

# Complications of cardiac catheterization in children with congenital heart disease

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Catheterization procedures for congenital heart disease include a broad range of procedures with a large spectrum of potential adverse outcomes. We aimed to determine the incidence of various complications during pediatric cardiac catheterizations and to designate the relative risk factors for such complications.

All pediatric patients undergoing cardiac catheterizations between January 2005-December 2010 were included. Data are collected prospectively by filling out computerized catheterization reports. Patient records were scanned for potential risk factors retrospectively. Groups were divided based on cardiac diagnosis; type of procedure. Adverse events were categorized into major or minor events. A total of 2662 cardiac catheterizations were performed during this period. The mean age of patients was 53.2±64.3 months. Diagnostic catheterizations were done for 1797 (67.5%) patients, and interventional procedures were done in 865 (32.5%) cases. Adverse events were observed in 688 patients (26%) during 941 procedures. Minor and major events were seen in 21.4% and 7.1% of the procedures respectively. Most frequent major complications were anesthesia related (6%), most frequent minor complications were vascular complications (45.2%). Complications were more frequent in younger patients ( $p=0.0001$ ), during interventional procedures ( $p=0.0001$ ). Thirteen patients died after a cardiac catheterization; they were younger and had longer procedures compared to those who survived ( $p=0.0001$ ). Vascular complications were frequent among younger patients, with prolonged procedure time and vessel access ( $p<0.0001$ ). Cyanotic patients had more complications ( $p<0.05$ ; OR for major and minor complications: 3.5 and 2 respectively). Minor complications were 2.7 times more likely in ventricular outflow obstructions ( $p<0.05$ ).

The complication rates of cardiac catheterization in children are low, but not negligible. Defining risk factors will help anticipate adverse events, which will guide in preparation for rescue procedures and improvement of patient safety systems in catheterization laboratories.

**Key words:** pediatric, catheterization, complications.

The role of pediatric cardiac catheterization has changed dramatically over the last two decades and it has become a common therapeutic interventional tool in the current era. Both interventional and diagnostic procedures are associated with some risk because of the invasive nature of the procedures.<sup>1</sup> Catheterization

procedures for congenital heart disease include a broad range of procedures with a large spectrum of potential adverse outcomes.<sup>2</sup> The aim of this study was to determine the incidence of various complications during pediatric congenital cardiac catheterizations and to designate the relative risk factors for such complications.

## Material and Methods

All patients undergoing diagnostic or interventional pediatric cardiac catheterizations between January 2005 and December 2010 at our institution were included. An adverse event was defined as any event for which injury occurred or could have occurred, potentially or definitely as a cause of catheterization procedure. Informed consent was obtained from the parents of all individual participants included in the study.

This study was evaluated by “the Medical and

Health Sciences Research Committee” and “Medical Ethics Committee” of our institution. It was approved and assigned as a research project with a registration number of KA11/51. All procedures performed were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Data were collected prospectively. In every case, the pediatric cardiologist performing the procedure was required to fill out a computerized catheterization report about the details of the procedure focusing on the

**Table I.** Potential Risk Factors for Adverse Outcome in Pediatric Cardiac Catheterization Procedures.

Demographic data	Age <ul style="list-style-type: none"> <li>• Newborn (1-30days)</li> <li>• Infant (1 month-1 year)</li> <li>• Child (1-12 years)</li> <li>• Adolescent (12-21 years)</li> </ul>
Cardiac diagnosis	Body weight Left-to right shunt <ul style="list-style-type: none"> <li>• Preoperative</li> <li>• Palliation/residual</li> <li>• Total correction</li> </ul> Cyanotic <ul style="list-style-type: none"> <li>• Preoperative</li> <li>• Palliation/residual</li> <li>• Fontan operation</li> <li>• Total correction</li> </ul> Outflow obstructions* Cardiomyopathies Cardiac transplantation
Procedural details	Time taken to vascular access Procedure time Vascular access <ul style="list-style-type: none"> <li>• Venous</li> <li>• Arterial</li> </ul> Procedure type <ul style="list-style-type: none"> <li>• Diagnostic</li> <li>• Interventional</li> </ul> Fluoroscopy time Amount of contrast used Hemoglobin <ul style="list-style-type: none"> <li>• Preprocedural</li> <li>• Postprocedural</li> </ul>
Anesthesia/sedation details	General anesthesia /Conscious sedation Endotracheal intubation Inotropic drug infusion

\*Obstructive lesions are; aortic stenosis, pulmonary stenosis, coarctation of aorta.

complications. The patients were observed throughout the period of admission; those occurring after the procedure were added at the time of identification. All catheterization records and computerized patient records were scanned thoroughly for potential risk factors (given in Table I) retrospectively. If more than one complication was observed, both events were considered separately.

The patients were divided into groups based on their diagnoses (Table I). The procedures were categorized as diagnostic or interventional. Severity of complications was designated as minor or major complications. In addition, adverse events were categorized into: cardiac events (ie, cardiac arrest, myocardial ischemia, cyanotic spell, decompensation requiring inotropic support), arrhythmias, vascular complications (ie, bleeding, occlusion), catheter

**Table II.** Classification of Complications.

Major Complications			Minor Complications
Death			
Cardiac	Myocardial ischemia		
	Inotropic support		
	Hypoxic spell		
	Cardiac arrest		
	Transfer to ICU		
	Emergent surgery		
Arrhythmia	Requiring DC cardioversion, defibrillation, PM, antiarrhythmic drugs		Transient and not requiring medication or intervention
Vascular complications	Prolonged ischemia/occlusion		Transient ischemia/occlusion
	Pseudoaneurism		Spontaneous recovery or after heparin streptokinase or TPA
	a-v fistula		
	Any complication requiring surgery		
	Bleeding requiring transfusion		Bleeding not requiring transfusion
	Retroperitoneal intrapsoas bleeding		
Catheter intervention related	Vessel injury/ perforation		Inability to advance sheaths, catheters
	Cardiac injury/ perforation		
	Device embolization, dislodgement, deformation, breaking		Device, sheath, catheter deformation
Anesthesia and airway management related	Apnea + bradycardia*		Transient desaturation**
	Bronchospasm*		Transient apnea**
	Desaturation*		
	Atelectasis*		
Infections	Sepsis		Local infections
	Pneumonia		
	Necrotizing Enterocolitis		
Allergic / other reactions	Anaphylaxis		Urticaria
	Major pyrogenic reaction (>39°C)		Minor pyrogenic reaction (37.8-38.9°C)
	Prolonged hypothermia		Transient hypothermia
	Convulsions		Methemoglobinemia

\*leading to intubation or positive airway respiration (bag+mask); \*\*recovery with nasal oxygen  
a-v: arteriovenous, DC: direct current, ICU: intensive care unit, PM: pacemaker, TPA: tissue plasminogen activator

**Table III.** Adverse Events Seen during Interventional Procedures.

Interventional Procedure		N (%)	All Complications	Major Complications	Minor Complications
Balloon	Coarctation angioplasty	175 (20.2)	122 (36.6)	29 (8.7)	93 (27.8)
	Pulmonary angioplasty*	129 (14.9)	22 (6.6)	5 (1.5)	17 (5.1)
	Aortic valvuloplasty	90 (10.5)	39 (11.7)	7 (2.1)	32 (9.6)
	Pulmonary valvuloplasty	84 (9.7)	28 (8.4)	6 (1.8)	22 (6.6)
	Atrial septostomy	103 (12)	55 (16.5)	24 (7.2)	31 (9.3)
	Other procedures	14 (1.6)	0	0	0
Device occlusion	PDA occlusion	79 (9.1)	34 (10)	6 (1.8)	28 (8.3)
	ASD occlusion	46 (5.3)	7 (2.1)	6 (1.8)	1 (0.3)
	VSD occlusion	2 (0.2)	3 (0.9)	1 (0.3)	2 (0.6)
	Other coil occlusions	11 (1.2)	5 (1.5)	2 (0.6)	3 (0.9)
Stent implantation/redilatation		15 (1.7)	8 (2.4)	5 (1.5)	3 (0.9)
PM/ICD	Temporary PM	10 (1.1)	5 (1.5)	5 (1.5)	0
	Permanent Endo PM	4 (0.4)	0	0	0
	ICD	1 (0.1)	0	0	0
Endomyocardial biopsy		102 (11.8)	6 (1.8)	3 (0.9)	3 (0.9)

\*cutting balloon was used in 3 patients

or intervention related events (including those resulting from the material or its manipulation), related to anesthesia and airway management, infections, allergic reactions and miscellaneous. All cardiac events were considered major events. Major adverse events related to anesthesia were airway and ventilation problems requiring intubation; hypotension and/or bradycardia observed shortly after introduction of the anesthetic drugs and necessitating bag ventilation, intubation or any medication to stabilize the patient. The classification of complications is detailed in Table II.

#### Catheterization Technique

All procedures were done via femoral veins or arteries by a percutaneous technique; except in patients with bilateral cavopulmonary anastomosis; internal jugular veins were used to access the pulmonary arteries. General anesthesia was used only in 54 patients (2%) during closing of VSD, ASD or stenting the PDA. Others (2574 patients; 98%) received conscious sedation. Heparin sulphate (100 IU/kg) was administered intravenously after introducing the arterial sheaths. Additional heparin (50 IU/kg) was given only if the procedure continued for more than one hour. Cineangiography was performed with a low osmolar, non-ionic contrast agent at a dose

of 1-2 ml/kg.

#### Statistical Analysis

Data were expressed as percentages, medians with ranges, or means with standard deviations. Chi-square analysis or Mann-Whitney U test was used to examine the differences between groups. Linear regression test was applied to compare risk factors and adverse reactions. Statistical analyses were performed with the SPSS 17.0 program. A p value of less than 0.05 was considered statistically significant.

#### Results

Between January 2005 and December 2010, 2662 pediatric cardiac catheterization procedures were performed in 2628 patients. The mean age of patients undergoing cardiac catheterization was  $53.2 \pm 64.3$  months (median: 25 months; range 1 day -21 years). Of all the procedures, 1797 were diagnostic (67.5%) and 865 were interventional procedures (32.5%) Among the interventional procedures, 68.9% were carried out using a balloon catheter; 15.8% were device occlusion procedures; 11.9% were endomyocardial biopsies; 1.7% were stent implantations, and 1.7% were pacemaker implantations (Table III).

Vascular access was through a vein in 1334

**Table IV.** Distribution of Adverse Events Observed during Pediatric Catheterization Procedures.

Event	Major n (%)	Minor n (%)	Overall n (%)
Death	13 (1.4)	NA	13 (1.4)
Cardiac	35 (3.7)	NA	35 (3.7)
Arrhythmia	29 (3.0)	21 (2.3)	50 (5.3)
Vascular complications	40 (4.2)	425 (45.2)	465 (49.4)
Catheter/intervention related	26 (2.7)	1 (0.1)	27 (2.8)
Anesthesia/airway management related	56 (6.0)	27 (2.9)	83 (8.9)
Infections	14 (1.5)	0	14 (1.5)
Allergic reactions	11 (1.3)	200 (21.2)	211 (22.5)
Miscellaneous	37 (3.9)	6 (0.6)	43 (4.5)
Total	261 (27.7)	680 (72.3)	941 (100)

(50.8%), through an artery in 412 (15.7%), and through both vessels in 882 patients (33.5%). In 9.8% of them (n=257) vascular access was obtained percutaneously for monitoring and was not used for catheterization. Time to introduce a sheath to the vessel was  $6.7 \pm 8.9$  minutes (range: 1-105 minutes, median 4 minutes). Vascular access was obtained in  $\leq 3$  minutes in about half of the cases (n=1317, 49.5%). On average, total duration of the procedure was  $45.4 \pm 23.1$  minutes (range 10-200 minutes; median: 40 minutes), and fluoroscopy time was  $10.3 \pm 7.9$  minutes (range 0.5-150 minutes; median 8.4 minutes). The dose of the contrast material used during the angiography was  $2.0 \pm 1.2$  ml/kg (range 0.76-4 ml/kg; median 2.8 ml/kg).

A total of 941 adverse events were observed in 688 patients (26%). The frequency of minor events was 21.4% (n=680); major events were only 7.1% (n=261). The most frequent major complications were anesthesia and airway related complications (n=56, 6%), whereas most frequent minor complications were vascular complications (n=425, 45.2%). The distribution of adverse events observed during pediatric cardiac catheterization procedures is given in Table IV.

The patients with major complications were younger (mean age:  $20.7 \pm 39$  months), compared to those without complications (mean age:  $55.7 \pm 65.2$  months) ( $p=0.0001$ ). Newborns comprised 32.3% of patients (n=341) with complications while 7.6% (n=71) were newborns in patients without complications. Univariate analysis showed that major complications were

2.1 times more frequent during interventional procedures (10.6% major complication during interventions versus 5.5% during others;  $p=0.0001$ , CI:1.5-2.7, OR: 2.1). The mean procedure ( $60.7 \pm 33.9$  minutes) and fluoroscopy times ( $13.1 \pm 9.5$  minutes) were longer in patients with major complications compared to those (mean procedure time  $44.2 \pm 21.5$  minutes; mean fluoroscopy time  $10.1 \pm 7.8$  minutes) in patients without complications ( $p=0.0001$ ). Although the mean vascular access time ( $9.2 \pm 14.1$  minutes) was also longer in procedures with major complications (compared to mean access time of  $6.5 \pm 8.3$  minutes in patients without complications), this was not statistically significant ( $p=0.051$ ). All types of major complications were more frequently observed during interventional procedures except for arrhythmias, infections and allergic reactions ( $p>0.05$  for the latter).

Thirteen patients died within 48 hours after cardiac catheterization. Those who died were younger (age of deceased patients:  $11 \pm 23$  months, median: 0.8 months; age of patients alive:  $60.6 \pm 75.9$  months, median 28 months;  $p=0.0001$ ), and had longer procedures (deceased patients:  $77.5 \pm 31.8$  minutes, median: 78 minutes; patients alive:  $45.2 \pm 22.9$  minutes, median 40 minutes;  $p=0.0001$ ). Seven of them (53.8%) were critically ill newborns (age: 9 hours – 40 days). They were mechanically ventilated and received inotropic agents before cardiac catheterization. Two patients had balloon atrial septostomy procedures, one patient had balloon coarctation angioplasty and the remaining four had diagnostic procedures. In the older

**Table V.** Cardiac Catheterizations Resulted with Death.

Age	Gender	Diagnosis	Procedure	Cause of death
4 years	M	BT shunt, dextrocardia, superior-inferior ventricles, Patresia, VSD, ASD	Diagnostic	Desaturation and bradycardia, resuscitated during catheterization (shunt stenosis)
38 days	F	Down syndrome, cAVSD, PDA, CoA	Diagnostic	Critically ill before catheterization, death in ICU due to decompensated CHF
40 days	F	TAPVC (mixed type)	Diagnostic	Critically ill before catheterization, death in ICU due to CHF
6 years	M	Restrictive CMP	Endomyocardial biopsy	Cardiac perforation
2 days	F	TGA, PDA, PFO	Balloon atrial septostomy	Critically ill before catheterization, resuscitated during catheterization, pneumothorax, death in ICU
10 months	F	VSD, Patresia, stented PDA (stent stenosis)	Redilation of PDA stent	Stent occlusion
5 months	M	Williams syndrome, AS (supravalvular)	Diagnostic	Myocardial ischemia due to impaired coronary perfusion
25 days	F	VSD, Patresia, PDA	Stenting of PDA	Stent migration and occlusion
10 days	M	DILV, VSD, ASD, Pstenosis, ASD	Balloon pulmonary valvuloplasty	Bradycardia and cardiac arrest during balloon dilatation
8 hours	M	TGA	Balloon atrial septostomy	Critically ill before catheterization, resuscitated during catheterization, death in ICU
9 hours	M	HLHS	Diagnostic	Critically ill before catheterization due to CHF, death in ICU
5 days	F	TAPVC (infradiaphragmatic)	Diagnostic	Critically ill before catheterization due to pulmonary venous hypertension (obstructive pulmonary venous return), death in ICU
3 days	F	HLHS, PDA, CoA	Balloon coarctation angioplasty	Critically ill before catheterization due to CHF, death in ICU

AS: aortic stenosis, ASD: atrial septal defect, BT shunt: Blalock-Taussig,shunt, cAVSD: complete atrioventricular septal defect, CHF: congestive heart failure, CMP: cardiomyopathy, CoA: coarctation of aorta, DILV: double inlet left ventricle, F: female, HLHS: hypoplastic left heart syndrome, ICU: intensive care unit, M: male, Patresia: pulmonary atresia, PFO: patent foramen ovale, PDA: patent ductus arteriosus, TAPVC: total anomalous pulmonary venous return, TGA: transposition of great arteries, VSD: ventricular septal defect.

patients, three stent related complications (occlusion/stenosis), two myocardial injuries during catheterization (perforation/ischemia) and one during balloon dilatation procedure led to death after catheterization. Details of the deceased patients are given in Table V.

Patients with minor complications were also younger (mean age:  $20.5 \pm 48.1$  months), than those without complications (mean age:  $62.3 \pm 65.3$  months) ( $p=0.0001$ ). Risk of having a complicated procedure was 1.5 times more

frequent in interventional procedures compared to diagnostic procedures ( $p=0.0001$ , CI: 1.2-1.8, OR: 1.5).

All vascular (both minor and major) complications were more frequent among younger patients, especially when the time to access vessel and the duration of the procedure were prolonged ( $p<0.0001$ ).

When the patients were compared in terms of congenital heart defect and the frequency of complications, cyanotic patients had significantly

more frequent major and minor complications ( $p < 0.05$ ; Odds ratio for major and minor complications: 3.5 and 2 respectively). Patients having obstructive lesions of the ventricular outflow tracts were 2.7 times more likely to have minor complications ( $p < 0.05$ ; Odds ratio 2.7).

## Discussion

This study revealed that adverse events are more frequently seen in younger patients undergoing prolonged interventional procedures. The risk is amplified if the patient is cyanotic and the vascular access is difficult. Comparison of outcomes with other studies may be difficult due to highly variable case mix, differences in definition of the adverse events, collection of data, and length of the period of observation. Nevertheless, similar to others we observed higher adverse event rates among neonates and infants and in interventional cases.<sup>3-6</sup>

Fortunately, death is not common. Although those that are deceased are younger and have undergone prolonged procedures, death after cardiac catheterization seems to be more associated with the patient's general status than the procedure itself. In pediatric patients, one process is dependent on or linked with the outcomes of prior or succeeding processes. Those who are moribund prior to catheterization will have little chance of survival.<sup>3</sup> More than half of our patients who died after cardiac catheterization were critically ill newborns. Even diagnostic procedures may be troubling in these patients. In older patients intervention related mortality is more probable. Bergensen L, et al.<sup>4</sup> reported mortality rate of 0.29% among 3855 cases from six institutions; seven out of the eleven deceased patients were neonates. Cyanotic patients had increased risk of mortality.

Thirty-day mortality has been used as a marker for quality of health care provided; however it has also been advocated that 30 day mortality does not adequately characterize the quality of outcome in terms of pediatric interventional cardiology.<sup>3</sup> We did not use 30 day mortality; instead, we considered death as a complication of catheterization if it were seen within 48 hours of the procedure. Even in some of these cases, it was not certain whether death was attributable to the catheterization procedure,

to other procedures during the care, or to unrelated patient comorbidities. In the study by Backes CH et al.<sup>3</sup>, deaths attributed to catheterization were more likely to be in urgent cases. Different studies similarly revealed that deaths were more frequent among the prolonged procedures and interventions, especially during atrial septostomy or balloon interventions.<sup>3,7,8</sup> Comparably in our study, the adverse event frequency was higher in balloon procedures (overall complication rate 44.7%, major complications 11.9%). Then again, they were the most frequent interventions during the study period. While stent implantations were less frequent procedures, overall events (53.3%) and major adverse event rates (33%) were significantly high among these patients. As Moore JW et al.<sup>8</sup>, we found out that procedures directed to ASD and PDA were among the safest interventions for congenital heart disease.

In a multicenter prospective study, Bergensen L et al.<sup>2</sup> have assigned procedures into risk categories and correlated high risk category groups (like stent implantations to pulmonary arteries and veins, atrial septostomies, balloon procedures in newborn babies etc.) with higher adverse event rates. The type of procedure is definitely consequential in terms of adverse outcomes, but intrinsic patient characteristics, operator skill and experience should also be taken into account. Especially the variables related to the operator are not easily scalable, which creates a major pitfall.<sup>9</sup>

Over the last few decades the congenital catheterization laboratory has evolved to have therapeutic function. Therefore, complication rates of recent studies are slightly higher than those conducted in the 1990's.<sup>4,10</sup> In single center retrospective studies, major adverse events were previously reported as 0.9-6%.<sup>7, 11-13</sup> However, in a multicenter, prospective study by Bergensen L et al.<sup>3</sup>, the incidence of major adverse events in interventional cases differed substantially (range: 7-25%) due to diversity of the case mix among centers. In our study, overall adverse event rate was 26% and major adverse event rate was 7.1%

Most frequent major complications in our study were anesthesia and airway related complications (6%). This is remarkable because general anesthesia was used only in 2% of all

cases. This may imply that critically ill patients who are already mechanically ventilated have less airway problems. Therefore, intubating a hemodynamically unstable patient and using general anesthesia instead of conscious sedation may prevent airway related complications in these patients.

Data collection and case entry is the key in prospective studies. The caveat is that, event capture rate tends to be more reliable when the complication is a high severity event, while low severity events may have less reliable reporting.<sup>3</sup> Dedicated time and commitment is needed to collect complete and accurate data. Larger databases can only be possible if the data collection is faster and the burden of data entry is reduced with improved computerized programming.<sup>3</sup> Although data collection in our study was prospective and meticulous, the retrospective evaluation of the medical details and self-reporting of the adverse events may have led to bias.

The outcomes of cardiac catheterization procedures in pediatric patients need to be evaluated continuously since there is constant evolution and improvement in these procedures. Defining risk factors will help anticipate adverse events, which will guide in preparation for rescue procedures, organization of catheterization laboratories and improvement of patient safety systems. Patients and families will be provided with more specific counseling and informed consent. Modification of practice to decrease preventable events will definitely contribute to quality improvement acts.<sup>5</sup> Simple but important precautions like alternative vascular access methods especially in small babies and difficult cases, better anesthetic management by experienced pediatric anesthesiologists, judicious catheter manipulation, stabilizing the patient hemodynamics and correcting any metabolic abnormality beforehand will reduce complications. Using low profile tools and avoiding arterial access whenever possible will avoid vascular injury. Any effort to reduce the procedure time, like studying the case and planning thoroughly before the procedure, will abate most of the adverse outcomes. Defining operator error and establishing guidelines regarding technique and type of material to be used during each intervention will help prevent adverse events.

Our study should be interpreted in the context of several potential limitations. Data are self-reported and self-reporting may lead to possible reporting bias. Late complications occurring after discharge could not be collected. Some low severity events like self-limiting arrhythmias, transient hypotension, metabolic acidosis, stridor, emesis, hypoglycemia might have been underestimated, although a detailed form was filled-out right after the procedure. Assessing outcomes for low frequency procedures may be statistically problematic.

Overall, the complication rates of cardiac catheterization in children are low, but not negligible. The most frequent adverse events in general are vascular complications, whereas events related to anesthesia and airway management seem to be among the most frequent major complications. Cardiac interventions, especially balloon dilatation procedures, catheterizations in cyanotic patients or newborns carry the highest risk. Awareness of complications, improved intensive care, improvement in technique and equipment will decrease or avoid the incidence of complications.

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