Changing Trends in Pediatric Cardiac Catheterization of Congenital Heart Diseases in the Last three Decades: From a Tertiary Care Center

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Abstract

Background: Recent advances in the field of nonsurgical, transcatheter interventions in pediatric cardiology, have metamorphosed the management of congenital heart disease. There is a significant change, with adoption of new techniques. Objective: To study the changing pattern of cardiac catheterization in congenital heart diseases over the last 3 decades. Materials and Results: This is a retrospective, single center study of 8,708 cases who underwent cardiac catheterization for various congenital heart diseases between April 1981 to Dec 2015. Age group ranged from 14-hour old neonate to 18 years. The study included 4,754 (54.6%) boys and 3,954 (45.4%) girls. Various clinical details were noted with particular emphasis on indication for catheterization, age, gender and details of interventions. Commonest conditions catheterized were atrial septal defects 2,015 (23.1%), ventricular septal defects 1,653 (18.9%), patent ductus arteriosus 1,179 (13.5%), Tetralogy of Fallot 1,102 (12.7%), Pulmonary stenosis 882 (10.1%), rest were coarctation of aorta and other complex conditions. Patients were divided into three groups -Group-1(1981-1997), Group-2(1998-2006) and Group-3(2007-2015). Results showed that Group-1 mainly comprised of diagnostic catherisations. Group 2 and 3 showed both diagnostic and therapeutic indications for catheterization and the number of interventional catheterizations increased from 28% (n=652) in Group-2 to 56% (n-1439) in Group-3 (p<0.001) and number of diagnostic catheterization decreased from 98% in Group-1 to 72% (n=1677) in Group-2 to just 44% (n=1150) in Group-3(p < 0.001). Conclusions: There is significant shift from diagnostic interventions in the last 3 decades. Availability of expertise and infrastructure have been mainly responsible for this

Keywords: Catheterization trends; Congenital heart diseases; Diagnostic catheterizations; Therapeutic interventions.

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Introduction

The modern era in pediatric cardiology began in 1947 when Bing et al. described catheterization

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for diagnosis of Congenital Heart Disease (CHD).¹ Pediatric interventional catheterization began in 1968 with balloon atrial septostomy and quickly became a common procedure in pediatric intervention.² During the last fifteen years, major developments have occurred in the use of interventional techniques in pediatric cardiology.³-8 During the same period, advances have also occurred in the imaging techniques in CHD, which have rationalized the indications for diagnostic cardiac catheterization, leading to more selective use of diagnostic cardiac catheterization services

in the cardiac catheterization laboratories. Most of the anatomical information required for making decisions on treatment of CHD can be obtained by Transthoracic Echocardiography (TTE) and colour Doppler. Additional anatomical information can be obtained by cardiac CT and Cardiac Magnetic Resonance imaging (CMR). Shunt quantification can be derived from nuclear medicine techniques. This allows pediatric cardiologists to perform diagnostic cardiac catheterization with the aim of obtaining specific information that has not been obtained by other imaging techniques. Interventional catheterizations have increasingly become a mainstay of pediatric cardiology care. Modern pediatric cardiac catheterization can now treat a number of conditions including Patent Ductus Arteriosus (PDA), Atrial Septal Defects (ASD), Ventricular Septal Defects (VSD), collateral vessels, valve stenosis, vessel stenosis and conduction abnormalities.9 The use of catheterization for the diagnosis of congenital heart disease has decreased dramatically in the last decade.

Background

Catheterization and angiography are considered as gold standard in preoperative and postoperative management of complex CHD's. 10 Recently noninvasive 2D transthoracic, transesophageal, 3D echocardiography, cardiac CT and MRI are being used increasingly in evaluation of cases with temporal association of decrease in diagnostic cardiac catheterization. 10,24 Currently, angiography is used mainly for interventional purposes.¹¹ The development of a wide range of interventional devices in a variety of sizes has led to significant increase in the number of conditions which are now amenable to treatment in the cardiac cath laboratory. Improvements in hardware and techniques have allowed the performance of invasive procedures reliably and safely, even in the neonates and young children. 12,13

Objective: To study the changing pattern of cardiac catheterization in congenital heart diseases over the last 3 decades.

Patients and Methods: This is a retrospective single center study of 8,708 children aged <18 years who underwent cardiac catheterization at our institute, over 3 decades between April 1981 to Dec 2015 either for diagnostic or for therapeutic purpose. All these children were referred from various hospitals with a provisional diagnosis of CHD. As per institutional protocol, detailed clinical examination was done and meticulous TTE was performed in all patients. The majority

of patients were assigned either to medical or surgical management based on their diagnosis and clinical condition. The cardiac catheterization was performed in remaining patients in whom there was a dilemma over diagnosis/decision or who needed intervention.

The patients were hospitalized a day prior to cardiac catheterization. They were kept nil orally for 4 hours before procedure. Procedure was done under sedation with Ketamine (1-2 mg/kg) or epidural anesthesia. Arterial and venous access were obtained after puncturing right or left femoral artery and vein by Seldinger's technique. 50-100 units/kg heparin was given at the beginning of the procedure. The variables recorded were age, sex, type of malformation, presence of other defects and operability assessment, in presence of PAH after pulmonary vasoreactivity testing with oxygen. Data of all cases were meticulously maintained in database. For the purpose of analysis, the study population was divided into 3 groups. Group 1 consisting of children who underwent catheterization from April 1981 to December 1997(comprising 16 yr data), Group 2 consists of children who underwent catheterization from January 1998 to 2006 and Group 3 consists of children who underwent catheterization from 2007 to Dec 2015. Groups 2 and 3 comprised of data over next 17 yrs.

Statistical tools

Data analysis was done with the help of computer using SPSS statistical package- Version. ¹⁷ Using this software, measures of central tendency, measures of dispersion, 't' value, *chi* square and 'p' values were calculated. ANOVA and Student's 't' test was used to test the significance of difference between quantitative variables and Yate's and Fisher's *chi* square tests for qualitative variables. A 'p' value less than 0.05 denotes significant relationship.

Results

In the last 3 decades (between April 1981 to Dec 2015) 8,708 cases underwent cardiac catheterization. There were 4,754 (54.6%) males and 3,954 (45.4%) females. Out of 8,708 children, 6661(76.5%) cases had a diagnostic and 2047(23.5%) cases underwent therapeutic catheterization. But in the last 2 decades therapeutic catheterization is steadily increasing as shown in Group 2 and 3 combined, in which only 2827(57.5%) cases had a diagnostic indication whereas 2091(42.5%) underwent therapeutic catheterization. CHD's like ASD, VSD, PDA,

Tetralogy of Fallot (TOF) and Pulmonary Stenosis (PS) formed the majority of cases.

• Types of Congenital Heart Diseases

Atrial Septal Defect was the commonest indication for catheterization among the various CHD's.

The total number of ASD cases were 2,015(23.1%), of which 295(14.6%) cases underwent ASD device closure. The total number of VSD cases were 1,653(18.9%), of which 132(7.9%) cases underwent VSD device closure. 412(24.9%) cases of VSD had significant Pulmonary Artery Hypertension (PAH) but were operable. However, 285(17.2%) cases had Eisenmenger complex and were inoperable. The total number of PDA cases were 1,179(13.5%), of which 645(54.7%) cases underwent device closure and 230(19.5%) cases underwent coil closure and remaining 304 were sent for surgery. The total number of PS cases were 882(10.1%), of which patients 389(44.1%) cases underwent Pulmonary Balloon Valvuloplasty (PBV) and the rest were referred for surgery due to associated lesions. The total number of TOF cases were 1,102(12.7%).

In Group-1: Catheterized from April 1981 to December 1997 (Table 1 and Fig. 1A): Out of 3970 cases commonest condition was ASD with 1479(39%) cases. The youngest was 3 months old. Twenty-four cases had Triology of Fallot or ASD with associated PS or PFO (1.6 %) and eight had peripheral pulmonary artery stenosis (0.5%). Ninety-one cases (6%) had irreversible PAH. VSD was the second most common anomaly with 730(19.3%) patients. The youngest was one year old. Sixty-six VSD patients had associated PS (9%). One hundred and ninety-five patients (26.7%) had

irreversible PAH. Forty-two patients (5.8%) had mild to moderate Aortic Regurgitation (AR).

Pulmonary Stenosis with intact interventricular and interatrial septum was the third most common condition, found in 377(9.9%) patients. The fourth commonest anomaly catheterized was TOF in 334(8.8%) cases. Twenty-three patients had an associated ASD (Pentalogy of Fallot). Pulmonary atresia was found in 11 patients. Though PDA is a common anomaly, only 177 patients of PDA with clinically suspected cases of PAH were taken up for hemodynamic evaluation rest were sent for surgery without hemodynamic studies.

In Group-2: Totally 2329 cases were catheterized from January 1998 to 2006 (Table 1 and Fig. 1B). The age distribution of this group was <1 year-186(8%) cases, 1-3 years-465 (20%) cases, 3-5 years- 349(15%) cases, 5-10 years- 630(27%) cases and >10 years-699(30%) cases (Fig 2). The mean age was 7.27 yrs (SD-4.94 yrs). VSD was the commonest indication unlike in Group 1 where ASD was common. The total number of VSD cases were 569 (24.4%), of which 5(0.9%) cases underwent device closure, 228(40%) cases of VSD had pulmonary hypertension, but were operable, 49(8.6%) cases had Eisenmenger complex and 23(4.1%) cases of small VSDs had significant AR requiring early surgery. TOF was the next common condition, 533(22.9%) cases were catheterized.

PDA was next common, the total number of PDA cases were 328(14.1%), of which 106(32.3%) cases of PDA underwent device closure and 165(50.3%) cases underwent coil closure. The total number of ASD cases were 225(9.7%) of, which 88 cases (39%)

Congenitalheart Disease	Group 1 April 1981-Dec1997 (n=3790)	Group 2 Jan 1998-2006 (n=2329)	Group 3 2007–Dec 2015 (n=2589)
Total Duration	16 yrs	17 y	vrs
Atrial septal defect	1479(39%) *	225(9.7%) **	311(12%) **
Ventricular septal defect	730 (19.3%) *	569 (24.4%) * and**	354(13.7%) **
Pulmonary stenosis	377(9.9%)	198(8.5%)	307(11.9%)
PDA	177(4.7%)	328(14.1%)	674(26%)
TOF	334(8.8%)	533(22.9%)	235(9.1%)
TAPVC/PAPVC	71(1.9%)	80(3.4%)	36(1.3%)
CoA	62(1.6%)	47(2.0%)	104(4%)
cTGV	56(1.5%)	27(1.2%)	20(0.8%)
RSOV	50(1.3%)	7(0.3%)	1(0.04%)
Miscellaneous	388(10.2%)	270(11.6%)	192(7.4%)

^{*} Diagnostic, ** Device closure

PDA-Patent Ductus Arteriosus, TOF-Tetralogy of Fallot, TAPVC-Total Anomalous Pulmonary Venous Connection, PAPVC-Partial Anomalous Pulmonary Venous Connection, CoA- Coarctation of Aorta, cTGV-corrected Transposition of Great Vessels, RSOV-Ruptured Sinus of Valsalva.

underwent device closure. The total number of PS cases were 198(8.5%), of which 189(95.5%) patients underwent PBV and the rest were referred to surgery due to associated lesions.

Coarctoplasty was done in 47(2%) cases. Balloon aortic valvotomy was done in 42(1.8%) cases of Aortic stenosis. Interventions were done in total of 28%. The miscellaneous group included complex CHD's, Pulmonary AVF and others.

In Group-3: Totally 2589 cases underwent cardiac catheterization from 2007 to Dec 2015. (Table 1 and Fig. 1C): The age distribution of this study population showed <1 year-285 (11%) cases, 1–3 years-621(24%) cases, 3–5 years-495(19.2%) cases, 5–10 years-721(27.8%) cases, >10 years-466(18%) cases (Fig. 2). The mean age was 5.91 yrs (SD-4.48 yrs).

PDA was the commonest indication of cath unlike Groups 1 and 2. The total number of cases were 674(26%), of which 539(80%) cases underwent device closure and 65(9.6%) cases underwent coil closure. VSD was the next common, the total number

of cases were 354(13.7%), of which 127(35.9%) cases underwent device closure. 184(52%) cases of VSD had pulmonary hypertension, but were operable, 41(11.6%) cases had Eisenmenger complex and 11(3.1%) cases of small VSDs had significant AR requiring early surgery. Next common was ASD, total number of cases were 311(12%), of which 207(66.6%) cases underwent device closure. The total number of PS cases were 307(11.9%), of which 200(65.2%) patients underwent PBV and the rest were referred to surgery due to associated lesions. The total number of TOF cases catheterized were 235 (9.1%). Co-arctoplasty was done in 104(4%) cases. Balloon aortic valvotomy was done in 235 (9.1%) cases. There was a definite increase in interventions from 28%(n=652) in Group 2 to 56% (n=1439). Also increase in catheterization in the younger age groups was noted (From 8% to 11% in <1 yr, 20% to 24% in 1-3 yrs among Groups 2 and 3).

• Interventional trends: (Table 2, Fig 3)

In Group 1, majority of cardiac catheterization was for diagnostic purpose (98%). Interventions

Table 2: Therapeutic catheterization details of various CHD's at the referral centre.

Interventions	Group II (No=652)	Group III (No=1439)	p value*
ASD Device Closure	88(13.5%)	207(14.4%)	
VSD Device Closure	5(0.8%)	127(8.8%)	< 0.001
Pulmonary Balloon Valvotomy	189(29%)	200(13.9%)	< 0.001
PDA Device Closure	106(16.3%)	539(37.5%)	< 0.001
PDA Coil Closure	165(25.3%)	65(4.5%)	< 0.001
Balloon Aortic Valvotomy	42(6.4%)	115(8.0%)	
Coarctoplasty	47(7.2%)	104(7.2%)	
Miscellaneous	10(1.5%)	82(5.7%)	< 0.001

^{*}p<0.001 is considered significant

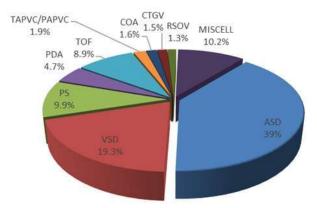


Fig. 1A: Major indications for cardiac catheterization in Group-I (April 1981-December 1997).

ASD-Atrial Septal Defects, VSD-Ventricular Septal Defects, PS- Pulmonary Stenosis, PDA- Patent Ductus Arteriosus, TOF- Tetralogy of Fallot, TAPVC-Total Anomalous Pulmonary Venous Connection, PAPVC-Partial Anomalous Pulmonary Venous Connection, COA-Coarctation of aorta, cTGV-Corrected Transposition of Great Vessels, RSOV-Ruptured Sinus of Valsalva.

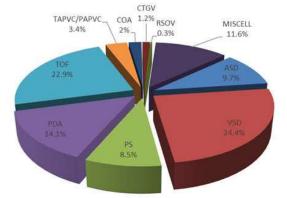


Fig. 1B: Major indications for cardiac catheterization in Group-2 (1998-2006)

ASD-Atrial Septal Defects, VSD-Ventricular Septal Defects, PS- Pulmonary Stenosis, PDA- Patent Ductus Arteriosus, TOF- Tetralogy of Fallot, TAPVC-Total Anomalous Pulmonary Venous Connection, PAPVC-Partial Anomalous Pulmonary Venous Connection, CoA-Coarctation of aorta, cTGV-Corrected Transposition of Great Vessels, RSOV- Ruptured Sinus of Valsalva.

were done occasionally. Intergroup comparison between Group-2 and 3, showed that there was a significant increase in the number of transcatheter interventions from 28% to 56% (p<0.001). In Group-2, PDA closure accounted for majority of cases 41.6% (including device and coil closure) this was followed by PBV in 29% of cases. In Group-3 also the PDA closure again accounted for majority of cases 43.2%. A significant increase in number of

PDA device closures from 16.3% to 37.5% (p < 0.001) was noted and a significant decrease in number of PDA coil closures from 25.3% to 4.5% (p < 0.001) was noted between the two groups. Comparing trends of major individual interventional procedures between two groups showed that ASD device closure did not show significant increase (13.5% to 14.4%). VSD device closure increased from 0.8% to 8.8% (p < 0.001).

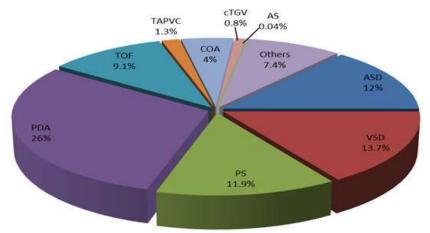


Fig. 1C: Major indications for cardiac catheterization in Group-3 (2007 – 2015).

ASD-Atrial Septal Defects, VSD-Ventricular Septal Defects, PS-Pulmonary Stenosis, PDA-Patent Ductus Arteriosus, TOF-Tetralogy of Fallot, TAPVC-Total Anomalous Pulmonary Venous Connection, CoA-Coarctation of aorta, cTGV-Corrected Transposition of Great Vessels, AS- Congenital Aortic Stenosis.

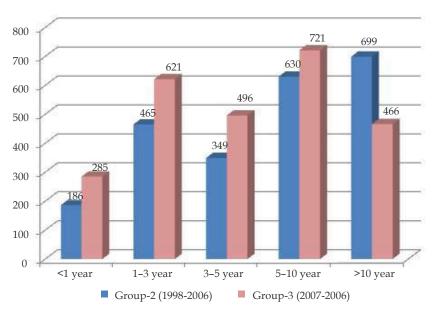


Fig. 2: Age distribution of the study population (n=4738).

Further analysis of interventional trends in Group-3 year wise (Fig. 4) showed a steady increase in theurapeutic catheterizations such as ASD device closure (Fig. 5), VSD device closure (Fig. 6) and Coarctoplasty (Fig. 7) except from the period between 2013–2015. A decrease in the number of VSD patients undergoing cath study and also patients of VSD with PAH was noted due

to improved noninvasive techniques and early referral by peripheral center's. A steady increase in PDA closure was noted with decline in use of coils (Fig. 8). A steady decline in the number of PS cases and PBV was unexplained (Fig. 9). Yearly average of total catheterizations in Group 1 was 226 cases which steadily increased to 245 cases in Group 2 to 305 cases in Group 3.

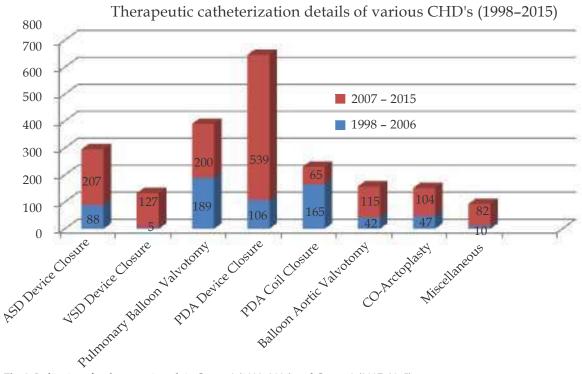


Fig. 3: Indications for therapeutic cath in Group 2 (1998-2006) and Group 3 (2007-2015).

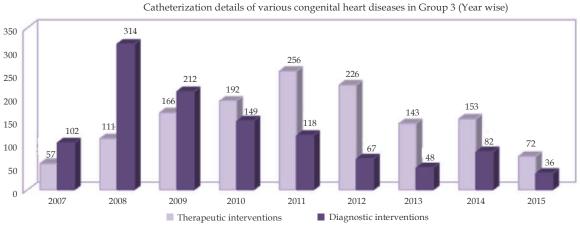


Fig. 4: Catheterization trends (year-wise): 2007-2015 (Group 3).

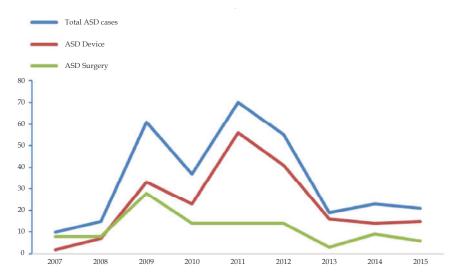


Fig. 5: Trends in ASD device closure.

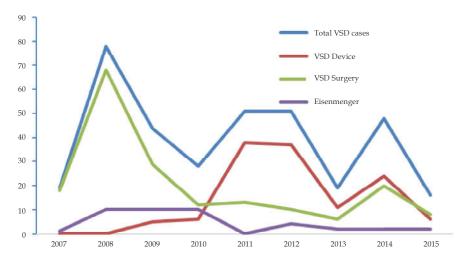


Fig. 6: Trends in VSD device closure

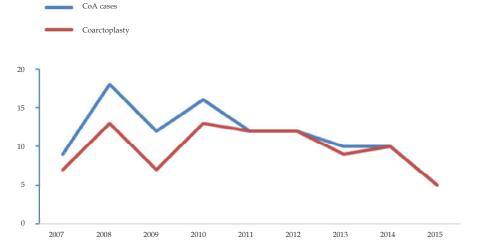


Fig. 7: Trends in Coarctoplasty.

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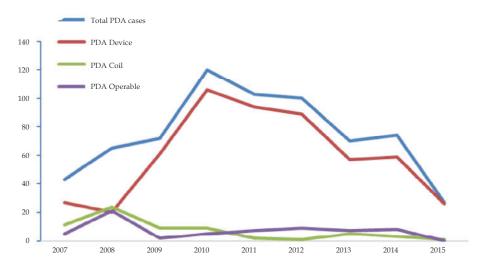


Fig. 8: Trends in PDA closure.

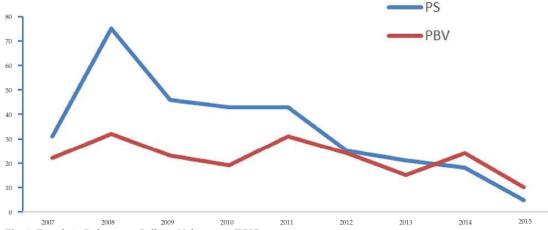


Fig. 9: Trends in Pulmonary Balloon Valvotomy (PBV).

Discussion

Pediatric cardiac catheterization is a gold standard for diagnostic as well as therapeutic trans catheter interventions. This study shows the trend of diagnostic/therapeutic catheterization in the last 3 decades. In consonance with the rapid advancements occurring in the field of pediatric cardiology, there was a definite shift from a diagnostic to therapeutic catheterization. This was particularly true in Group 3(2007-2015). While developed countries have noticed this paradigm shift from diagnostic to therapeutic cath trend few decades earlier, similar trends have been reported in recent years from other Asian countries including Indian subcontinent. 15,18-22 A previously published large scale study from this Institute had noted the availability of tertiary care facility for pediatric catheterization but emphasized on the incidence

of various CHDs.²³ A more recent study from India points to a similar trend as observed in present study and reflects the current practice in most of the tertiary care pediatric cardiology units across the country.¹⁵ This data highlights the availability of skilled operators with appropriate support team, infrastructure and adoption of latest technology in pediatric catheterization in India has changed the trend of management.

Our results indicated that the number of interventional catheterizations increased from 28% in Group-2 to 56% in Group-3(p value-<0.001) and also the number of diagnostic catheterization decreased from 72% in Group-2 to 44% in Group-3 (p value-<0.001). The year-wise sub analysis of Group-3 indicated a steady increase in interventions and a steady decrease in the percent of diagnostic procedures. This pattern is similar to that noted by Yang et al.¹⁸ and Kumar et al.¹⁵

The study showed a quantum jump in catheterization for PDA from 4.7% of diagnostic catheterization to theurapeutic cath of 26.8% and continues to dominate the indication for pediatric catheterization with only a small proportion of children with PDA requiring surgery. Early diagnosis due to screening in schools (loud machinery murmur is readily audible) and referral by primary and secondary care pediatric centres due to increased awareness is a major factor contributing to this change. This has been the trend noted in other studies as well.^{8,19,22}

There has been a significant increase in VSD device closure procedures in the current study. Availability of newer techniques, devices, like Amplatzer Duct Occluder II(ADO-II) and expertise could be possible reasons for this trend. Hijazhi et al, and Allen et al. have reported a similar trend. 19,22,25 ASD device closures were performed increasingly year after year in the current study but the increase was not statistically significant. Iranian study by Hijazhi et al. 22 concurs with our observations with respect to ASD.

As a result of recent technological advances, more rare cases of congenital heart disease are amenable to treatment in the cardiac catheter laboratory than ever before. 17,26-29 Our study provides evidence for this trend with interventions performed for a wide range of indications such as device closures(ASD, VSD and PDA), coarctation of aorta, balloon aortic valvotomy and PBV. What is heartening is the incidence of Eisenmenger's complex decreased from 26.7% to 11.6%, probably due to increased awareness, timely detection and management. Also, an increase in the number of procedures in infants and young children was noted in the study indicating early referral of cases, operator expertise and compatible infrastucture. Similar trends were noted by Kumar et al¹⁵ and Shim et al. ³⁰

To the best of our knowledge, this is the largest Indian study till date, for trends in pediatric cardiac catheterization in India. This is the only study available which determines the pattern of catheterization laboratory data with two major strengths-long longitudinal period and massive in sample volume.

Limitations: The limitations of our study are 1. It is a retrospective study 2. Single unit experience. 3. The actual cause of the changing trends cannot be determined from the data presented, and probable reasons given are the opinions based on the observations made during the time of study. 4. The procedural complications, could not be analyzed as there was inadequate documentation.

Conclusion

There has been a significant shift from diagnostic to therapeutic indications for catheterization in the last 3 decades. Patients who need cardiac catheterizations for diagnostic purpose and for preoperative work up has come down drastically, due to improved noninvasive techniques. Hence most are referred for surgery directly without diagnostic catheterization. However, number of cardiac catheterizations for interventions has increased steadily, due to advent of nonsurgical transcatheter interventions like device closure, stenting and balloon dilatations in a variety of conditions which are now amenable to this attractive and safe alternative to surgery. Pediatric catheterization trends in our Institute are on par with current trends worldwide.

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Conflicts of Interest: None.

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