# **Original Research Article**

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# Peri-procedural outcome of transcatheter interventions for congenital heart diseases in children in a tertiary level hospital in South Tamil Nadu, India

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### **ABSTRACT**

**Background:** Transcatheter based therapies in congenital heart defects have gained popularity, as the morbidity associated with the correction of these defects has been dramatically reduced. Complication rates in this group of children are low and our centre is striving to achieve the same outcome as other major centres. Objective of this study sought to determine the institutional complication rates in a group of children who underwent transcatheter interventions for their congenital heart disease

**Methods:** This prospective observational study enrolled 125 patients who underwent elective transcatheter cardiac interventions for congenital heart defects between February 2014 and January 2018. Major and minor complications were predefined.

**Results:** The age of these children ranged from 9 months to 18 years (mean age 9.22 years). The success rate was 99.2% (124/125). Few children (16%) had minor procedure related complications. Only 1 child had a major complication.

**Conclusions:** Transcatheter cardiac interventions in children are highly successful. Meticulous planning and proper case selection are the major contributors for the success of any centre.

**Keywords:** Transcatheter Heart Disease

#### **INTRODUCTION**

Catheter based therapies are available for a wide variety of congenital cardiovascular defects. Transcatheter occlusion devices are available to safely and effectively treat patients with ostium secundum atrial septal defects (ASD), ventricular septal defects (VSD) and patent ductus arteriosus (PDA). Balloon dilatation has become an effective means to relieve congenital pulmonary stenosis and aortic stenosis. Coarctation of aorta can be managed by non-surgical means either by balloon dilatation or balloon-expandable stenting. With transcatheter based therapies in congenital heart defects

(CHD) gaining popularity, the morbidity associated with the correction of these defects has been dramatically reduced. Although technically less challenging, these procedures require accurate assessment of the structure and size of the CHD to be corrected, whether it be a valvular stenosis or a left to right shunt defect. The paediatric cardiologist has to be well trained in these interventional procedures for the successful outcome of these procedures. Our hospital is a tertiary care hospital located in a rural village in south Tamil Nadu with all available infrastructure and technical expertise to carry out these procedures. The patients that we cater to predominantly come from a poor socio-economic

background and the interventional procedures are done free of cost with the help of a government sponsored health insurance scheme. We conducted this study to ascertain the peri-procedural results of transcatheter interventions for CHD in our hospital and compare it with other major centres.

### **METHODS**

This prospective observational study was conducted in the Department of Paediatrics and the division of Paediatric Cardiology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari district, Tamil Nadu. We enrolled patients upto 18 years of age who underwent transcatheter interventions for CHD in our hospital from February 2014 to January 2018. A written informed consent was obtained from the parents of all these patients prior to procedure. The children were diagnosed to have ASD, VSD, PDA, pulmonary stenosis (PS), aortic stenosis (AS), and coarctation of aorta. Children with ASD were evaluated by transthoracic echocardiography (TTE). Evaluation before procedure included a standard 12 lead ECG, chest X-ray, and TTE. Transesophageal ECHO (TEE) was used in selected older patients. The initial TTE was done to confirm the diagnosis and then assess the suitability for device closure. Sub costal window, parasternal short axis and apical 4 chamber were used in TTE to determine the location of the ASD, its diameter and all relevant margins. The inferior vena cava margin, superior vena cava margin, atrioventricular valve margin, superior margin, aortic margin, posterior margin and coronary margin were measured. Recommended sinus echocardiography exclusion criterion was used before making a final decision about procedure suitability. Vascular access was obtained from the femoral vein. The Amplatzer septal occluder (AGA Medical Corporation, USA) was the only device used. After the procedure, residual interatrial shunting and device position was examined by TTE or TEE.

Children with VSD were evaluated by transthoracic echocardiography (TTE). Evaluation before procedure included a standard 12 lead ECG, chest X-ray, and TTE. The initial TTE was done to confirm the diagnosis and then assess the suitability for device closure. Sub costal window, parasternal long axis, parasternal short axis and apical 4 chamber were used in TTE to determine the location of the VSD and its diameter. Recommended echocardiography exclusion criterion was used before making a final decision about procedure suitability. Vascular access was obtained from the femoral artery and femoral vein. The Amplatzer ductal occluder I and II (AGA Medical Corporation, USA) were the only devices used. After the procedure, residual interventricular shunting and device position was examined by TTE and left ventricular angiography. Children with PDA were evaluated by transthoracic echocardiography (TTE). Evaluation before procedure included a standard 12 lead ECG, chest X-ray, and TTE. The initial TTE was done to confirm the diagnosis and then assess the suitability for device closure. Parasternal short axis and ductal view are used to determine the diameter and shape of PDA. Vascular access was obtained from the femoral vein and femoral artery (if needed). The Amplatzer ductal occluder I (AGA Medical Corporation, USA) was the only device used. After the procedure, residual PDA shunting and device position was examined by TTE. Children with PS AS were evaluated by transthoracic echocardiography (TTE). Evaluation before procedure included a standard 12 lead ECG, chest X-ray, and TTE. The initial TTE was done to confirm the diagnosis and then assess the valve characteristics and diameter of valve annulus. Sub costal window, parasternal short axis, parasternal long axis and apical 4 chamber were used in TTE. Recommended echocardiography inclusion and exclusion criterion was used before making a final decision about procedure suitability. Vascular access was obtained from the femoral artery and femoral vein. TYSHAK II balloon was the only balloon used. After the procedure, residual gradient and valve regurgitation was examined by TTE and catheterization measures.

Children with coarctation of aorta was evaluated by transthoracic echocardiography (TTE) and angiography of aorta. CT angiography was done to confirm the diagnosis and then assess the diameter of aorta above and below the coarctation and relation of coarctation to adjacent left subclavian artery. Vascular access was obtained from the femoral artery. ATLAS balloon (BARD medical corporation) was the only device used. After the procedure, residual gradient and diameter were determined by pressure measurements and angiography respectively. Demographic profile, size of ASD, VSD and PDA, device sizes, size of valve annulus, size of balloons for dilatation, and complications were tabulated and analyzed using SPSS. p-value taken significant at <0.05.

#### **RESULTS**

A total of 125 patients were enrolled in the study during the study period from February 2014 to January 2018.

Table 1: Number of cases who underwent each procedure.

Procedure	Number of cases
ASD DC	68
VSD DC	19
PDA DC	25
BPV	10
BAV	1
Coarctation dilatation	2
Total	125

DC: Device closure; BPV: Balloon pulmonary valvotomy; BAV: Balloon aortic valvotomy

Table 2: Demographic details of patients who underwent each procedure.

Procedure	Minimum age	Maximum age	Mean age	Males	Females
ASD DC	4	18	9.42	24	34
VSD DC	7	16	11.05	12	7
PDA DC	0.75	17	5.97	7	18
BPV	1.5	17	11.55	4	6
BAV	7	7	7	0	1
CO A DIL	12	18	15	2	0

DC: Device closure; BPV: Balloon pulmonary valvotomy; BAV: Balloon aortic valvotomy; Co A dil: Coarctation balloon dilatation

Table 3: Procedure related details in device closure.

Procedure	Size of defec	Size of defect			Size of device (mm)	
Procedure	Minimum	Maximum	Mean	Minimum	maximum	
ASD DC	7	29	16.3	8	30	
VSD DC	2	6.4	3.4	4 ADO II	8 ADO I	
PDA DC	1.5	7	3.12	4	10	

DC: Device closure; BPV: Balloon pulmonary valvotomy; BAV: Balloon aortic valvotomy; ADO: Amplatzer ductal occlude

Table 4: Procedure related details in balloon dilatation procedures.

Duo oo duus	Predilatation	Predilatation gradient			Post dilatation gradient		
Procedure	Minimum	Maximum	Mean	Minimum	Maximum	Mean	
BPV	51	130	84.6	11	62	24.7	
BAV	75	75	75	20	20	20	
CO A	47	62	54.5	18	28	23	

CO A: coarctation of aorta

Table 5: Peri procedural complications.

Complication	No. of cases	Percentage
Major complications		
Deaths	0	0
Device embolisation	1	0.8
Emergency cardiac surgery	1	0.8
Major bleeding manifestations	0	0
Minor complications		
Puncture site haematoma	3	2.4
Femoral vein thrombosis	1	0.8
Mild pericardial effusion	1	0.8
Transient AV block	1	0.8
Transient SVT	2	1.6
Moderate tr after VSD DC	1	0.8
Mild residual flow after DC	3	2.4
Fever within 24 hours	7	5.6
Moderate PR after BPV	1	0.8

The age of these children ranged from 0.75 years to 18 years (mean age 9.22 years). There were 49 males and 76 females (M:F ratio 1:1.55). 68 children underwent ASD device closure, 25 underwent PDA device closure, 19

underwent VSD device closure, 10 underwent balloon pulmonary valvotomy, 1 underwent balloon aortic valvotomy and 2 underwent coarctation balloon dilatation (Table 1). The success rate was 99.2% (124/125).

One case of PDA device closure had embolization of device into right pulmonary artery which could not be retrieved. The child was immediately shifted to OT for device retrieval and surgical closure of PDA. There was no death in periprocedural period.

Few children (16%) had minor procedure related complications. Puncture site haematoma was there in 3 patients which spontaneously cleared after 2 weeks. 1 child had features suggestive of femoral vein thrombosis. She was started on heparin and symptoms improved in 1 day. Heparin was continued for 2 more days.

1 patient with ASD device closure had transient 2:1 AV block in ICU which reverted to sinus rhythm after 2 hours. 2 patients had transient SVT which reverted with further catheter manipulation. 1 child after ASD device closure had residual flow through a small additional ASD near IVC which did not seem haemodynamically significant. 2 children who underwent VSD device closure had mild residual flow after device deployment.

#### **DISCUSSION**

The paediatric cardiology division of the department of paediatrics was started in our hospital in February 2014 and since then we have started doing paediatric cardiac interventions on a regular basis. The patients for transcatheter interventions are selected based on strict criteria followed by major publications or reference textbooks.

Sadiq M et al published his outcome of device closure of secundum atrial septal defects in 2012.4 He attempted ASD device closure in 205 patients with a success rate of 98%. Early complications occurred in 38 patients (18.5%). Death occurred in 1 patient (0.5%). Major complications occurred in 10 patients and minor complications in 28 patients (13.6%). During the study period from February 2014 to January 2018, 68 patients underwent ASD device closure in our centre and device was deployed successfully in all patients. We had no deaths and no major complications in our ASD device closure patients. Among our 68 patients, 9 patients (13.2%) had minor complications which included puncture site haematoma (1), femoral vein thrombosis (1), mild pericardial effusion (1), transient AV block (1), transient SVT (2), residual shunt (1) and fever (2).

Regarding VSD device closure, Wang L et al published a multi institutional experience of having successfully treated 502 children with VSD by transcatheter closure. Among the 502 patients, 3 (0.6%) had major adverse events while 104 (20.7%) had minor complications. Among our 19 patients who underwent VSD device closure, there were no major complications, while 4 (21%) had minor complications which included puncture site haematoma (1), moderate TR after VSD device closure (1) and mild residual shunt after device deployment (2).

In an article published by Parra-Bravo et al, 39 patients were included in the study with a mean PDA size of 3.6 mm. The success rate of their procedure was 92.3%. 8 out of the 39 patients (20.5%) had minor complications while 12 patients (30.7%) has residual flow immediately after procedure.<sup>6</sup> Among our 25 patients, the mean PDA size was 3.1 mm with a success rate of 96%. One patient had device embolization into right pulmonary artery. 5 children had fever within 24 hours (20%). None of the children had residual flow after device deployment.

Liu S et al published their data on 38 children who underwent balloon pulmonary valvuloplasty (BPV) in their hospital. The children group had a right ventricle-pulmonary artery (RV-PA) systolic gradient of 52.79±35.08 mm of Hg that decreased to 22.55±12.92 mm of Hg following BPV (P <0.001). None of the children who underwent graded dilation developed evidence of serious complications. Mild pulmonary regurgitation (PR) occurred in eight (21.1%) children. Among our 10 cases, the mean RV-PA systolic gradient

prior to procedure was 84.6±22.5 mm of Hg which reduced to 24.7±11.9 after BPV. No major complications occurred but mild PR occurred in 4 patients (40%) and moderate PR in 1 patient (10%).

Long term follow up of these patients are required as many studies have revealed that a small section of children who have undergone transcatheter cardiac interventions can have multiple issues in future, including need for re-interventions.<sup>8-10</sup>

First and perhaps most importantly, our inclusion and exclusion criteria were vigorous with priority given for safety of procedure and only patients with a suitable anatomy and meeting the criteria were included for the attempted intervention. Second, this is a small-scale study involving only 1 medical centre. A large-scale study is needed to provide a more representative comparison.

#### CONCLUSION

Based on strict inclusion and exclusion criteria, transcatheter cardiac interventions for CHD is associated with excellent success rates and low mortality or morbidity. The transcatheter approach provides a less-invasive alternative avenue for open heart surgery. Meticulous planning and proper case selection are the major contributors for the success of any centre. The high success rate and the minimal complication rates of the transcatheter cardiac interventions in our centre is reassuring for any cardiac centre planning to start a paediatric cardiology programme.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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