objective: The study was undertaken to find out the immediate outcome of critically ill neonates who needed emergency cardiac interventions like balloon atrial septostomy (BAS), PDA stenting, balloon aortic or pulmonary valvuloplasty, coarctoplasy.

Methods: This retrospective study was conducted in the cardiac centre of Bangladesh Shishu Hospital & Institute between June 2014 to June 2022.Total 322 sick neonates required cardiac interventions during the study period. Clinical parameters, SPO_2, echocardiographic data, cathlab data & outcome were recorded. Statistical analysis was done by using SPSS version 24.

Results: Among 322 patients balloon atrial septostomy was done in 143(44%) patients mostly for DTGA PFO/small secundum ASD ± small PDA. 113 (35%) patients underwent PDA stenting for duct dependent pulmonary circulation. For severe stenosis with or without ventricular dysfunction 14 patients underwent balloon aortic

valvuloplasty, 17 patients for balloon pulmonary valvuloplasty and 31 patients for coarctoplasty. There was significant reduction of mean gradient across the stenosis ($p<0.05$). Three patients with membranous pulmonary atresia with intact IVS underwent pulmonary valve perforation using CTO guide wire & one neonate with TOF with severe cyanosis underwent RVOT stenting successfully. Mean age for BAS patients was 14 days ± 10 days and mean weight 2.6 ± 0.72 Kg. Mean age for PDA stenting patients was 16 days ± 12 days and mean weight 2.5± 0.69 Kg. Baseline SPO_2 was significantly improved immediately after the procedure & at discharge in both BAS and PDA stenting patients($p<0.05$). Common complications were sepsis, over-shunting, vascular complication and renal impairment. The overall mortality was 16.4% & procedural failure rate was 2.17%.

Conclusion: Percutaneous cardiac interventions in neonates are safe & effective especially in resource limited setup. It requires proper diagnosis, stabilization, prompt intervention, and team work. Early identification and well planned catheterization procedures improves outcome.

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INTRODUCTION

Congenital heart disease varies from benign to serious conditions which the baby needs immediate diagnosis and management for survival. In developing countries like Bangladesh neonates with heart defects remain undiagnosed until after developing serious manifestations. Critical CHD (cCHD) usually requires surgery or catheter-based intervention in the neonatal period. The incidence of CHD has been estimated to be 6–8/1,000 live births in the general population [1-3]. Infant's death from CHD accounts for around 3%[4]. Atrial-septostomy was the oldest and still the most utilised procedure. If the foramen ovale is restricted, PGE_1 alone could not achieve clinical improvement and emergency balloon atrial septostomy can dramatically improve oxygen saturations by allowing mixing in the atrial level, and the infant can wait in a better clinical condition for the arterial switch operation. PDA stenting is now believed to be a reasonable alternative to surgical aorto-pulmonary shunts in securing pulmonary blood flow in duct-dependent cyanotic heart disease. Transcatheter valvotomy using CTO guide wire and balloon dilation offer a promising alternative to surgery as the primary therapy in selected patients with PA-IVS. Stenting RVOT has been described as a palliative procedure in newborns with TOF with severe pulmonary flow obstruction & who depend on continuous infusion of E1 prostaglandin. Transcatheter balloon dilatation (valvuloplasty) for critical pulmonary stenosis (PS) or aortic stenosis (AS) is technically difficult, but is performed as rescue procedures. In critical aortic coarctation with heart failure, palliative balloon angioplasty may be the method of choice as bridging for corrective surgery. The objective of the study was to evaluate the patient profile, type of intervention, complications, and immediate outcome of all neonates undergoing percutaneous cardiac intervention in Bangladesh Shishu Hospital & Institute between June 2014 to June 2022.

MATERIALS & METHODS

This retrospective study was conducted in the cardiac centre of Bangladesh Shishu Hospital & Institute between June 2014 to June 2022. The detailed diagnoses were first

established by two dimensional and Doppler echocardiography. The procedure was offered as an alternative to surgical palliation after parental informed consent was obtained. Neonates with duct dependent circulation with severe cyanosis required prostaglandin infusion. Some neonates with critical pulmonary or aortic stenosis, severe coarctation of aorta and LV dysfunction who presented to us with either cardiogenic shock or heart failure with respiratory distress were admitted to the paediatric cardiac intensive care unit for stabilisation before the procedure. Clinical and hemodynamic profile, associated cardiac and noncardiac structural anomalies, procedural details and complications, immediate outcome were recorded.

Statistical analysis was done by using SPSS version 24. The descriptive statistical analysis of the quantitative variables was carried out by calculating the median, mean and standard deviations. The Student paired t test was used to compare pre procedure and post procedure SpO2, pressure gradients. A p value <0.05 was considered statistically significant.

RESULTS

Total 322 sick neonates required cardiac interventions during the study period. Among 322 patients balloon atrial septostomy (BAS) was done in 143(44%) patients mostly for DTGA PFO/small secundum ASD ± small PDA. 113 (35%) patients underwent PDA stenting for duct dependent pulmonary circulation. Number of neonatal cardiac intervention has increased gradually over the years. If we exclude balloon atrial septostomy (BAS) then in 2014 our procedure number was 7 which was increased to 39 in 2021 (Fig-1). Male to female ratio was 1.4: 1(Fig-2). Mean age for BAS patients was 14 days ± 10 days and mean weight 2.6 ± 0.72 Kg. Mean age for PDA stenting patients was 16 days ± 12 days and mean weight 2.5± 0.69 Kg. Mean age for Balloon angioplasty for coarctation patients was 22 days ± 4 days and mean weight 2.6± 0.84 Kg. Mean age for Balloon aortic valvuloplasty patients were 25 days ± 3 days and mean weight 3.1 ± 0.88 Kg. Mean age for Balloon pulmonary valvuloplasty patients were 15 days ± 10 days and mean weight 2.65 ± 0.69 Kg.

Balloon angioplasty (BA)of discrete native coarctation was done in 31 patients. All patients had signs of congestive heart failure (CHF)or very diminished femoral pulses. Nineteen (64%) of patients have severe LV dysfunction. Isolated CoA was diagnosed in nine patients; the remaining 22 patients had other cardiac defects including PDA in five, bicuspid aortic valve in three, ASD/PFO in twelve, small VSD in seven, PAPVD in one patient and mild aortic arch hypoplasia in eight patients. The diameter of the balloon for angioplasty was equal to the diameter of the aorta at the level of diaphragm. Mean fluro time was 9.8 minutes. CHF improved markedly in most of the patients immediately after BA, with a reduction in systolic pressure gradient from 47 ± 12.0 to 9 ± 6.0 mmHg ($p < 0.001$). No deaths related to the procedure occurred. Six patients died due to sepsis, pneumonia, low birth weight, delayed diagnosis & referral. Transient loss of femoral pulse occurred in four patients after balloon dilation; one resolved spontaneously, and the other three resolved after an infusion of heparin for 24 hours. Four patients had systemic hypertension requiring beta blocker therapy.

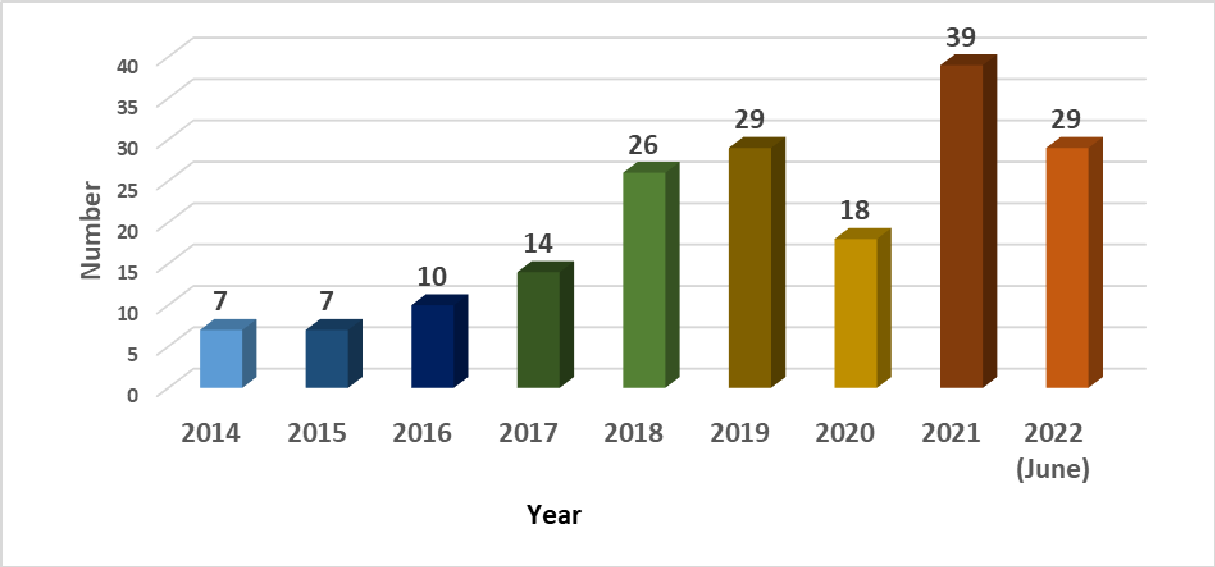

Figure-1: Distribution of neonatal interventions year wise (excluding BAS).

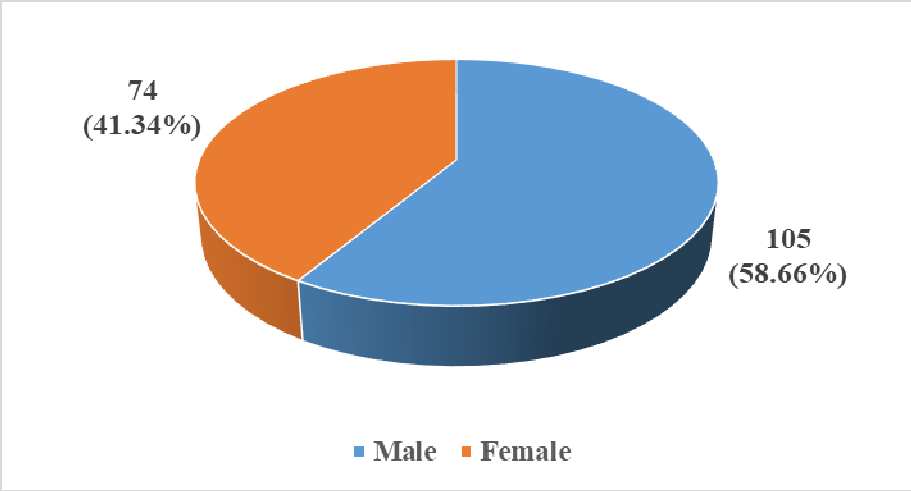

Figure-2: Distribution of Genders.

Percutaneous balloon valvuloplasty of aortic valve done in 14 neonates. Six patients were in congestive heart failure, three were in hemodynamically unstable condition. Associated cardiovascular lesions included a PDA in three patients, ASD/PFO in three, mild coarctation of aorta in three patients. The balloon size is chosen to approximately equal the valve annulus diameter as estimated by echocardiography. Mean fluro time was 20 minutes. Balloon aortic valvuloplasty reduced the peak systolic gradient from an average of 64 ± 8 mm Hg to 15 ± 3 mm Hg (P value <0.05). Moderate aortic regurgitation was created in two patients. One patient, the aortic valve could not be passed with wire. Three patients developed transient bradycardia during the procedure. One patient developed ventricular fibrillation after passing wire. There were two procedure related deaths & two patients died due to persistent low cardiac output. Loss of femoral pulse was present in 5 neonates & returned after heparin therapy in three & persistent feeble pulse was present in two patients.

Percutaneous balloon pulmonary valvuloplasty done in 17 neonates. Eleven patients were cyanotic & duct dependent, having critical stenosis. Associated cardiovascular lesions included a PDA in nine patients, ASD/PFO in eleven. A graded balloon dilatation, usually exceeding the diameter of the valve by one- quarter to one-third was done. Mean fluro time was 37 minutes. The peak systolic gradient reduced from an average of 66 ± 7 mm Hg to 16.5 ± 5 mm Hg (P value <0.05). No major complication occurred except mild PR, RV dysfunction, Transient bradycardia. Two patients died due to sudden cardiac arrest after six hours of procedure. It was thought due to pulmonary over circulation or due to unrecognised ventricular arrhythmia. Thereafter all critical PS patients ventilated & sedated for 24 hours after procedure & low dose diuretics was given. Additional three patients died due to sepsis, aspiration pneumonia. One patient procedure could not be done due to failure to take vascular access at the beginning of our series.

Transcatheter intervention for pulmonary atresia with intact ventricular septum(IVS) is an effective but technically difficult primary palliative treatment in newborns. Three neonates with membranous pulmonary atresia with intact IVS underwent pulmonary valve perforation using coronary total occlusion (CTO) guide wire conquest Pro. We also incorporate ductal stenting as RV was intermediate or borderline. Mean age was days & mean weight was Kg. Detailed echocardiographic examination focused on right ventricle size, and tricuspid valve morphology and coronary sinusoids were performed in all the patients before the intervention. Right ventricular systolic pressure fell significantly from 112±21 to 49.6±9.7 mm Hg (p value 0.001).

One symptomatic neonate with TOF having severe cyanosis & persistent metabolic acidosis underwent RVOT stenting using 4 mm coronary stent. Systemic arterial oxygen saturation was 45% before the procedure and increased to 86% immediately after the procedure. The baby had transient cardiac arrest during the procedure and also had a long ICU stay due to sepsis. 143 neonates underwent Balloon atrial septostomy (BAS). 94% have the diagnosis of d- TGA with restricted ASD/PFO with intact interventricular septum ± PDA, 3% of mitral atresia, 2% of tricuspid atresia & 1% of TAPVC with restricted PFO. All patients except seven, the procedure was done in the catheterization laboratory. These seven patients underwent Echo guided BAS while Cathlab machine was out of order for a month. Reason behind fluoroscopy guidance was to do coronary angiogram to accurately inform surgeons of coronary artery anomaly whenever suspected by echocardiography. Coronary angiogram could be done in 42 (29%) patients of BAS & coronary anomalies found in 7 (4.8 %) patients. The diameter of the atrial communication increased from 1.4 ± 0.25 mm to 4.88 ± 0.79 mm ($p < 0.0001$). Oxygen saturations increased significantly just after the procedure from 42.32 ± 10 % to 79.28 ± 10.34% ($p < 0.0001$). Transient cardio-respiratory arrest in four patients during the procedure occurs in BAS patients. Other complications encountered were sepsis (33), pneumonia (14) and renal impairment (06), femoral venous obstruction (04) patients. There were three procedural failures and overall mortality was 11.8% mostly from sepsis. Our 2nd largest procedure was ductal stenting in neonates. Among study population 39.8% (45) patients were having Pulmonary artesia with VSD, Pulmonary atresia with intact IVS constitute 29.2%(33), different kinds of Single ventricle physiology with Pulmonary atresia was 26.5%(30). Five patients (3.8%) had CTGA, VSD, pulmonary atresia (Table-1).

Table-1: Distribution of Diagnosis (by Echocardiography) of PDA stenting patients.

	Frequency	Percent
Diagnosis		
Pulmonary atresia VSD	45	39.8
Pulmonary atresia intact IVS	33	29.2
Pulmonary atresia single ventricle physiology	30	26.5
CTGA VSD Pulmonary atresia	5	3.8

Table-2: Distribution of origin of duct from arch of aorta.

	Frequency	Percent
Duct origin		
Vertical duct from under surface of arch	27	23.7
Indirect duct from subclavian artery	17	15.4
Duct from distal arch (Intermediate origin)	48	42.7
Duct from proximal descending aorta	21	18.2

In 27 patients (23.7%), the PDA arose from under the surface of the arch. Highest number of patients (48) duct arose from distal aortic arch. In 21 patients the ductus arose normally from the proximal descending aorta and had a straight tubular or conical course and in seventeen patients the ductus arose from the subclavian artery, giving the appearance of a modified BT shunt (Table-2).

Table-3: Distribution of arterial approach to enter the duct & diameter of stent used.

	Frequency	Percent
Approach to enter the duct		
Femoral artery	70	62.0
Femoral vein	13	22.0
Axillary artery	30	26.0
Diameter of stent		
2.5mm	2	2.0
3mm	17	15.0
3.5mm	26	23.0
4mm	68	60.0
Drug eluting stent	13	11

The procedure was done using a retrograde approach via femoral artery in 70 patients, antegrade from femoral vein in 13 patients & via axillary artery in 30 patients (Table-3). The great majority of stents implanted were of 4.0 mm diameter (60%)

because of unavailability of smaller stents & intentionally in biventricular physiology patients. The mean stent length was 14.3± 3.65 mm (range 8 to 22 mm). Twenty-six patients of PAIVS also underwent BAS as an additional procedure. The mean fluoroscopy time was 42.5 minutes (range 14 to 175 min).

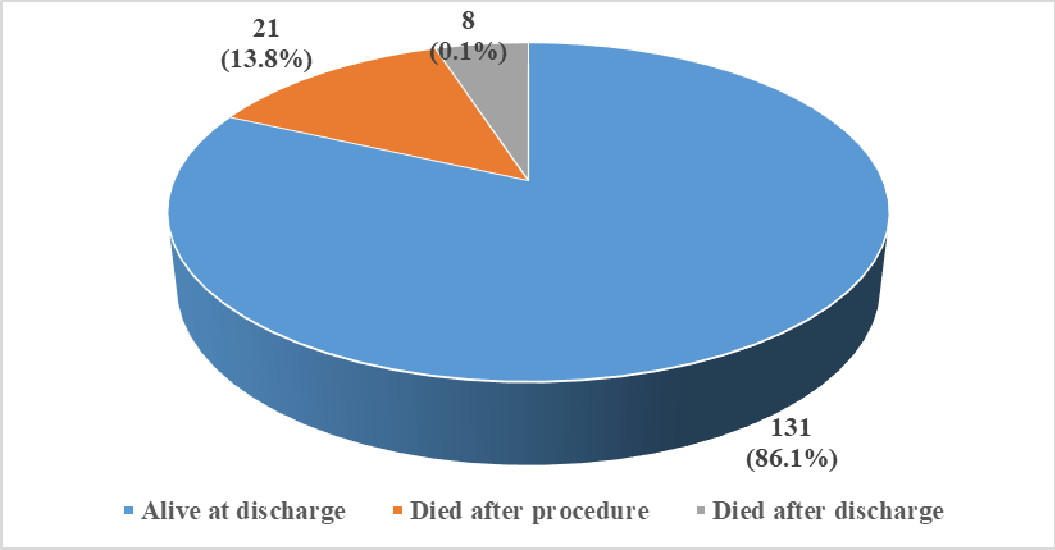

Figure-3: Distribution of outcome after PDA stenting.

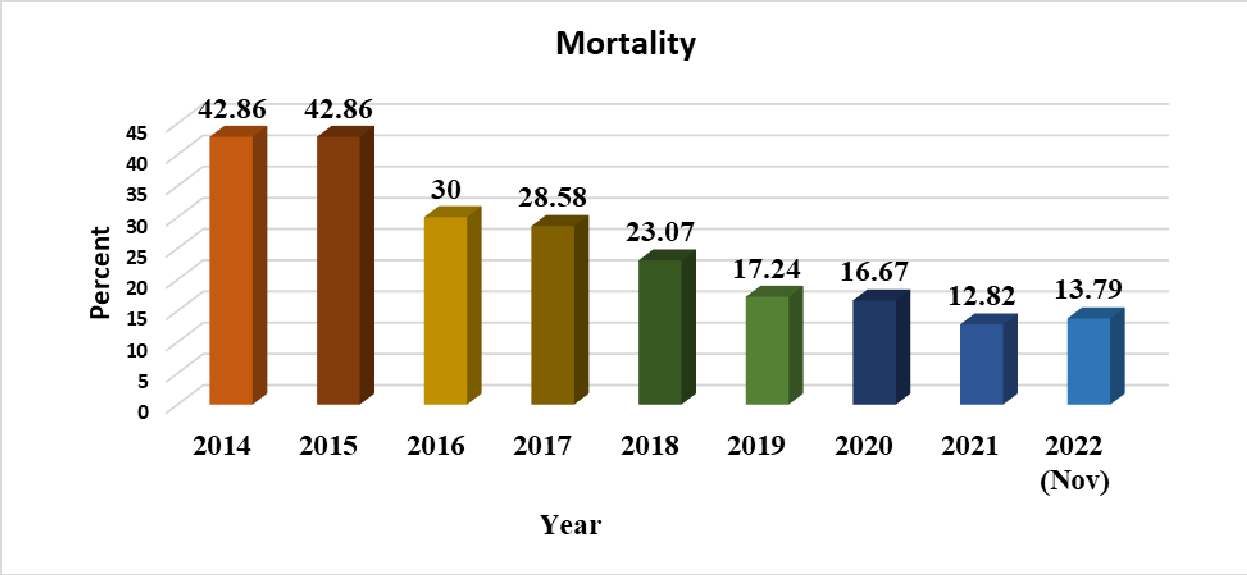

Figure-4: Distribution of mortality year wise.

Baseline SPO2 was significantly improved after the procedure from 40.1±8.7% to 83.4±9.9% at discharge. The procedure was unsuccessful for two patients due to tortuosity of the duct during the initial part of the study. The most common complication of PDA stenting was sepsis (25%). Procedure related complications were vascular injury (3), acute stent thrombosis (2), stent malposition/migration (2), duct spasm during wire manipulation (6), over shunting/Heart failure (14), Jailed PA branch (7). Others like renal impairment, transient severe bradycardia, temporary pulse loss in lower limb requiring

heparin infusion in six. The procedure was unsuccessful in two patients. Twenty-one patients expired and overall mortality was 13.8%. eight more patient died on follow up. (Fig-3) The overall mortality rate was 16.4% which has decreased from 2014 from 43% to 13.8% in recent years. The procedural failure rate was overall 2.17% (Fig-4).

DISCUSSION

Catheter-based therapies are good alternatives to surgery both in terms of initial palliation and cure[5]. In neonates, less invasive interventions are preferred because open heart surgery cannot be performed at all centres and is associated with a high mortality risk, especially in developing countries.[6] Currently, percutaneous cardiac interventions afford higher success rates with lower morbidity com- pared with surgery in newborns in poor general condition.[7] There are controversy over routine use of balloon angioplasty in treatment of neonatal coarctations , it may certainly be utilised in special circumstances,[8] namely, neonates with shock-like picture and severe cardio-respiratory decompensation;[9,10] severe myocardial dysfunction, secondary to "hypertensive cardiomyopathy" (due to coarctation),[11] prior cerebral haemorrhage,[8] and liver dysfunction associated with biliary atresia.[8] We found balloon angioplasty to be useful in neonates with CHF & severe LV dysfunction with significant reduction of systolic gradient & improvement of CHF in most of the patient. Liang C-D et al showed CHF improved markedly in all patients immediately after BA, with a significant reduction in systolic pressure gradient [12]. The treatment of critical aortic stenosis in early infancy continues to be a challenge for paediatric cardiologists and cardiac surgeons, and the optimal management strategy remains controversial [13]. Aortic valve balloon dilation has become the procedure of choice in many centres for the treatment of critically ill infants with severe aortic valve disease [14]. We have attempted balloon valvuloplasty of aortic valve in 14 neonates & was successful in 13 patients. There were two procedure related deaths & two patients died due to persistent low cardiac output. Kasten-Sportes et al. [15] attempted transfemoral balloon valvuloplasty in 10 newborns with critical aortic stenosis and reported effective gradient reduction in all 7 infants who had a technically satisfactory procedure. Beekman et al showed after using improved catheter technology since March 1989, all five neonates presenting with critical aortic stenosis were treated successfully by balloon valvuloplasty mostly by transumbilical approach [16]. PAIVS has a wide anatomic spectrum. Alwi et al showed concomitant PDA stenting at the time of RFV in PAIVS patients with intermediate RV size is feasible and safe and eventually required bidirectional cavopulmonary shunt (1½-ventricle) [17]. In our study we have done pulmonary valvotomy with concomitant PDA stenting in three patients with PAIVS with intermediate RV like Alwi et al showed in his study as feasible & safe. This treatment strategy largely obviated the need for emergency procedures to augment pulmonary blood flow although acute stent thrombosis may occur in a small percentage. Perione et al from Argentina in a multicenter study has shown efficacy and safety of RVOT stenting as a bridge to corrective surgery. We are still at our learning curve for this type of challenging procedure as we have attempted one neonate with severe TOF [18]. Baseline SPO_2 was significantly improved immediately after the procedure & at discharge in all our patients with BAS consisting of other studies all over the world. Size of Interatrial defect increased significantly as well as pressure gradient across left & right atrium decreased significantly shown in our study was similar to Matter M et al. [19]We have high mortality rate (11.8%) after BAS not related to procedure but due to sepsis because of delayed diagnosis, referral, multiple ICU stay before we receive these neonates. Patent ductus arteriosus

stenting seems a reasonable alternative to a modified BT shunt in securing pulmonary blood flow in duct-dependent cyanotic heart disease. We did PDA stenting retrogradely via the femoral artery in 70 patients (62%), of which Alwi et al[20] did 84.3% cases, the mean fluoroscopy time was 42.5 minutes in our series which was 29.4 minutes in Alwi et al series. Baseline SPO_2 was significantly improved at discharge 83.4± 9.9 % in our study consistent with Odemis et al[21] study 81.88 ± 6.95%, from Turkey. Clinically significant heart failure from overshunting is uncommon in other studies but happened in 14 patients in our series.

CONCLUSION

Transcatheter intervention in neonates stabilise or palliate them to surgical next step and sometimes primarily treat the condition. It can effectively reduce the burden of cardiac surgery especially in developing countries like us where there are few cardiac surgical centres capable of doing neonatal surgery. Delayed diagnosis & referral leading to sepsis prior to the procedure adds challenge to these high risk procedures. Early detection and well planned catheterization procedures improves outcome.

Conflicting Interests: The authors declare that there are no conflicts of interest.

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