Complications of cardiac catheterization in pediatric patients: a single center experience

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We analyzed 519 catheterization procedures performed over a period of two years retrospectively. Several risk factors related to the patient or catheterization were analyzed. The incidence of complications was 6.2%. The most common major and minor complications were arterial thrombosis that required intervention and transient arrhythmias, respectively. The incidence of complications during interventional studies was higher (9.7%) when compared to that in diagnostic procedures (5.4%). The independent risk of any complication was greatest up to 1 year of age (p=0.02). The risks of a major complication (p=0.003) and development of arterial thrombosis (p=0.02) were significantly greater in patients <1 year of age by univariate analysis. The risks of pediatric cardiac catheterization continue to decline. The complication rates associated with interventional catheterization were significantly higher than with diagnostic catheterization in this study. Younger age, particularly <1 year of age, is the strongest predictor of development of any complication.

Key words: pediatric, complications, catheterization, diagnostic, interventional.

Cardiac catheterization procedures generally are considered safe procedures in pediatric patients. However, as with all invasive procedures, catheterization procedures involve significant risks that may occur at all steps of the procedure, and these risks could be relevant to all structures of the circulation[1]. Appropriate patient selection and pre-catheterization assessment may reduce the risks that are associated with complications [2,3]. The incidence of major complications and death that may result from pediatric cardiac catheterizations is reported to have decreased obviously compared to the results from previous decades[4]. Currently, the increased use of cardiac catheterization in the treatment of congenital heart defects has contributed partially to the development of new complications.

As stated by the father of cardiac catheterization, Charles Mullins, the complications related to all cardiac catheterization procedures are more frequent during the "learning phases" of the procedures. The "learning curve" also pertains to the development and use of new products and procedures by otherwise experienced catheterizing physicians and/or in laboratories[1]. This study was undertaken to determine the incidence and predisposing factors of pediatric cardiac catheterization in a relatively new pediatric cardiac catheterization laboratory.

Material and Methods

In the present study, we evaluated the complication rate among 519 catheterization procedures, both diagnostic and therapeutic, which were performed in 445 patients between January 2007 and May 2009. Patients having complications were identified, and all files and medical records of inpatients were assessed retrospectively. Cardiac catheterization procedures were grouped as interventional or diagnostic. Interventional studies consisted of pulmonary valvuloplasty, aortic valvuloplasty, balloon atrial septostomy, closure of secundum atrial septal defect (ASD), closure of patent ductus arteriosus (PDA), and cardiac pacemaker

Table I. Type of Interventional Procedures and Complications

Type of procedures	n (%)	Complication (n)
Pulmonary balloon valvuloplasty	42 (45%)	2
Aortic balloon valvuloplasty	13 (14%)	3
Coarctation angioplasty	11 (12%)	-
ASD device	12 (13%)	2
PDA device	5 (5%)	1
Balloon atrial septostomy	5 (5%)	1
Pacemaker implantation	5 (5%)	-

ASD: Atrial septal defect. PDA: Patent ductus arteriosus.

implantation (Table I). Diagnostic studies were performed to evaluate the anatomic structures and the hemodynamic status. Catheterization procedures were done using previously described techniques [1]. For patients >1 year of age, a cardiologic mixture containing diphenhydramine, chlorpromazine and meperidine hydrochloride was administrated one hour before the procedure. All catheterization procedures were performed under general anesthesia and done with Innova 2100-IQ device (GE, Piscataway, NJ). Heparin was given particularly in interventional procedures. Cineangiography was performed in nearly all patients. Non-ionic, low osmolality contrast material was used at a maximum dose of 5-6 ml/kg/catheterization. Catheterization reports permitted us to record patient age, weight, gender, type of procedure, technical information, any complication and its short-term course, as well as times of fluoroscopy and overall procedure. Procedures were performed by two senior physicians and by five operators in training. Catheterization reports were written by the main operator, under supervision of the chief of the department.

Complications were classified into two main categories as major and minor. A life-threatening event requiring immediate treatment that was considered a major complication included 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 specific treatment were classified as minor complication (e.g., transient arrhythmias, bleeding at access site). However, analysis of complications can be difficult due to differences in definitions and collection of data [5].

Statistical Analysis

All statistical analysis was performed using the Statistical Package for the Social Sciences version 11 (SPSS Inc., Chicago, IL, USA). All continuous variables were tested for normal distribution by Kolmogorov-Smirnov test. T-tests were used for continuous variables and expressed as mean and standard deviation. Categorical variables such as gender were expressed in terms of frequency and percentage, and differences in frequencies were analyzed using chi-square test. Data were expressed as mean±standard deviation or median and ranges. Several risk factors related to the patient or catheterization were analyzed by univariate analysis. Variables that were tested included patient age, weight and gender, and type of procedure (diagnostic or interventional). A p value of <0.05 was used for selection entry into the model, and stepwise multiple logistic regression analysis was performed. A p value <0.05 was considered statistically significant.

Results

General Information

Among the 519 catheterizations, one or more complications occurred in 27 procedures. A total of 32 complications (6.2%) occurred (Table II). There were 12 major (2.3%) and 20 minor (3.9%) complications in our patient population. The most common major and minor complications were arterial thrombosis

Table II. Complications of Diagnostic and Interventional Procedures

	Diagnostic	Interventional
Deaths		2
Ventricular tachycardia	1	
Supraventricular tachycardia	1	
Complete AV block		1
Bundle-branch block	2	
ST-segment elevation	4	1
Bradycardia	3	
Cardiac arrest	1	1
Arterial thrombosis	4	2
Hypotension	1	
Myocardial/vessel strain	3	
Catheter wire complication (kink)	2	
Balloon rupture		1
Device embolization		1
Relating to anesthesia	1	
Total	23	9

that required intervention and transient arrhythmias, respectively. Of the 519 cardiac catheterizations, 426 (82%) were diagnostic and 93 (18%) were interventional procedures. There were 23 (5.4%) complications in the diagnostic and 9 complications in the interventional (9.7%) procedures. Ventricular septal defect (VSD) (21%) and tetralogy of Fallot (TOF) (19%) were the most common reasons for diagnostic catheterization, while pulmonary valvuloplasty (8%) was the most common interventional procedure in this study. Among the interventional procedures, the highest complication rate (3/9; 33%) was seen with aortic balloon valvuloplasty (Table I). No complications were determined with pacemaker implantation. Table I shows the interventional procedures and rates of complication.

A total of 32 complications were recorded, including death (n: 2), cardiopulmonary arrest (n: 2), arterial thrombosis (n: 6), arrhythmias (n: 13), interventional procedure-related (n: 2), catheter manipulation-related (n: 5), hypotension requiring medical management (n: 1), and anesthesia-related (n: 1) (Table III).

Categories of Complications (Tables II and III)

Death: Deaths in 2 patients (0.4%) were directly related to catheterization. All were neonates and critically ill, requiring ventilatory support prior to the procedure. The first neonate died during balloon angioplasty of aortic coarctation. The patient had a seizure when the balloon inflated into the middle of the coarctation. Shortly thereafter, he developed cardiopulmonary arrest and did not respond to cardiopulmonary resuscitation of more than 30 minutes.

The second case had complete transposition of the great arteries and died 6 hours after the balloon atrial septostomy. The baby was severely hypoxic and acidotic before the procedure and required ventilation. Balloon atrial septostomy did not result in an adequate increase in arterial oxygen saturation, and the baby's clinical condition worsened progressively. The patient arrested 6 hours after septostomy. This also shows that death may be the inevitable outcome in patients that are severely hypoxic and acidotic before septostomy.

Arrhythmias: Among the 32 complications, arrhythmias were the most common (41%). Two of the arrhythmias (ventricular tachycardia and complete atrioventricular block) were major, and of 13 episodes, 11 were minor, including persistent ST elevation, supraventricular tachycardia, sinus bradycardia, and bundle branch block. All of the arrhythmias classified as minor recovered immediately. We witnessed a serious episode of monomorphic ventricular tachycardia in a 6-year-old patient

Table III. Distribution of Complications as Major and Minor

	Major	Minor	
Deaths	2		2 (6.25%)
Arrhythmias	2	11	13 (40.62%)
Ventricular tachycardia	1		
Supraventricular tachycardia		1	
Complete AV block	1		
Bundle-branch block		2	
ST-segment elevation		5	
Bradycardia		3	
Cardiac arrest	2		2 (6.25%)
Arterial thrombosis	6		6 (18.7%)
Hypotension		1	1 (3.12%)
Relating to catheter manipulation		5	5 (15.6%)
Myocardial/vessel strain		3	
Catheter wire complication (kink)		2	
Relating to interventional procedures		2	2 (6.25%)
Balloon rupture		1	
Device embolization		1	
Relating to anesthesia		1	1(3.12%)
Total	12	20	32 (100%)

with TOF during contrast material injection with multipurpose catheter into the right ventricle. The hemodynamic condition of the patient was stable, but then the blood pressure started to decline significantly. Ventricular tachycardia with a rate of 150/ beats per minute did not cease with bolus administration of intravenous lidocaine, but responded promptly to synchronized DC cardioversion. There were no episodes of sustained or non-sustained ventricular tachycardia or ventricular ectopic beats in the follow-up. Complete atrioventricular block occurred in a 7-year-old girl with a ventricular rate of 54/bpm 1 hour after Amplatzer device implantation for secundum ASD. The patient was treated with oral steroid and remained hemodynamically stable. She regained 1:1 atrioventricular conduction within 24 hours after the procedure. However, bradycardia or AV block did not recur in the follow-up.

In the current study, the most common minor complication was S-T segment elevation that was transient in all 5 patients. Transient ST segment elevation, possibly reflecting transient ischemia of myocardial tissue, may be caused by the use of multipurpose catheter during contrast material injection or injuries triggered by high pressure injection. Therefore, we prefer to use pigtail catheter for injection that requires higher pressure. We noted supraventricular tachycardia that was considered as a minor complication in only one patient, which resolved spontaneously, similar to the other minor complications.

Arterial complications: In the current study, we did not consider cases that resolved spontaneously or cases that responded to short-term heparin infusion as arterial complications. Since most

of these conditions result from vasospasm rather than true thrombosis, we did not include these situations as complications. Six cases of arterial thrombosis were noted and all were classified as major events. Four of the six occurred in patients <1 year of age, and the two remaining events were noted in children aged 5 and 6 years of age. We usually use 5 French sheath and catheter in patients <1 year of age. The possibility of arterial thrombosis occurring in either type of catheterization procedure (diagnostic and interventional) was similar. Decreased pulses in the limb in which an arterial catheter had been placed did not return to normal following intravenous heparinization at a dose of 100 U/kg/bolus followed by 20 U/kg/hr for at least 24 hours. Pentoxifylline, dipyridamole and dextran 40 were administrated following heparin infusion. All patients required surgical intervention, having failed medical therapy within 3 days.

Cardiopulmonary arrest and hypotension: Two patients had cardiopulmonary arrest during the diagnostic catheterization. One of these patients was a neonate with critical valvular pulmonary stenosis who experienced cardiopulmonary arrest during balloon valvuloplasty. Cardiopulmonary arrest can be attributed to the baby's poor clinical status before the intervention. This newborn infant responded promptly to resuscitation, and no problem regarding cardiopulmonary arrest was seen in the follow-up period. The other patient was 10 years old and had been diagnosed with tricuspid atresia and single ventricle. The patient suffered cardiopulmonary arrest through the injection of radiopaque dye. Although the mechanism is not clear, we may postulate that the allergic reaction related to injection of radiopaque dye caused this complication.

One patient had hypotension during the procedure, which resolved spontaneously. This patient was 10 years old and had perimembranous VSD. Inefficient intravenous fluid infusion during the procedure and use of anesthetic agent and oxygen, which may lower peripheral vascular resistance, are blamed for the hypotension in this patient.

Catheter problems: As a minor complication, we observed kinking of the catheter in two infants, but it was withdrawn successfully through the introducer sheath. A myocardial strain in 3 patients were considered as a minor complication and resolved spontaneously. No other catheter-related complication, such as cardiac perforation, cardiac tamponade or air embolism, was established in our database.

Incidents related to interventional procedure: There were two complications concerning the intervention. The first occurred after the implantation of a Sideris buttoned device for closure of secundum ASD. The counter-occluder was detached and displayed in the right ventricle adjacent to the outlet tract. This device is different from an Amplatzer septal occluder because the loading wire and sheath is not removed following the procedure due to the risk of detachment. Consequently, we placed the device with the purpose of adhesion of the device to the septum for 24 hours. Hence, we retrieved the device successfully with the use of its own loading wire and snare. We classified this incident as a minor complication since it did not require surgical intervention or additional vessel access. One instance of balloon rupture was considered as a minor complication, seeing as no further intervention was required for the removal of balloon fragments.

Complications associated with anesthesia: A drug reaction associated with anesthesia was noticed in one patient. Bronchospasm and increase in tracheal secretion occurred during the diagnostic procedure, after which it was decided to terminate the procedure.

Association of Patient or Catheterization Variables and Complications

From the findings of univariate analysis, several variables were associated with complications (Table IV). Independent risk factors associated with the presence of complications included weight, type of procedure (interventional or diagnostic) and age at the time of the procedure. Risk was independently increased if the patient was <1 year of age, <5 kg and had an interventional procedure. There was no significant association between gender and complications in univariate analysis. The significant variables for complication from the univariate analysis were entered into a stepwise multiple logistic regression model. The only independent risk factor for any complication included the age of the patient in multivariate

Table IV. Association between Patient Variables and Complications by Univariate Analysis

	Odds ratio (95% confidence interval)	P value
Age (<1 year old)	3.6 (1.67-8.09)	0.001
Type of procedure (interventional)	2.42 (1.05-5.59)	0.037
Weight (<5 kg)	2.83 (1.14-7.01)	0.02
Gender	1.0 (0.46-2.19)	0.9

analysis (Table V). The independent risk of complication was greatest up to 1 year of age (Odds ratio [OR]/95% confidence interval [CI]: 3.52/1.59-7.79) (p=0.02). In accordance with this result, the risk of a major complication (OR/95% CI: 6.71/1.93-23.17) (p=0.003) and development of arterial thrombosis (OR/95% CI: 7.5/1.35-41.4) (p=0.022) were significantly greater in patients <1 year of age by univariate analysis.

Discussion

Despite the considerable improvement in catheterization techniques, equipment and skills of the interventionist, the risks of catheterization continue to complicate these procedures[4,6-9]. The current risk is reported to have decreased significantly when compared to previous results within the same institution[4,10]. The incidences of major and minor complications were 2.3% and 3.9% in our study population currently. Tavlı et al.[2] reported an incidence of 3.4% for major and 10.9% for minor complications 10 years ago, significantly higher compared to our current results. However, these results may be assumed to be reasonable considering the reported data reflect initial experience.

Previous authors have reported overall complication rates of 7.8% to 24% (4,6,11-13) and mortality rates ranging from 0.14% to 2.7%[4,6,11-16]. Furthermore, major complications have been reported to vary from 1.4% to 11%[11-16] and minor complications from 6% to 11.7% [6,11-13,15,16]. In the present study, the complication rate particularly in minor events (3.9%) was lower compared to previous reports. Catheterization equipment, patient selection and pre-catheterization medical management may have decreased catheterization-related complications in our population. Since Agnoletti et al [5]. analyzed only severe procedural complications and not the minor complications (e.g. supraventricular tachycardia) that required no treatment, they reported complications in 4.1% of patients who underwent interventional procedures. Likewise, we did not analyze the transient vascular events that required no treatment or necessitated short-term heparin infusion. Hence, the differences in methods and criteria in collecting data are amenable for the variability of results. One could say that if we report benign arrhythmias, we would expect that the most common complication was arrhythmia[15]; otherwise, it can be supposed that vascular events were most common[6,9]. Arrhythmias were the most common total and minor complication, while vascular complications were the most common major events in the former study. Currently, more permanent arterial thrombotic occlusion was present in children <1 year of age, similar to that reported by others[6,17]. In previous studies, younger children, longer procedure times, and difficult access have been observed to be more susceptible to thrombosis[4,6,13,17-20]. In our study, half of the arterial injuries were associated with an interventional procedure in which large French size catheters were used. Eventually, in our study population, a significant association was detected between development of arterial thrombosis and younger age in the univariate analysis (p=0.022).

Table V. Result of Stepwise Multiple Logistic Regression Analysis

	Odds ratio (95% confidence interval)	P value
Age (<1 year old)	3.52 (1.59-7.79)	0.02

Studies addressing prevention of arterial thrombosis have not investigated the use of pre-catheterization antiplatelet therapy.

Previous reports suggested that mortality was most common in children with younger age, lower weight and interventional procedures[4,7,9,11,12,14,15,17]. In our study, the two deaths (0.4%) were directly attributed to complications of the catheterization. In most of the reviews, mortality was significantly higher in children <1 year of age and particularly higher in neonates[9,15]. Indeed, the mortality rate in neonates seems to have decreased over the last 20 years[4,9]. It can be suggested that this reduction is achieved by a decrease in the number of procedures in neonates and infants, by improvements in the care of the critically ill child, by introduction of new catheters and other support materials, and by initiation of prostaglandin E1 infusion[4,9]. In the current study, no such analysis was performed since the number of deaths was too small for statistically valid conclusions. Arrhythmias are a well-known complication of catheterization in children. Most of the arrhythmias classified as minor were transient and never required pharmacological treatment in this study. We observed a complete AV block after deployment of ASD device, but it converted to sinus rhythm within a short time. Judicious catheter manipulation and correction of metabolic abnormalities are crucial to preventing serious arrhythmias.

From the evidences of previous reports, it was noted that complications have tended to be more frequent in interventional rather than diagnostic catheterization[6,7,9]. In our study, the incidence of complications during interventional studies was higher (9.7%) when compared to that in diagnostic procedures (5.4%). Furthermore, a statistically significant correlation was found between interventional procedures and risk of any complication in the univariate analysis. However, this correlation was not valid for a multivariate model. The only independent risk factor for any complication included the age of the patient being <1 year of age. Our finding suggests that younger children may experience more complications during cardiac catheterization, which is in agreement with other reports[4,9,15]. In a study in infants <1 year of age, Cohn et al[15]. also described that the complication rate was significantly higher in infants <4 months compared to those aged 4 months - 1 year. Studies to date have described that complications occur more commonly in children under 10 kg or 5 kg[6,9,12,16,21]. In this study, we demonstrated that children <5 kg appear to be at a greater risk, although we did not find any association between weight and complications in the multiple logistic regression analysis.

Finally, as noted in our study, it is clear that the majority of the complications were successfully treated or were self-limited. It is essential for pediatric cardiologists to plan carefully and to keep the duration of the procedure as short as possible. One should also bear in mind that management of relatively inexperienced personnel and recognition of high-risk procedures should certainly decrease the possibility of complications.

There are some limitations to this study. This is a retrospective analysis of a complications database. We did not record the vascular events that needed no therapy or required short-term heparin infusion. In all of the studies related to the pediatric catheterization complications, the variables to be analyzed were chosen by the authors of the study, due to the lack of any consensus or guidelines for analysis of complications.

In conclusion, despite advances in non-invasive evaluation, cardiac catheterization continues to be essential for patients with congenital heart disease, and it is certain that catheterization possesses some risk. Fortunately, the risks of pediatric cardiac catheterization continue to decline. The complication rates associated with interventional catheterization are significantly higher than with diagnostic catheterizations. Therefore, younger age, particularly <1 year of age, is the strongest predictor of development of any complication. The incidence of overall complications in our series has significantly decreased compared to previous incidences. This reduction may be attributed to the previously mentioned improvements in pre-catheterization management, patient selection, techniques, and particularly operator experience. Further studies should be directed to determining the factors that may lead to the reduction of complications.

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