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Original Research Article

CLINICAL PROFILE AND OUTCOME OF PATIENTS WITH CONGENITAL HEART DISEASE TREATED WITH PERCUTANEOUS TRANSCATHETER INTERVENTION

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ABSTRACT

Background: Congenital heart diseases (CHDs) are the most common birth defects, responsible for nearly one third of all congenital birth defects. CHD is often associated with malnutrition and failure to thrive, the prevalence being as high as 64% in developed countries of the world. We conducted this study to find out the Clinico-epidemiological profile of patients with CHD admitted for percutaneous transcatheter intervention (PTI), to evaluate anthropometric profile of children with CHD who underwent PTI and to study immediate and 6 months post procedural clinical outcome. **Materials and Methods:** This is a prospective observational cohort study which is being conducted among patients with CHD who underwent percutaneous transcatheter intervention. **Result:** 85 cases were managed successfully with PTI with favorable immediate and 6 months outcome. The commonest CHD treated with PTI was PDA. CHD were found to be more common in females. Commonest symptom was dyspnea. No major complication (except for one event of ASD device embolization) observed with reduced hospital stay. Pediatric age group patients required general anesthesia but the remaining patient were treated with local puncture site anesthesia only. Pediatric age group patients especially < 5 years of age get benefit in terms of physical growth parameters too. This single study encompassing all CHD which are amenable for percutaneous transcatheter intervention. **Conclusion:** Percutaneous transcatheter intervention in Congenital heart disease with suitable anatomy are very safe procedures with excellent immediate and 6 months follow up outcomes irrespective of age. Malnourished children of less than 5 years of age showed significant catchup growth in follow up.

INTRODUCTION

Congenital heart diseases (CHDs) are the most common birth defects, responsible for one third of all congenital birth defects.[1] The birth prevalence of CHD is reported to be 8–12/1000 live births.[2,3] If access to screening, early diagnosis, and treatment is available, over 90% of patients born with CHD survive to adult life with good long-term outcome.[4] Most middle- and low-income countries lack such advanced level of care for children with CHD. Considering a birth prevalence as 9/1000, the estimated number of children born with CHD every year in India approximates 240,000, posing a tremendous challenge for the families, society and healthcare system.

Congenital heart disease (CHD) is often associated with malnutrition and failure to thrive, the prevalence being as high as 64% in developed countries of the world.[5] The problem is more severe in the developing regions of the world, where malnutrition is common even in otherwise normal children.[6]

Severe malnutrition may occur in children with congenital heart defects due to an imbalance between

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energy intake and consumption. Heart failure and pulmonary hypertension are the most important factors for the development of the severe malnutrition.[7]

Weight and height are affected equally in cyanotic patients. Acyanotic lesions especially in combination with septal defect, left to right shunt will affect weight only. In short, acyanotic lesions are related to acute malnutrition whereas cyanotic lesions were related to chronic malnutrition.[8]

Failure to thrive can result in permanent physical or developmental impairment.[9] There must be an effort between parents, physicians, nurses and other health care professionals to develop a plan that will be appropriate on an individual basis.[10]

Acyanotic congenital heart disease in the adult population primarily involves left-to-right shunts, such as atrial septal defect, ventricular septal defect, patent ductus arteriosus, and obstructive lesions such as coarctation of the aorta. The most common form of cyanotic congenital heart disease in adults is tetralogy of Fallot. Results of PTI are excellent in the adult population.[11]

Surgical method of treatment of CHD is an established method. But non-surgical device closure is an alternative mode replacing the surgical method.[12] Surgical method has more morbidity and mortality. Surgery is subjected to complications of cardiopulmonary bypass which not infrequently leads to perfusion injury to brain and other vital organs.[13] Moreover, the hazards of blood transfusion, prolonged anesthesia, prolonged hospital stay, psychological trauma to the patients and parents and finally the ugly scar on chest preclude the final outcome of surgical closure.[14]

We have 2 groups of interventions, either balloon based or device based.[15]

We planned to study prospectively the patients of CHD who underwent percutaneous transcatheter intervention with focus on:

1. The clinico-epidemiological profile of patients with congenital heart disease who required percutaneous transcatheter intervention.
2. The immediate post intervention clinical outcome and outcome at 6 months post percutaneous transcatheter intervention.
3. To evaluate anthropometric profile of children with congenital heart disease who underwent percutaneous intervention.

MATERIALS AND METHODS

The present study was conducted in the department of Cardiology, Dr. S. N. Medical college, Jodhpur. Patients fulfilling the inclusion criteria were included. It was a single center observational study.

Inclusion criteria:

Patients with congenital heart diseases attending cardiology OPD and suitable for percutaneous transcatheter intervention were included.

1. OS ASD with left to right shunt, associated with evidence of right ventricular volume overload with suitable anatomy.
2. Large/moderate/small PDA with left to right shunt
3. Midmuscular VSD, anterior muscular VSD
4. Asymptomatic or symptomatic patients with AS having gradient by echo-Doppler of >64 mmHg peak or >40 mmHg mean
5. Asymptomatic or symptomatic patients with valvular PS having peak instantaneous gradient by echo-Doppler of >64 mmHg

Indian guidelines for indications and timing of intervention for common congenital heart diseases were followed.[25]

Exclusion criteria:

1. Severe pulmonary arterial hypertension or irreversible pulmonary vascular occlusive disease determined by echocardiography in patients of ASD/VSD/PDA.
2. Presence of Aortic regurgitation in patients of VSD
3. Supravalvular AS or presence of subaortic membrane or presence of AR
4. Supravalvular PS or peripheral PS or presence of PR
5. Children with history of prematurity (by history/birth records), intrauterine growth retardation (history/birth record), suspected clinical genetic malformations, dysmorphic features and neurologic disability including cerebral palsy and hemiparesis
6. Associated other systemic comorbidity: Pneumonia (evident on x-ray by consolidation), renal failure (determined by eGFR <60 ml/min/m2), chronic liver disease, active infection (elevated total leucocyte count)
7. Anemia (Hb <10gm/dl)
8. Sepsis (positive blood culture/nutrophillia/leucocytosis)

The study protocol approval was taken from Institutional Ethics Committee. Informed consent was taken by the patient/parent/guardians. All patients were clinically evaluated after detailed history taking. Anthropometric and clinical were carried out for each subject at the time of admission. Blood pressure was recorded in left arm in supine position with an appropriately sized cuff using a sphygmomanometer. Routine complete hemogram and biochemistry (blood urea, serum creatinine, liver function test), viral markers such as hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) was done. ECG, Chest X ray PA view (digital) and transthoracic echocardiography (TTE) were performed in each case. Transesophageal echocardiography (TEE) was done in OS ASD cases to assess adequate rims and in cases where doubt regarding size and amenability for device closure was suspected. Weight for age, weight for height, height for age (using standard WHO growth charts) and BMI were measured with participants standing without shoes in light clothes.

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Bodyweight was measured in kilograms to the nearest 0.1 kg using a digital scale, which was calibrated regularly. Length/height was measured using infantometer or stadiometer. Body mass index (BMI), was also calculated using Quetlet's formula as weight in kg/square of the height in meters. After a routine workup preanesthetic checkup was made for fitness of the procedure.

Cath lab percutaneous Intervention: Standard procedure for ASD device closure/VSD device closure/ PDA duct occluder/ Balloon pulmonary or aortic valvotomy was followed, Vitals were monitored, procedure time and fluro time was noted, any intraprocedural complication were noted. After the procedure patient were monitored for vitals for next 24 hours for any complication. Repeat echo was done for seeing the success of the procedure and documentation. Course of oral antibiotics was given (amoxicillin + clavulanic acid) according to weight for 3 to 5 days. Additionally, aspirin 3 mg/kg was prescribed after OS ASD device closure. Analgesic was given for symptomatic requirement. A follow up visit after 6 months of index procedure was made for clinical and anthropometric assessment of children.

Continuous variables were expressed as mean ± standard deviation whereas categorical variables were given as numbers (percentages).

RESULTS

In our study, total 85 out of 86 patients were treated with percutaneous transcatheter intervention. Overall, the mean age of patients was 13.1 years, with minimum mean age was 8.4 years in PDA patients and maximum mean age was 23.4 years in OS ASD patients. CHD was found to be 1.9 times more common in female. Highest male to female ratio was observed among PDA patients (1:3.1). Patients with CHD were found to be undernourished with mean BMI=17.47 kg/m2. with minimum in PDA patients (16.6 kg/m2) and maximum in ASD patients (19.3 kg/m2). Commonest symptom observed was dyspnoea on exertion. History of lower respiratory tract infection was present in 43.4% of ASD patients and 56.5% patients with PDA. Only one patient of VSD was treated who also had dyspnoea and history of lower respiratory tract infection. 23 cases were of < 5 years of age. One had OS ASD and remaining 22 cases had PDA. These children were wasted and stunted as per WHO child growth standards.

Atrial septal defect (ASD)

Echocardiographic assessment of OS ASD patients showed the mean ±SD size of ASD was 28.6±6.2 mm with Qp:Qs (mean±SD)= 2.2±0.14. TEE showed adequate rims for device closure. Mean procedural time was 41.6 min with mean fluoroscopy time was 11.6 min. General anesthesia was required in 11 patients. In the immediate post procedure Echo residual left to right shunt was observed in 5 (21%) cases. Patient stayed for 2 days after the procedure. At 6 months follow up all patients were healthy and showed significant catch-up in their anthropometric parameters. Repeat TTE at follow up showed no residual shunt at atrial septal level across the device. One patient had accidental device embolization during the procedure. Patient was immediately shifted to cardiothoracic surgery department where she was managed with open heart surgery for device retrieval as well as for ASD patch closure.

Patent ductus arteriosus (PDA)

Echocardiographic assessment showed the defect size of 4.5 ±1.3 mm (mean ±SD), with Qp: Qs ratio(mean±SD) = 2.3±0.17. General anesthesia was required in 40 cases The mean size of duct occluder was 7.8 X9.8 (Range=4X6 to 14X16). Mean procedural time was 33.7±5.9 and mean fluoroscopy time was 16.6±2.4. No significant complication was noticed . Residual shunt was seen in 8 (17%) cases in immediate post procedure echo. Patient stayed for 2 days after the procedure. At 6 months follow up all patients were healthy and showed significant catch-up in their anthropometric parameters. Repeat TTE at follow up showed no residual shunt across the device.

Pulmonary stenosis (PS)

12 patients of valvular PS underwent balloon pulmonary valvotomy. Seven patients required GA. Mean gradient across the pulmonary valve was 71.3 mm of Hg which was reduced to 15 mm of Hg post BPV. Mean size of Tyshak balloon was 17.6X46.6 (range=12X30-22X50). Mean procedural time was 39.9 min with mean fluoroscopy time 16.6 min. No significant complication was observed. Patient stayed for 2 days for monitoring and followed after 6 months. At follow up mean gradient was 21.5 mm of Hg across the pulmonary valve.

Aortic stenosis (AS)

3 cases of bicuspid aortic valve with aortic stenosis underwent balloon aortic valvotomy with mean age of 12 years. The Mean BMI was 19.2 kg/m2. Dyspnea was present in 2 cases. Mean Gradient across the aortic valve was 69 mm of Hg which was reduced to 31.3 mm of Hg post BAV. Balloon size was 14X100. Mean procedural time was 48.3 minutes and fluoroscopy time was 19.3 minutes. Patients were discharged after 2 days and followed at 6 months. No significant complaints were noticed among patients. Follow up TTE showed a mean gradient across aortic valve was 35.4 mm of Hg.

Muscular VSD

One 16-year-old male patient of muscular VSD with BMI 17.7 kg/m2 having dyspnea and history of respiratory tract infection underwent device closure. Defect size was 3 mm with Qp: Qs ratio= 2. Defect was closed with device of 4 mm. the procedural time was 60 min with fluoroscopy time was 20 min. No post procedural complication was seen. Patient was healthy at 6 months follow up with TTE showed no shunt across the device.

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Table 1: Patient demographic details.

Parameter	CHD	ASD	PDA	PS	AS	VSD
Total no. (n)	86	24	46	12	3	1
Age (year) (Mean±SD)	13.3±13.1	23.4±17.8	8.4±8.7	12.5±6.8	12±3.4	16
Sex (male/female)	29/56 1:1.9	10/13 1:1.3	11/35 1:3.1	6/6 1:1	1/2 1:2	1
BMI (Kg/m2) (Mean±SD)	17.47±4.32	19.3±4.6	16.6±4.1	16.7±3.9	19.2±3.2	17.7
Commonest symptom	Dyspnoea	Dyspnoea (73.9%)	Dyspnoea (47.8%)	Dyspnoea (66.6%)	Dyspnoea (66.6%)	Dyspnoea
History of LRTI	--	43.4%	56.5%	--	--	Yes
Age (<5 year/> 5year)	23/62	1/22	22/24	0/12	0/3	0/1
Weight for age (<5 year) (WHO chart)	--	< -3SD	<-3SD= 10 -2 to-3SD=9	--	--	--
Height for age (< 5 year) (WHO chart)	--	b/w -2 & -3 SD	<-3SD=6 -2to-3SD=11	--	--	--

Table 2: Echocardiographic assessment and procedural details

Parameter	CHD	ASD	PDA	PS	AS	VSD
Defect size (Mean ±SD)	--	28.6±6.2 mm	4.5 ±1.3 mm	--	--	3 mm
Pressure gradient (Mean ±SD)	--	--	--	71.3±4.9 mm of Hg	69±3.6 mm of Hg	--
Qp: Qs ratio	--	2.2±0.14	2.3±0.17	--	--	2
General anaesthesia	--	11	40	7	2	-
Device size	--	28.6 (Range=20-40)	7.8 X9.8 (Range=4X6 to 14X16)			4mm
Balloon size	--	--	--	17.6X46.6 (range=12X30-22X50)	14mmX100 mm	--
Procedural time (Min)	--	41.6±6.9	33.7±5.9	39.9±4.3	48.3±2.88	60
Fluoroscopy time (Min)	--	11.6±1.5	9.9±1.4	16.6±2.4	19.33±1.1	20
Complication (Major)	NIL	1 (device embolized)	NIL	NIL	NIL	NIL
Immediate post procedure residual shunt/pressure gradient (mm of Hg)	--	21% (n=5)	17% (n=8)	Mean 15.0±3.1	Mean 31.3±2.3	Nil
Hospital stay post procedure	2 day	2 day	2 day	2 day	2 day	2 day
Follow up	6 months	6 months	6 months	6 months	6 months	6months

Table 3: Follow up details

Parameter	CHD	ASD	PDA	PS	AS	VSD
BMI (Kg/m2)	20.2±8.6	21.6±4.1	20.6±11.1	16.3±3.6	18.7±2.4	18.6
Weight for age	--	> -2SD	>-2SD=21/ <-3SD=1	--	--	--
Height for age	--	> -2SD	>-2SD=5 -2to-3SD=9 <-3SD=8	--	--	--
Residual shunt	--	NIL	NIL	--	--	--
Residual gradient (mm of Hg)	--	--	--	21.5±3.2	35.4±3.6	--
Any history of fever		NIL	NIL	NIL	NIL	NIL

DISCUSSION

In 1966, Rashkind and Miller,[16] described balloon enlargement of an atrial septal communication in 3 infants to facilitate intracardiac mixing in the setting of transposition of the great arteries. Porstmann.[17] published his initial experience with transcatheter occlusion of the persistent arterial duct, while less than a decade later King et al,[18] would go on to perform transcatheter atrial septal defect (ASD) closure in 5 patients with startling success, considering the limitations of the technology then available. Transcatheter ventricular septal defect (VSD) closure was first described in 1987. Transcatheter PDA occlusion has become the most established congenital heart intervention since its initial description in 1967. Balloon valvuloplasty remains the treatment of choice for congenital

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pulmonary valve stenosis with excellent outcomes.[19]

We have found a few studies from literature demonstrating the clinico-epidemiological profile of patients with congenital heart diseases undergoing percutaneous intervention as well as showing immediate outcome of the procedure.

Behjati et al,[20] in their study of 63 patients of ASD found that the mean ASD diameter, measured with transthoracic echocardiography and balloon catheter was 19.5± 5.5 mm and 20.9± 6.2 mm, respectively. The mean follow up period was 32.4±18.8 months. Deployment of the device was successful in 57 (90.5%) and failed in 6 (9.5%) patients. The major complication included dislodgement of device in 1 patient and device embolization to right ventricular inlet (surgically removed) in 1 patient. At 24 hours, 1 month, 6 month and 1 year follow up, total occlusion rates were 73.6 %, 91%, 94.7%, and 94.7%, respectively. In our study 23 patients underwent ASD device closure successfully with mean device size of 28.6 (range 20-40mm). Total occlusion was ,79% at 24 hour and 100% at 6 months. 1 child showed significant catchup growth after the procedure.

Azhar et al,[21] in their study of 121 patients of PDA device closure, four patients had pulmonary artery embolization of the occluder device which was successfully retrieved in the catheterization laboratory, while two others had embolization that required surgical intervention. Four patients had temporary residual leak, nine had protrusion of the device into the aorta without significant Doppler pressure gradient or hemolysis on follow-up, and five had partial hemodynamically insignificant obstruction to the left pulmonary artery. Above study favors transcatheter occlusion of PDA as it is safe and effective alternative to surgery. Surgical backup was important for such interventional procedures. In our study mean device size was 7.8X9.8mm. No device embolization or aortic pressure gradient was noted. 83% cases had total occlusion at 24 hour which increased to 100% at 6 months. Children showed significant catchup growth at 6 months follow up.

Mandal et al,[22] studied a total 186 patients (95 male, 91 female) who had catheter-based intervention of peri membranous VSD. The device was successfully implanted in 180 patients (96.8%). Immediate post-procedural echocardiography showed complete occlusion in all but one patient had trivial residual shunt. Complete AV block occurred in a 9 years old boy, managed with temporary pacemaker and one patient had complete left bundle branch block, which recovered fully after steroid therapy. We did only one case with successful outcome.

Jijeh et al,[23] studied sixty infants of aortic stenosis. Peak-to-peak gradient at AV was 64 ± 27 mmHg, which was reduced to 27 ± 13 mmHg by BAV. Forty-nine (82%) patients had adequate results (residual AV gradient <35 mmHg). There was no significant aortic insufficiency (AI) before procedure, while 6 (10%) patients had increased AI immediately after BAV. Out of 48 patients, 14 (29%) required an additional BAV, 8 (17%) required surgical interventions following BAV. We found the mean gradient of 69±3.6 mm of Hg which reduced to 31.3±2.3 post procedure.

Lip GY et al,[24] studied patients with Pulmonary stenosis. Before the procedure, the mean transpulmonary valve gradient was 53.2 +/- 24.8 mmHg SD, with a mean right ventricular systolic pressure of 74.6 +/- 28.4 mmHg SD, and mean pulmonary artery pressure was 21.4 +/- 6.4/10.2 +/- 3.9 mmHg. The procedure was successful in 19 patients (6 men, 13 women) and was well tolerated and free of complications. Following the procedure, the mean transvalvular gradient was 15.5 +/- 11.5 mmHg, with a mean right ventricular systolic pressure of 40.5 +/- 13.6 mmHg and a mean pulmonary systolic pressure of 24.3 +/- 7.4 mmHg. We found a mean gradient of 71.3±4.9 mm of Hg which reduced to mean ±SD of 15.0±3.1 post procedure.

CONCLUSION

In our study the commonest CHD treated with percutaneous intervention was PDA. CHD were found to be more common in females. Commonest symptom was dyspnea. No major complication (except for one event of ASD device embolization) was observed with reduced hospital stay. Pediatric age group patients required general anesthesia but the remaining patient were treated with local puncture site anesthesia only. Percutaneous transcatheter interventions in congenital heart disease with suitable anatomy are very safe procedures with excellent immediate and 6 months follow up outcomes irrespective of age. Pediatric age group patients especially < 5 years of age get benefit in terms of physical growth parameters too. This is the single study encompassing all congenital heart diseases which are amenable for percutaneous transcatheter intervention.

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