

Pediatric Cardiac Catheterization Outcome - A Single Center Experience

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Abstract

Background: Pediatric cardiac catheterization now has a major role in management of structural and congenital heart disease (SACHD) with progressive increase in interventional procedures over time.

Objectives: This study aimed to describe the frequency, level of severity, and cause of complications in a tertiary center and point out patient and procedural predictors related to these complications.

Materials and Methods: This was a retrospective observational study which included a total of 1129 cases admitted to the cardiology department congenital and structural heart disease unit Ain Shams university hospitals over a 1-year period.

Results: The overall complication, major complication, and mortality rate was 10.5%, 2.2%, and 0.5%, respectively. The predictors that increased the risk of overall complications included weight (p-value<0.0001), age at the time of the procedure (p-value<0.0001), age group (<0.0001), category of CHD (p-value<0.0001), invasive haemodynamic as mean pulmonary artery pressure(PAP) (p-value=0.0016), oxygen systemic saturation (p=0.0030) and dose of heparin given during the procedure (p<0.0001), number of catheterizations before the procedure (p=0.0345), anesthesia type (p<0.0001), procedure type risk category (p=0.0001), access type (p<0.0001) and number of sheaths used during the procedure (p=0.0313).

Conclusion: The complications risk in congenital and structural heart disease catheterization was independently increased if the patient was <2 year of age, use of local anesthesia, arterial access, more than one sheath used and procedure risk category 4.

Keywords: Heart disease; Computed tomography; Anesthesia; Echocardiography

Abbreviations: aPTT: Activated Partial Thromboplastin Time; ASD: Atrial Septal Defect; BAS: Balloon Atrial Septostomy; BAV: Balloon Aortic Valvuloplasty; BPV: Balloon Pulmonary Valvuloplasty; BMV: Balloon Mitral Valvuloplasty; CT: Computed Tomography; CMRI: Cardiac Magnetic Resonance Imaging; CHB: Complete Heart Block; CAVC-PH: Common Atrioventricular Canal-Pulmonary Hypertension; CPR: Cardiopulmonary Resuscitation; D-TGA: Complete Transposition of Great Arteries; DILV-PAB: Double Inlet Left Ventricle- Pulmonary Artery Band; GA: General Anesthesia; IQR: Interquartile Range; IV: Intravenous; PAP: Pulmonary Artery Pressure; PDA: Patent Ductus Arteriosus; PT: Prothrombin Time; P-Cath CCU: Post Catheterization Cardiology Care Unit; SHD: Structural Heart Disease; SACHD: Structural And Congenital Heart Disease; TEE: Transesophageal Echocardiography; VF: Ventricular Fibrillation; VSD: Ventricular Septal Defect

Introduction

Before the current era of modern echocardiography, cardiac catheterization was used in the diagnosis of structural and congenital heart diseases (SACHD) [1]. Even with the development of recent diagnostic modalities such as computed tomography (CT) and cardiac magnetic resonance imaging (CMRI), cardiac catheterization is still

maintaining its diagnostic role especially in haemodynamic studies [1-3]. Cardiac catheterization laboratories recently have an increasing role in interventional procedures with progressive increase in the number of procedures performed yearly especially with the advances in the technology and the prolonged survival of patients with SACHD.

Both diagnostic and therapeutic cardiac catheterizations due to its invasive nature are not without risks. Cardiac catheterization complications include vascular complications in the form of thrombosis and bleeding, arrhythmias, technique related complications as embolization, and anesthesia related complications as hypoxemia which remains a major concern [4-6]. Our hospital represents a tertiary high volume congenital and structural heart disease center with a workload of 1000-1200 catheterizations per year. We sought to describe the frequency, level of severity, and cause of complications in our patients and point out patient and procedural predictors related to these complications.

Materials and Methods

The study was approved by our institutional review board and informed consent was obtained from all patients or their related guardians prior to performing cardiac catheterization.

Study population

A retrospective analysis was performed using the data collected from patients who underwent cardiac catheterization at the Congenital and Structural Heart Disease Unit, Cardiology department, Ain Shams university hospital over one-year period to evaluate and categorize the complication rate in these procedures. All procedures were performed by an experienced paediatric cardiac interventionalist with a minimum of 3 years' experience in performing diagnostic and interventional procedures and under supervision of interventional cardiologists with minimum of 5 years' experience. All patients were followed up by the attending physician in charge of our post-catheterization cardiology care unit (P-Cath CCU).

Data collection

All records electronic and paper chart were reviewed and meticulously revised by 3 experienced interventional congenital cardiologist to obtain full proper information, including patients age at procedure, age group, gender, weight, underlying structural heart disease (SHD) diagnoses, usage of antithrombotic agent, prothrombin time (PT)/activated partial thromboplastin time (aPTT) before procedure, total number of cardiac catheterizations underwent by each patient before the procedure, anaesthesia method, access type, status of the procedure whether elective or emergency, usage of transoesophageal echocardiography (TEE), type of probe used and the intervention performed during the procedure, procedural risk category and complications within 24 hours of the procedure.

The catheterization procedures were divided into interventional, diagnostic, TEE under general anaesthesia (GA), combined. Diagnostic studies were performed to evaluate the anatomic structures and the hemodynamic status. Interventional studies included all procedures where an attempted therapy was performed, including balloon pulmonary valvuloplasty (BPV), balloon aortic valvuloplasty (BAV), balloon dilatation of coarctation or stenting, peripheral pulmonary tree balloon dilatation or stenting, balloon atrial septostomy (BAS), closure of secundum atrial septal defect (ASD), patent ductus arteriosus (PDA) or ventricular septal defects (VSD), balloon mitral valvuloplasty (BMV) and other miscellaneous procedures. Catheterization procedures were done using the standardized known diagnostic and interventional techniques according to the guidelines [7]. General anaesthesia was used for most of the procedures, Heparin sulphate was administered intravenously in all diagnostic (50 IU/Kg) and interventional procedures (75-100 IU/Kg) according to type of procedure. Angiography was performed using a non-ionic contrast agent with average total dose of 4 ml/kg.

Complications were classified into two main categories major and minor. A life-threatening event requiring immediate treatment was considered a major complication including death, cardiac arrest, life-threatening arrhythmias (e.g., ventricular tachycardia, complete atrioventricular block), hypotension requiring treatment, neurological complications, an event requiring surgery (e.g., device embolization, perforation of the cardiac structures), and vascular injuries. Events that had no long-term deleterious effect on patients and resolved without or with minor medication were classified as minor complication (e.g., transient arrhythmias, bleeding at access site, lost pulsation regained with no intervention or minor medication [8]).

Statistical Analysis

All data were collected, tabulated, and statistically analyzed using the MedCalc for windows statistics software program version 11.6.1 (MedCalc Software Broekstraat 52 B-9030 Mariakerke Belgium). Patient and procedural characteristics were tabulated and reported as frequencies or medians. Numerical variables were expressed as mean \pm standard deviation, or median and interquartile range using Mann whitney test and categorical variables were expressed as a percentage. Statistical significance was assessed by paired t-test for numerical values and Chi-square test for categorical values. Values were considered significantly different when p was less than 0.05. Logistic regression was used to establish a multivariate model for the occurrence of complications. A p value <0.05 was required for retention in the final model.

Results

Baseline characteristics

A total of 1129 patients with SACHD were admitted to the cardiac catheterization unit in our tertiary care hospital over a 1-year period. The median age was 4 yrs and interquartile range (IQR) 8.8 yrs, and the median body weight was 18 and IQR 21 kg, 51% (576 cases) of the study population was females.

Interventional cases represented 46% of all cases included in the study (n=526), diagnostic cases were 481 (43%), and 122 patients (11%) underwent TEE under either general anaesthesia or conscious sedation (Figure 1). The pre-Fontan study and hemodynamic study for pulmonary hypertensive cases were the most common indications for diagnostic procedures. Of the interventional procedures performed, BPV cases (19.9%) were the most common interventional procedures followed by PDA coil closure (7%). According to the procedural status, most of the cases (95.45%) were elective, while 52 cases (4.5%) required emergent intervention with the most common cause of emergency procedure being critical pulmonary stenosis followed by BAS's mainly for complete transposition of great arteries (D-TGA) cases. Only 173 cases (15.4%) had previous catheterization once or twice before the procedure.

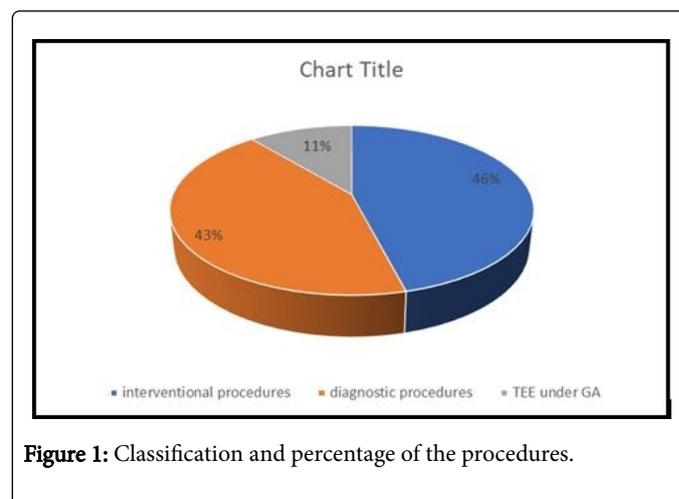


Figure 1: Classification and percentage of the procedures.

According to our institutional policy, general anaesthesia and intubation are the main stay for most of the procedures, only 90 cases (8%) were done under IV sedation mainly being TEE and 10 cases

(0.9%) were performed under local analgesia which were the balloon atrial septostomy cases. About 591 cases (52.3%) had both arterial and venous access most of them were diagnostic cases while 342 (30.3%) had venous access only and 74 cases (6.6%) had arterial access only. Intra venous heparin sulphate was administered in 74.5% of the procedures.

The study population were categorized according to their procedural risk category into category 1 (52.3%) most of them were diagnostic cases and category 2 (39.1%) including the ASD device, PDA device or coil cases and BPV cases while 6.5% of the cases were category 3 including BAV, aortic or pulmonary stenting cases and the critical BPV cases, and only 2.1% were category 4 including the BMV and VSD device closure cases [9].

TEE was used in our study in 223 cases (about 19.7%), using the paediatric probe in 107 (47.9%) and the adult probe in 116 cases (52.1%). Baseline demographic and clinical data for the patient population and procedure characteristics are listed in Table 1.

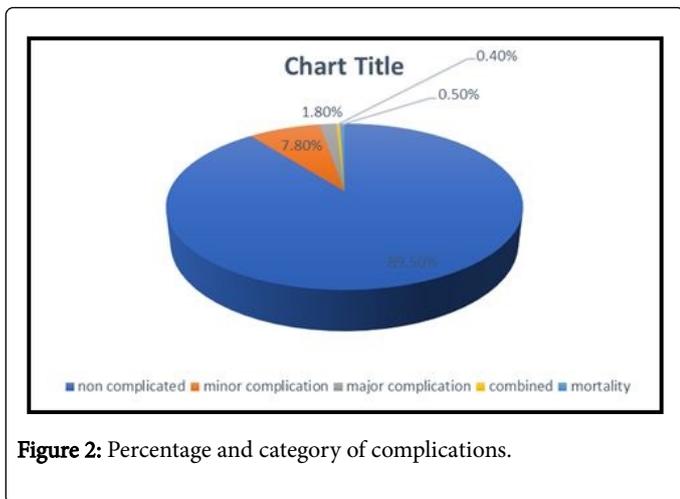
| Population Characteristics | |
|---|--------------|
| Gender | |
| Male | 553 (49%) |
| Female | 576 (51%) |
| Body weight(kg) median and IQ range | 16 (IQR 21) |
| Age(years) median and IQ range | 4 (IQR 8.8) |
| Age group | |
| <1 month | 29 (2.5%) |
| 1-6 months | 106 (9.3%) |
| 6-24 months | 228 (20.1%) |
| 2-10 yrs | 446 (39.5%) |
| 10-18 yrs | 154 (13.6%) |
| >18 yrs | 166 (14.7%) |
| CHD severity | |
| Mild complexity | 249 (22.1%) |
| Moderate complexity | 629 (55.7%) |
| Sever complexity | 251 (22.2%) |
| Number of catheterizations pre procedure | |
| None | 956 (84.7%) |
| 1 | 170 (15.1%) |
| 2 | 3 (0.3%) |
| Status of the procedure | |
| Elective | 1077 (95.3%) |
| emergency | 52 (4.7%) |
| Reason for catheterization | |
| Diagnostic | 474 (42%) |

| | |
|---|--------------|
| Interventional | 526 (46.5%) |
| Tee under GA | 122 (10.8%) |
| Tee and diagnostic | 7 (0.6%) |
| Procedure type risk category | |
| 1 | 591 (52.3%) |
| 2 | 441 (39.1%) |
| 3 | 73 (6.5%) |
| 4 | 24 (2.1%) |
| Anaesthesia | |
| GA | 1029 (91.1%) |
| IV sedation | 90 (8%) |
| Local anaesthesia | 10 (0.9%) |
| Access type | |
| None | 122 (10.8%) |
| Arterial | 74 (6.6%) |
| Venous | 342 (30.3%) |
| Combined | 591 (52.3%) |
| Number of sheaths used | |
| None | 122 (10.8) |
| 1 | 405 (35.8%) |
| 2 | 589 (52.1) |
| 3 | 13 (1.3%) |
| Dose of heparin given during the procedure (Mean+ SD) | |
| | 45.3+ _30.2 |
| TEE usage | |
| Yes | 223 (19.7%) |
| No | 906 (80.3%) |
| Type of probe | |
| Paediatric | 107 (47.9%) |
| Adult | 116 (52.1%) |
| Note: CHD=Congenital heart disease, GA= General anaesthesia, IV=Intravenous, IQ= interquartile TEE= Transoesophageal echocardiography | |

Table 1: Baseline demographic and clinical data for the patient population and procedure characteristics.

Complications

Among the 1129 cases, complications occurred in 119 procedures (10.5%). There were 20 major (1.8%) and 88 minor complication (7.8%), 5 cases had both minor and major complications (0.4%) and there were 6 mortality cases (0.5%) (Figure 2). The distribution of the major and minor complications according to the procedure type is enumerated in Table 2.



The most common overall complication was vascular thrombosis (6.9%) followed by complications related to intervention (0.7%), arrhythmias (0.5%), vascular bleeding (0.4%), catheterization related complications (0.4%), cardiac arrest and resuscitation (0.4%), respiratory complications (0.09%), then miscellaneous types of complications. The most common complication in the diagnostic group was vascular thrombosis (6.2% of all diagnostic cases) followed by arrhythmia (0.6%) and cardiac arrest and resuscitation (0.6%) whereas the most common complication in the interventional group was also vascular thrombosis (8.9%) followed by complication related to intervention (1.7%) (Table 3).

| Procedure type | Type of intervention | Total number of cases | Major complication | Minor complication | Combined | Mortality | Total number of complicated cases |
|------------------------------|----------------------|-----------------------|--------------------|--------------------|----------|-----------|-----------------------------------|
| Diagnostic Interventional | ASD | 604 | 10 | 35 | 4 | 1 | 50 |
| | BPV | 225 | 3 | 15 | 0 | 2 | 20 |
| | BAV | 20 | 1 | 4 | 0 | 1 | 6 |
| | BALLON COA | 9 | 0 | 3 | 0 | 0 | 3 |
| | BAS | 10 | 0 | 2 | 0 | 1 | 3 |
| | ASD DEVICE | 70 | 1 | 1 | 0 | 1 | 3 |
| | VSD DEVICE | 13 | 1 | 1 | 1 | 0 | 3 |
| | PDA DEVICE | 63 | 1 | 13 | 0 | 0 | 14 |
| | PDA COIL | 79 | 0 | 11 | 0 | 0 | 11 |
| | COA STENTING | 12 | 1 | 2 | 0 | 0 | 3 |
| | BMV | 4 | 1 | 1 | 0 | 0 | 2 |
| | MAPCA CLOSURE +BPV | 1 | 1 | 0 | 0 | 0 | 1 |

Note: ASD: Atrial Septal Defect, BPV: Balloon Pulmonary Valvuloplasty, BAV: Balloon Aortic Valvuloplasty, BAS: Balloon Atrial Septostomy, BMV: Balloon Mitral Valvuloplasty, COA: Coarctation, MPACA: Major Aortopulmonary Collateral, VSD: Ventricular Septal Defects, PDA: Patent Ductus Arteriosus.

Table 2: Classification of complications according to procedure type.

| Type of complication | Number (N) | Percentage (%) |
|---|------------|----------------|
| Non complicated | 1010 | 89.50% |
| Vascular thrombosis | 78 | 6.90% |
| Vascular bleeding | 4 | 0.40% |
| Arrhythmia | 6 | 0.50% |
| Complications related to catheterization manipulation | 4 | 0.40% |
| Complications related to intervention | 8 | 0.70% |

| | | |
|---|---|-------|
| Cardiac arrest and CPR | 4 | 0.40% |
| Respiratory | 1 | 0.09% |
| Mortality | 6 | 0.50% |
| Miscellaneous | 8 | 0.70% |
| Note: CPR=Cardiopulmonary resuscitation | | |

Table 3: Type of complications and its percentage.

Minor and major complications

The most common minor complication was arterial thrombosis (78 cases) representing 6.9%, in the form of lost pulsations (77 cases 6.8%) that recurred either by warming, antiplatelet (heparin infusion) or anti-thrombotic (streptokinase infusion) with both puncture sites being monitored for any bleeding and patients CBC and bleeding profiles being followed up till the pulsations were regained. One case experienced both lost pulsations and a pseudo-aneurysm formation at the puncture site which was managed conservatively by local compression and the lost pulsations were regained after streptokinase infusion was administered. Surgical thrombectomy was not needed in any case.

The next common minor complication was transient arrhythmia that recurred spontaneously or with medications mainly complete heart block (CHB) (0.5%), all the heart block cases occurred in diagnostic cases (two cases with double inlet left ventricle with pulmonary artery band (DILV—PAB) and one post Glenn shunt case and one common AV canal (CAVC) pulmonary hypertension (PH) case, all the CHB cases were managed conservatively or with administration of atropine and the rhythm was recurred to sinus immediately during the procedure except for one case that was kept in the P-Cath CCU and monitored for 24 hrs and recurred to sinus rhythm on the next day.

The most common major complication was cardiac arrest and resuscitation which occurred in 4 cases (0.4%), catheterization related complications in the form of pneumothorax and effusion that necessitated intercostal tube insertion in 4 cases (0.4%) and intervention related complications in the form of device embolization in 2 cases (0.16%).

Mortality

We had 6 mortality cases (0.5%) in our study, most of them were neonates and critically ill. The first 2 neonates died during BPV for

critical pulmonary stenosis. The first patient had a seizure when the balloon was inflated in the outflow tract. Shortly, he developed cardiopulmonary arrest and did not respond to cardiopulmonary resuscitation (CPR). The second one experienced right ventricle perforation during manipulation of the catheter with tamponade requiring urgent pericardiocentesis and autotransfusion, yet the patient arrested and didn't respond to the CPR.

The third case had TGA and died 2 hours after the BAS. The baby was severely hypoxic and acidotic and shocked before the procedure and required inotropic support. BAS did not result in an adequate increase in arterial oxygen saturation, and the baby's clinical condition worsened progressively. The patient arrested 2 hours after septostomy. This shows that death may even be the inevitable outcome in the patients that are severely acidotic and shocked before septostomy even with proper dilatation of the septum.

The fourth patient died during balloon dilatation of aortic stenosis. The patient experienced acute aortic regurgitation and acute pulmonary oedema after dilatation of the bicuspid aortic valve and couldn't be weaned from the ventilator. The patient died after 6 hours of the procedure. The fifth patient had complex CHD with PH and was undergoing an elective haemodynamic study and during catheter manipulation patient experienced ventricular fibrillation (VF) and didn't respond to CPR.

The 6th case was an adult 30 years old undergoing ASD device closure, the procedure went smoothly yet the patient developed recurrent attacks of severe vomiting followed by cardiac arrest after 12 hours of the procedure and didn't respond to the CPR, we thought the cause of death would be device embolization due to the recurrent attacks of vomiting which resulted in severe straining and elevated atrial pressure (Table 4).

| Number | Age | Weight (kg) | Diagnosis | Procedure | Procedure type category | risk of procedure | Status of procedure | Event leading to death |
|--------|----------|-------------|--------------|--------------------|-------------------------|-------------------|---------------------|--|
| 1 | 1 day | 2.5 kg | Critical PS | BPV | 3 | | Emergency | Seizures during the balloon inflation in RVOT and cardiac arrest |
| 2 | 2 days | 3.5 kg | Critical PS | BPV | 3 | | Emergency | RV perforation, tamponade, pericardiocentesis, autotransfusion |
| 3 | 1 day | 3.5 kg | DTGA | BAS | 3 | | Emergency | Circulatory arrest |
| 4 | 4 months | 5.5 kg | Severe AS | BAV | 3 | | Elective | Acute AR, APO, circulatory arrest |
| 5 | 6 months | 5 kg | Complex CHD | Haemodynamic study | 1 | | Elective | Circulatory arrest |
| 6 | 33 yrs | 90 kg | Secundum ASD | ASD device closure | 2 | | Elective | Circulatory arrest post procedure (query device embolization) |

Note: ASD: Atrial Septal Defect, AS: Aortic Stenosis, AR: Aortic Regurgitation, APO: Acute Pulmonary Oedema, BAS: Balloon Atrial Septostomy, BAV: Balloon Aortic Valvuloplasty, BPV: Balloon Pulmonary Valvuloplasty, CHD: Congenital Heart Disease, DTGA: D-Transposition Of Great Arteries, M: Months, RV: Right Ventricle, RVOT: Right Ventricular Outflow Tract, PS: Pulmonary Stenosis, Yrs: Years

Table 4: Mortality cases description.

Predictors of adverse events

After exclusion of the TEE under general anaesthesia cases, the study group was subdivided into two subgroups according to presence or absence of complications. There was significant difference between the two groups as regard weight, age at the time of the procedure, age group, category of CHD, invasive haemodynamic parameters as mean pulmonary artery pressure (PAP) and oxygen systemic saturation and dose of heparin given during the procedure, type of anaesthesia, number of catheterizations before the procedure, procedure type risk category, access type and number of sheaths used during the procedure (Table 5). There was no significant association between gender and complications in univariate analysis.

| Variables | Group uncomplicated 1 | Group complicated 2 | Chi square | p-value (Significance level) |
|--|-----------------------|---------------------|------------|------------------------------|
| Age (yrs) (median +IQR) | 5 (IQR 1.5-11) | 1.1 (IQR 0.5-2.9) | | <0.0001 |
| Weight (kg) (median +IQR) | 18 (IQR 10-32) | 8 (IQR 6-11) | | <0.0001 |
| Oxygen saturation | 95.88 ± 6.25 | 92.87 ± 8.72 | | 0.003 |
| Mean PAP | 21.80 ± 12.38 | 27.84 ± 16.17 | | 0.0016 |
| Dose of heparin | 44.07 ± 30.17 | 56.30 ± 29.15 | | <0.0001 |
| Age group | 889 (88.2%) | 118 (11.8%) | 78.727 | <0.0001 |
| Category of CHD | 889 (88.2%) | 118 (11.8%) | 155.65 | <0.0001 |
| Type of anaesthesia | 889 (88.2%) | 118 (11.8%) | 55.795 | <0.0001 |
| Number of catheterizations pre procedure | 889 (88.2%) | 118 (11.8%) | 6.731 | 0.0345 |
| Procedure type risk category | 889 (88.2%) | 118 (11.8%) | 20.302 | 0.0001 |
| Access type | 889 (88.2%) | 118 (11.8%) | 27.326 | <0.0001 |
| Number of sheaths used | 889 (88.2%) | 118 (11.8%) | 8.857 | 0.0313 |

Note: CHD: Congenital heart disease, PAP: Pulmonary artery pressure

Table 5: Risk factors for overall complications.

The significant variables for complication from the univariate analysis were entered into a stepwise multiple logistic regression model. The independent risk factors for any complication included age group, category of CHD, number of catheterizations before the procedure, access type and number of sheaths used during the procedure in multivariate analysis. The complications risk was independently increased if the patient was <2 year of age, arterial access, more than one sheath used and procedure risk category 4, and local anaesthesia (Table 6).

Another model was applied to predict the independent predictors for vascular access complications. Independent risk factors associated with the presence of vascular complications included weight, age group, access type, procedure type risk category and number of catheterizations before the procedure.

| Variables | Likelihood ratio | Odds ratio (95% confidence interval) |
|--|------------------|--------------------------------------|
| Age group (age <2 years) | 2.364 | 2.034 to 2.747 |
| Category of CHD | 4.015 | 3.322 to 4.851 |
| Type of anaesthesia (local anaesthesia) | 0.0951 | 0.0216 to 0.4183 |
| Number of catheterizations pre procedure | 1.115 | 1.047 to 1.187 |
| Access type (arterial access) | 2.287 | 1.377 to 3.800 |
| Number of sheaths used | 3.348 | 1.048 to 10.703 |

Note: CHD= congenital heart disease

Table 6: Association between patient variables and complications by univariate and multivariate analysis.

Discussion

Through decades cardiac catheterization gadgets and techniques have underwent marked improvement helped by the major advances in technology facilitating and expanding the role cardiac catheterization to complex interventional procedures and allowing managing patients with SACHD safely and efficiently especially patients with smaller age, body weight and more complex anatomy. Despite this marked improvement, complications still do happen and may be life threatening if not managed seriously.

In the current study, we analyzed all cardiac catheterization procedures performed for SACHD in our tertiary center by an experienced operator during almost 1-year period to identify the rate and category of complications and point out the related risk predictors to these complications. The overall complication rate reported in our study was 10.5% including major, minor and mortality cases. Our main complications were minor complications representing 7.8% of all study population and mortality rate was about 0.5%.

Other studies reported overall complication rates ranging from 8.8% to 24%, and mortality rates ranging from 0.14% to 2.7% [10]. Ko Lee et al., reported overall complication rate in their study of 16.2% including minor complications such as fever which accounted for 43.3% of all complications. In their study, the incidence of severe complications was only 1.15% and the mortality rate was only 0.19%. The complication rates were higher in the therapeutic interventional group than the diagnostic and haemodynamic catheterization group [5].

Tavli et al., [11] reported incidence of 3.4% for major and 10.9% for minor complications almost 20 years ago, significantly higher in comparison to our current study. Yet these results may be reasonable considering that the data reflected initial experience. Pediatric cardiac and structural heart catheterization has deviated from being a diagnostic tool to mainly a therapeutic one. Several studies in agreement with our study have showed that the rate of complications is higher in interventional and therapeutic procedures than in the diagnostic ones [5,7,12]. In our study the occurrence of complications during the interventional procedures were found to be 13% higher

than in diagnostic ones. Major complications and mortality occurrence have the liability to vary according to the practice and experience of the operator, the availability of different equipment's in the institution, and the percentage of interventional catheterization performed.

The occurrence of complications in each category

There is variability in the complication rate in each category seen in different reported previous studies. Vascular thrombosis was the most common minor and overall complication in previous studies [12,13-15], this is in an agreement with our study which represented 6.9% most of which in the form of lost pulsations while other studies as the Korean center revealed that fever was their most common complication, followed by nausea, and respiratory problems [5].

Most of our cases were done under GA (91.1%) and the rest were done with IV sedation or local anesthesia, that's why our study showed minimal respiratory complications with only one case representing 0.09% of the overall complication rate which was the same as the Toronto study where the majority of their procedures were done under general anesthesia [16], other studies as Lee et al., showed high percentage of respiratory complications due to the use of general anesthesia in only 9.6% of procedures; while the main number of procedures (71.1%) in their study were done by either IV sedation or local anesthesia that have a potential for desaturation necessitating support by oxygen or positive pressure ventilator support during the catheterization [17]. Previous studies [12] showed that the most common major complication was arrhythmia (0.48%), followed by cardiac arrest and resuscitation followed by death. Our study showed that most common major complication apart from the mortality (0.5%) was cardiac arrest and resuscitation (0.4%) and catheterization related complications (0.4%) followed by intervention related complications (0.16%), we attribute this to the fact that the majority of our cases were in the young age group category which was in agreement with other studies that showed that young patients were vulnerable to complications in the peri-procedural time [5,10,12], similarly 5 out of the 6 deaths in our study occurred in patients \leq 6 months of age.

Risk factors

Previous studies stated that the predictors of complications in the cardiac procedures includes young age, emergency procedure, long procedure time, pre-procedure heparin administration, PH presence, Interventional procedures, and the year the procedure is done in [5,12,14-15,17-23]. In agreement, our study showed that the incidence of severe complications was significantly greater in patients aged $<$ 6 months.

Our study showed that the independent risk factor for any complication included age group, number of catheterizations before the procedure, anesthesia type, procedure risk category, access type and number of sheaths used during the procedure. In accordance with this result, the complications risk was independently increased if the patient was $<$ 2 year of age, use of local anesthesia, arterial access, more than one sheath used and procedure risk category 4 which was similar to other previous studies [24].

Also, vascular thrombosis was evident in children $<$ 2 year of age, and weight $<$ 10 kg similar to that reported by others [6]. In previous studies, younger children, longer procedure times, and difficult access have been observed to be more susceptible to thrombosis [6]. In our study, vascular complications risk factors included weight ($p < 0.001$),

age group ($p < 0.001$), access type ($p < 0.0052$), procedure type risk category ($p < 0.0038$) and number of catheterizations before the procedure ($p < 0.0138$).

Study limitations

This was a retrospective observational study that included a large number of patients studied over a short period of time of 1 year. The heterogeneity of the study group and retrospective nature of the study may have some limitations regarding collection of some variables such as procedure and fluoroscopy time, contrast dose and radiation dose. Nevertheless, the variables to be collected and put to analysis were categorized by the authors of the study in consensus with previous authors and studies dealing with complications in the Cath Lab.

Conclusion

Congenital and structural heart disease catheterization is progressively increasing especially the interventional therapeutic procedures. Predictors of complications including major and mortality were young age, weight, use of heparin during procedure, access type, invasive haemodynamic, emergency status of the procedure. Proper patient selection is crucial especially in interventional procedures and enhanced techniques and well handling of the peri-procedural time are necessary to decrease the complication rate in pediatric cardiac procedures.

Conflicts of Interest

There are no conflicts of interest for the present study.

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