

Safety of pediatric cardiac catheterisation procedures performed in rural India in a catheterisation lab setup for adult work

Alisha Akhani¹, Jaishree Ganjiwale², Bhadra Trivedi³, Somashekhar Nimbalkar⁴

Introduction: The congenital heart disease (CHD) makes the largest group of congenital defects children are born with. The conservative estimate points towards 1% prevalence of CHD among the newborn. In India, each year approximately 2.4 lakh children are born with CHD, which is largest in the world. There are very centres offering paediatric cardiology services in India and they are unevenly distributed. Because of this, a lot of paediatric patients with CHD get treated at an adult cardiology facility, not always equipped with proper setup to handle complexities associated with paediatric cardiology work. The study aims to assess the safety and complications associated with paediatric cardiology catheterization-based procedures in a Cath lab is primarily used for adult cardiology work.

Methods: The current study is a retrospective review of pediatric cardiac cath-lab-based procedures performed between April 2018 and March 2021.

Results: During the study, 110 pediatric patients underwent 110 cath-lab-based procedures. A total of 20 procedures were performed as an emergency, and 90 were performed as planned procedures. Out of 110 procedures performed, 86.4% were completed without complications. Minor complications were observed in 9.1% of the procedure. Major complications were seen in 3 patients, and two patients died.

Conclusion: The analysis shows that the complications associated with pediatric cardiac procedures performed on rural-based cath-lab oriented toward adult cardiology work are comparable to those of other large-volume pediatric cardiac centres.

Key words: CONGENITAL HEART DEFECTS; CARDIAC CATHETERIZATION; PEDIATRICS; PATIENT SAFETY

INTRODUCTION

Congenital heart diseases (CHD) constitute a significant component of congenital birth defects. As per an estimate in 2011, CHD accounts for nearly 25% of all congenital birth defects (1). The prevalence of CHD globally is estimated to be 1.8 per 100 live births in 2017 (2). Saxena *et al.* estimated that around 240 thousand children are born with CHD each year in India, contributing to 10% of infant mortality (3). A status report by Ramakrishnan showed that only around 90 centres are dedicated to pediatric cardiology work. These centres are not uniformly distributed across the country (4). Many adult cardiology centres in various parts of the country care for pediatric patients with congenital heart diseases.

Such centres are not always well-equipped to manage pediatric cardiology cases and post-procedure complications. The study aims to assess the safety and complications associated with pediatric cardiology catheterization-based

¹ Pramukhswami Medical College, Bhaikaka University, Karamsad, India

² Central Research Services, Pramukhswami Medical College & Shree Krishna Hospital, Bhaikaka University, Karamsad, India

³ Department of Pediatrics, Parul University, Vadodara, India

⁴ Department of Neonatology, Pramukhswami Medical College & Shree Krishna Hospital, Bhaikaka University, Karamsad, India

Correspondence to:

Bhadra Trivedi, MD, consultant Pediatric Cardiologist & Professor;
Department of Pediatrics; Parul University, Vadodara, India;
e-mail: bhadra81@gmail.com

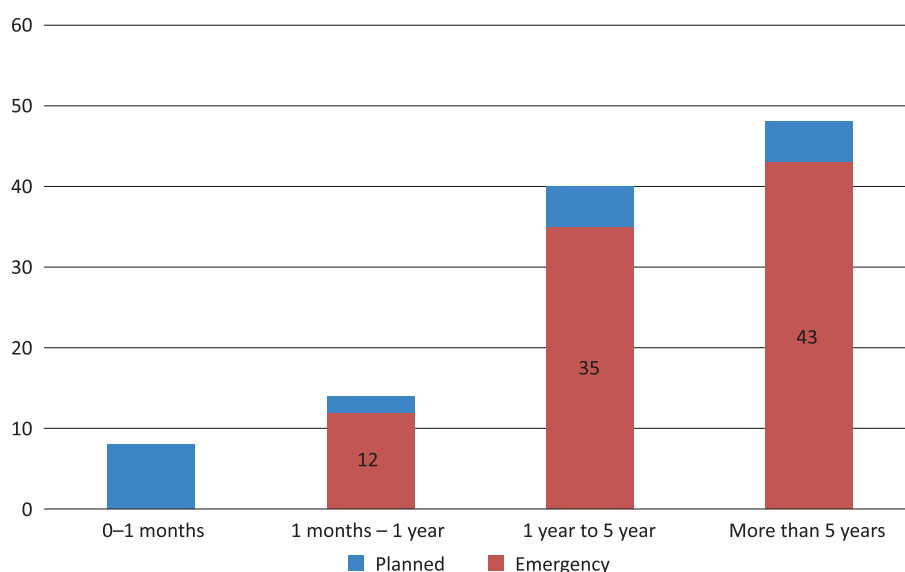


FIGURE 1. The distribution of cases in various age groups.

procedures in a centre in rural areas where the cath lab is primarily set up for adult cardiology work.

METHOD

The Ethics Committee of the institute approved the study. The study Design is a retrospective review. This is a review of complications of pediatric cardiac cath-lab-based procedures performed between April 2018 and March 2021 at B and M Patel Cardiac Centre at Bhaikaka University in Karamsad, Anand, India. The study included all the cath-lab procedures performed by a pediatric cardiologist. The patients' procedure notes, in-hospital documents, ICU documents, discharge summaries, and death summaries were reviewed. Patients with incomplete documents were excluded from the analysis. The classification of complications was adopted from a study by Tokel *et al.* (5). The statistical analysis was conducted using Stata 14 software.

RESULTS

110 pediatric patients underwent 110 cath-lab-based diagnostic or therapeutic procedures during the study period. All of them were included in the analysis. There were 63 fe-

TABLE 1. Emergency and planned cases performed each calendar year

Year	Emergency	Planned	Total
2018	3	21	24
2019	5	47	52
2020	9	15	24
2021	3	7	10
Total	20	90	110

TABLE 2. Procedures performed in a specified period at the centre

Procedure	Count	Per cent
Percutaneous device closure of patent ductus arteriosus	33	30.00
Percutaneous device closure of the atrial septal defect	13	11.82
Percutaneous balloon pulmonary valvotomy (BPV)	13	11.82
Diagnostic angiogram	12	10.91
Percutaneous balloon aortic valvotomy	6	5.45
Percutaneous balloon coarctoplasty	6	5.45
Catheterisation for operability in shunt lesions	6	5.45
Pre-Fontan diagnostic angiograms	10	9.09
Percutaneous device closure of the ventricular septal defect	3	2.73
Balloon atrial septostomy for TGA / TAPVC	2	1.82
Percutaneous device closure of the ASD with BPV	2	1.82
Coil embolisation	1	0.91
Fontan fenestration closure	1	0.91
Percutaneous closure of PDA with BPV	1	0.91
Pericardial effusion drainage	1	0.91

TABLE 3. Categorization of complications during pediatric cardiac catheterization

Category	Count	Per cent
1 No Complication	95	86.4 %
2 Minor Complication	10	9.1 %
3 Major Complication (including sentinel events)	3	2.7 %
4 Death (Included in Group 3)	2	1.8 %

Classification of complications as described by Tokel *et al.* [5]

male patients, which is 57% of all patients. The mean age of the patients included in the study is 65.56 months (IQR –

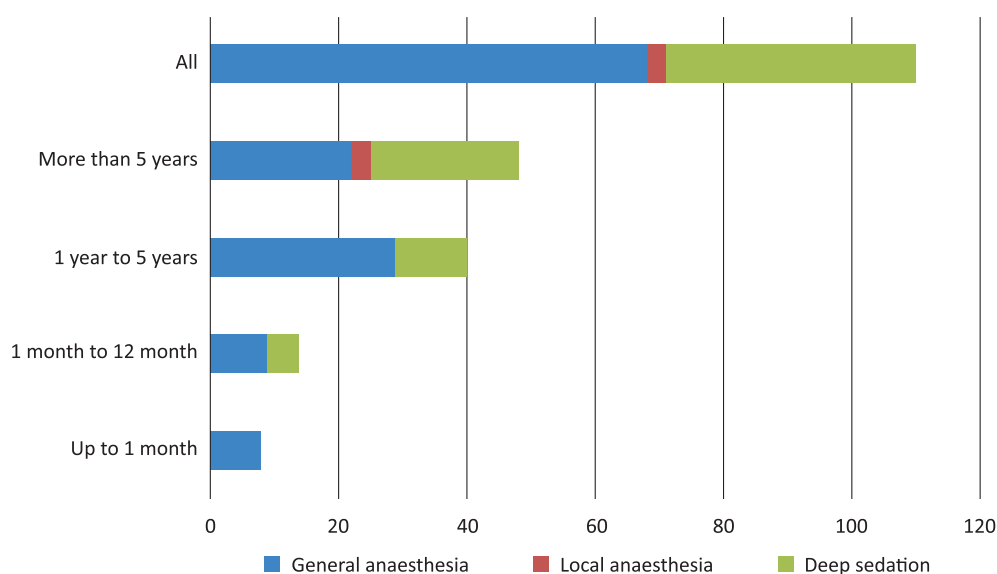


FIGURE 2. Anaesthesia plans for procedures vs age group of patients.

93.22 months). The mean weight of study participants is 13.7 kg, while the range is 2.3 kg to 44.13 kg (IQR – 9.9 kg).

Patients' mean height and weight were 95.95 cm and 13.769 kg, respectively. The mean BSA was 0.5996, and the mean hospital stay was 2.3 days. Patients were further divided into four age groups (Figure 1).

The total number of emergency procedures was 20 (18%) (Table 1). 80% (88) of all patients had acyanotic congenital heart disease.

Percutaneous PDA closure was performed in 33 patients, making up the largest group. Non-interventional diagnostic procedures were performed on 28 patients (Table 2). On the second day of the procedures, 96 children were either discharged or transferred to the surgical department (in case of diagnostic catheterisation)).

Out of 110 procedures performed, 86.4% were performed without complications, according to the classification of complications by *Tokel et al.* (5), Minor complications were observed in 9.1% of the procedure. Major complications were seen in 3 patients, and two patients died (Table 3).

In 3 patients, there was difficulty in deploying the device. Minor arrhythmias were encountered in 3 patients, while significant arrhythmia developed in 1. There was a procedure failure in 1 patient and a change of anaesthesia plan in 2 patients. Device embolisation occurred in 1 patient, while in 2 patients, there was a vascular compromise. The death occurred in 2 patients.

General anaesthesia was administered to 68 patients, of whom 67.8% were younger than five years. About 54% of those over five years old had anaesthesia without intubation (Figure 2).

DISCUSSION

The study reviews 110 procedures performed by a pediatric cardiologist. The therapeutic procedures were 78 %, while the remaining were diagnostic. It is similar to the results published by *Vincent et al.* in 2015 from the data collected in the IMPACT registry (6).

The analysis showed that 13.6 % of the procedures had associated complications. Major complications were seen in 2.7 % of the procedures. The overall complications reported by *Lee et al.* from Seoul were 16.2%, and severe complications were reported at 1.15% (7). Although the overall complications are comparable between the two studies, the major complications are higher in our study.

- (A) Minor arrhythmia - Minor arrhythmias were observed in 3 procedures. *Tokel et al.* reported minor arrhythmia in 2.3 % of the population who underwent pediatric catheterization (5). Similar results were published in 1998 in Canada, where the reported incidence of minor arrhythmia was 2.1% (8).
- (B) Arrhythmia requiring abandoning the procedures - A 22-month-old male child weighing 7.5 kg with restricted peri-membranous VSD was planned for device closure, and a complete heart block was developed while the device was deployed. The occluder device was returned to the sheath; the rhythm immediately returned to normal. Data published by *Tokel et al.* showed a 3% incidence of significant arrhythmia (5), while it was 0.9 % in our review. In their study, *Taner et al.* reported a lower incidence of significant arrhythmia of 1.2 % (9).
- (C) Vascular Compromise -Two cases had post-procedure femoral venous occlusion. A study published in 2014

reported a 2.7% incidence of a vascular compromise requiring heparin infusion for 12-72 hours (10). Another review from a large volume centre in Canada showed 165 arterial vascular and nine venous complications in 4952 catheterisations (8).

- (D) Change of Anesthesia Plan - An intra-procedural change of anaesthesia from non-intubated anaesthesia to intubation and general anaesthesia (GA) was done in two patients. It is like the incidence reported in an extensive sample review of 13611 patients, where 1.77% of participants had to be converted to general anaesthesia (11).
- (E) Device Embolization - One atrial septal defect occluder device embolisation incidence was in the study. In Ackermann's review of 238 ASD device closures, the incidence of embolisation in intra-procedure was 0.8%, and post-procedure was only 0.4% (12). *Rossi et al.* reported zero incidences of device embolisation associated with ASD device closure (13). Immediate embolisation of the ASD occluder device is related to the defect's anatomy and the primary operator's skill and experience (14).
- (F) Death - Two patients died following the procedures. The first case was a 3-day-old child weighing 3.2 kg who was presented to ICU in shock and sepsis. The child had transposition of great arteries and underwent an emergency balloon atrial septostomy. Following the procedure, the shock state persisted, and the child succumbed. The second case was multiorgan dysfunction with significant pericardial effusion and tamponade effects. The child underwent emergency pericardiocentesis with a transfusion of fresh frozen plasma. However, the child did not improve and died of multiorgan failure. *Vitiello et al.* reported a 1.2% incidence of mortality in their review in 1998 (8). With progressive improvement, the mortality has reduced to a range of 0.05% to 1%, as reported by *Manda et al.* in 2021 (16).
- (G) Procedure failure - Emergency balloon pulmonary valvotomy was attempted in a six-month-old 4 kg female child. But despite several attempts, the pulmonary valve could not be crossed; the procedure was abandoned. *Ghaffari et al.* reported a procedure failure rate of 19% for balloon pulmonary valvotomy (17). Another study reported a failure rate of 15% for balloon pulmonary valvotomy in infants (18).

CONCLUSION

The analysis shows that the complications associated with pediatric cardiac procedures performed on rural-based cath-lab oriented toward adult cardiology work are compa-

rable to those of other large-volume pediatric cardiac centres. The incidence of device embolisation is significantly higher than expected from large-volume centres. The limited sample size is a limiting factor.

REFERENCES

1. Dolk H, Loane M, Garne E, a European Surveillance of Congenital Anomalies (EUROCAT) Working Group. Congenital Heart Defects in Europe: Prevalence and perinatal mortality, 2000 to 2005. *Circulation* 2011;123(8):841-9.
2. Zimmerman MS, Smith AGC, Sable CA, et al. Global, regional, and national burden of congenital heart disease, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet Child Adolesc Health* 2020;4(3):185-200.
3. Saxena A, Relan J, Agarwal R, et al. Indian guidelines for indications and timing of intervention for common congenital heart diseases: Revised and updated consensus statement of the Working group on management of congenital heart diseases. *Ann Pediatr Cardiol.* 2019;12(3):254.
4. Ramakrishnan S. Pediatric cardiology: Is India self-reliant? *Ann Pediatr Cardiol.* 2021;14(3):253.
5. Tokel K, Gümüş A, Ayabakan C, Varan B, Erdoğan İ. Complications of cardiac catheterization in children with congenital heart disease. *Türk J Pediatr.* 2018;60(6):675-83.
6. Vincent RN, Moore J, Beekman RH III, et al. Procedural characteristics and adverse events in diagnostic and interventional catheterisations in paediatric and adult CHD: initial report from the IMPACT Registry. *Cardiol Young.* 2016;26(1):70-8.
7. Lee KE, Seo YJ, Kim GB, et al. Complications of cardiac catheterization in structural heart disease. *Korean Circ J.* 2016;46(2):246.
8. Vitiello R, McCrindle BW, Nykanen D, Freedom RM, Benson LN. Complications associated with pediatric cardiac catheterization. *J Am Coll Cardiol.* 1998;32(5):1433-40.
9. Kasar T. Doğumsal kalp hastalığı olan pediatrik hastalarda kalp kateterizasyonu sırasında gelişen ritim bozuklukları. *Türk Kardiyol Dern Ars.* 2018;46(8).
10. Kumar P, Joshi VS, Madhu PV. Diagnostic pediatric cardiac catheterization: Experience of a tertiary care pediatric cardiac centre. *Med J Armed Forces India.* 2014;70(1):10-6.
11. Lin CH, Desai S, Nicolas R, et al. Sedation and anesthesia in pediatric and congenital cardiac catheterization: A prospective multicenter experience. *Pediatr Cardiol.* 2015;36(7):1363-75.
12. Ackermann S, Quandt D, Hagenbuch N, et al. Transcatheter atrial septal defect closure in children with and without fluoroscopy: A comparison. *J Interv Cardiol.* 2019:1-9.
13. Rossi RI, Cardoso C de O, Machado PR, Francois LG, Horowitz ESK, Sarmiento-Leite R. Transcatheter closure of atrial septal defect with Amplatzer® device in children aged less than 10 years old: Immediate and late follow-up. *Catheter Cardiovasc Interv.* 2008;71(2):231-6.
14. Gokaslan G, Ustunsoy H, Deniz H, et al. Urgent surgical management for embolized occluder devices in childhood: single center experience. *J Cardiothorac Surg.* 2012;7(1).
15. Agarwal SK, Ghosh PK, Mittal PK. Failure of devices used for closure of atrial septal defects: Mechanisms and management. *J Thorac Cardiovasc Surg.* 1996;112(1):21-6.
16. Manda YR, Baradhi KM. Cardiac Catheterization Risks and Complications. In: StatPearls. Treasure Island (FL): StatPearls Publishing; June 5, 2023.
17. Ghaffari MR, Ghaffari, Sagafy. Pulmonary valve balloon valvuloplasty compared across three age groups of children. *Int J Gen Med.* 2012;5:479.
18. Saad MH, Roushdy AM, Elsayed MH. Immediate- and medium-term effects of balloon pulmonary valvuloplasty in infants with critical pulmonary stenoses during the first year of life: A prospective single center study. *J Saudi Heart Assoc.* 2010;22(4):195-201.

S A Ž E T A K

Sigurnost kateterizacije srca u pedijatrijskoj populaciji izvođenih u ruralnoj indiji u kateterizacijskom laboratoriju za odrasle

Alisha Akhani, Jaishree Ganjiwale, Bhadra Trivedi, Somashekhar Nimbalkar

Uvod: Prirođene srčane greške čine najveću skupinu prirođenih mana s kojima se djeca rađaju, s prevalencijom od 1% u novorođenačkoj dobi. U Indiji se svake godine rađa oko 2,4 milijuna djece s prirođenim srčanim greškama, tj. najviše u svijetu. U Indiji postoji veliki broj centara koji zbrinjavaju takve pacijente no oni su neravnomjerno raspoređeni. Zbog toga se veliki broj pedijatrijskih bolesnika liječi u kardiološkim ustanovama za odrasle koje nisu uvijek opremljene odgovarajućom aparaturom za rješavanje komplikacija pedijatrijske populacije. Cilj studije je procijeniti sigurnost i komplikacije povezane s pedijatrijskim kardiološkim postupcima koji su provedeni u kateterizacijskom laboratoriju koji se primarno koristi za kardiološko zbrinjavanje odrasle populacije.

Metode: Učinjena je retrospektivna analiza pedijatrijskih kardioloških kateterizacijskih postupaka koji su izvedeni između travnja 2018. i ožujka 2021.

Rezultati: Ukupno 110 pedijatrijskih pacijenata bilo je podvrgnuto 110 kateterizacijskih zahvata. U hitnom zbrinjavanju učinjeno je ukupno 20 zahvata, a elektivno ukupno 90 zahvata. Od 110 izvedenih zahvata, 86,4% je završeno bez komplikacija. Manje komplikacije uočene su u 9,1% zahvata. Veće komplikacije zabilježene su kod 3 bolesnika, a dvoje bolesnika je preminulo.

Zaključak: Zaključno, komplikacije povezane s pedijatrijskim kardiološkim zahvatima koji se izvode u ruralnom kateterizacijskom laboratoriju orijentiranom na zbrinjavanje odraslih bolesnika usporedive su s onima u drugim pedijatrijskim kardiološkim centrima velikog volumena.

Ključne riječi: PRIROĐENE SRČANE GREŠKE; KATETERIZACIJA SRCA; PEDIJATRIJA; SIGURNOST PACIJENATA