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Retrospective Evaluation of the Complications and Risk Factors Related to Cardiac Catheterization: Single Center Experience

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Abstract

Cardiac catheterization is an invasive procedure that carries the risk of life-threatening complications. The aim of our study is to evaluate the risk factors and complications of cardiac catheterization procedures performed over a 14-year period at the Department of Pediatric Cardiology, Erciyes University Faculty of Medicine. Complications of 2265 cardiac catheterization procedures in 1880 different patients between September 16, 1995, and December 30, 2009, along with risk factors, were evaluated. Complications occurred in 169 (7.5%) of the 2265 cardiac catheterizations. One hundred and twenty-four (5.5%) were minor and 45 (2%) were major complications. Among 1880 patients, 6 patients (0.31%) died within the first 24 hours. A statistically significant difference was observed between the type of procedure and anesthesia used when comparing minor and major complications. The overall complication rate was 12.9% in patients under one year of age, 11.3% in the cyanotic heart disease group, 8.7% in therapeutic procedures, and 10.9% in patients with a body weight of less than 10 kg. Retrospective studies examining risk factors and complications in cardiac catheterization procedures will provide insights for prospective studies.

Keywords: Cardiac catheterization, complication, risk factors

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Introduction

Cardiac catheterization is a technique in which a catheter is inserted into a peripheral vessel and guided into the heart chambers, and large blood vessels. This allows for the measurement of oxygen saturation in blood samples and the assessment of pressure levels in these regions[1,2]. It is used for determining the heart's anatomy, assessing the presence and size of shunts, measuring pulmonary vascular resistance, evaluating the response to vasodilators and oxygen, monitoring postoperatively, conducting myocardial biopsy and electrophysiological studies, as well as performing transcatheter ablation and therapeutic procedures[1,2].

Highlights

- Increasing number of cardiac catheterizations are being performed today, and complications related to catheterization develops unavoidable.
- The complication rates were found to be higher in therapeutic procedures, cyanotic congenital heart diseases, children under one year of age and weighing less than ten kg in our study.
- Retrospective studies focusing on risk factors will provide guidance for prospective studies.

Cardiac catheterization is an invasive procedure that carries complications, both major and minor, which can occur during or after the procedure. Complications may be related to patient-dependent and/or patient-independent risk factors. Arrhythmias, vascular complications, neurological complications, vasovagal reactions, cardiac perforation, phlebitis, infection, fever, hypertension, and allergic reactions are some of the complications[3-6].

The complication rate after diagnostic catheterization is shown as 4.1-19% in some studies[7-9]. Several studies have demonstrated that the rate of complications is higher in therapeutic procedures than in diagnostic procedures[5,8,10,11].

Low-weight (<2.5 kg) and younger age (≤7 days) at procedure time; prematurity; associated genetic syndromes; univentricular physiology; and high procedure risk category are reported as major risk factors for morbidity and mortality in neonatal age[12].

The aim of this study is to evaluate the risk factors and complications that occurred during and after cardiac catheterization procedures performed over a 14-year period at the Department of Pediatric Cardiology, Erciyes University Faculty of Medicine, and to discuss these findings in the context of the current literature.

Material and Method

Study Design

Risk factors and complications for 2265 cardiac catheterization procedures performed on 1880 different patients at the Department of Pediatric Cardiology, Erciyes University Faculty of Medicine, between September 16, 1995 and December 30, 2009, were evaluated.

The study was approved by the Ethics Committee of Kayseri City Hospital (date: 26.11.2024, approval number: 252/2024).

Definitions of Complications

Complications that are life-threatening, such as respiratory arrest, hemopericardium, hemothorax, cardiac perforation, device migration, and permanent rhythm disturbances were classified as major complications. Complications that do not pose a life-threatening risk, such as circulatory disturbances and temporary rhythm abnormalities, were classified as minor complications.

Deaths that occur during the procedure or within 24 hours after the procedure were considered procedure-related deaths. Complications that were directly related to the procedure, either during or after it, were classified as procedural complications.

Inclusion Criteria

A total of 169 cases that developed complications were included in the study.

Statistical Analysis

Statistical evaluation was conducted using SPSS version 26 (SPSS Inc., Chicago, IL, USA). Histograms, q-q graphs and Shapiro-Wilk normality tests were used to examine whether the data showed a normal distribution. Normally distributed parameters were expressed as mean ± standard deviation; parameters with abnormal distribution were expressed as median minimum-maximum and 25-75p. The chi-square test was used to evaluate non-parametric independent qualitative data in two groups. Mann-Whitney's U-test was used for the difference between two non-parametric quantitative independent groups. A p-value less than 0.05 was considered statistically significant in all statistical analyses.

Results

Among 2265 cardiac catheterizations, 1577 procedures were performed for diagnostic purposes. A total of 294 patients with isolated ventricular septal defect (VSD) and 147 patients with tetralogy of Fallot (TOF) comprised two major groups of the diagnostic study population.

A total of 688 therapeutic procedures were performed. The most frequently performed therapeutic procedures were: 165 valvuloplasty, 123 patent ductus arteriosus (PDA) embolization with coil, 73 PDA closures with amplatzer duct occluder (ADO), 116 atrial septal defect (ASD), and 26 VSD closures with amplatzer septal occluder, 99 angioplasty, 15 aortic coarctation (CoA) correction with stent, and 62 balloon atrial septostomies.

Complications occurred in 169 (7.5%) of the 2265 cardiac catheterizations. 124 (5.5%) were minor and 45 (2%) were major complications. Among 1880 patients 6 patients (0.31%) died within the first 24 hours.

The median age was 6 months (1 day-21 years), and the median weight was 6.6 kg (1.4-76) in patients with complications. Seventy-four (43.8%) of the patients were female and 95 (56.2%) were male. Among the patients, 58 (34.3%) had cyanotic congenital heart disease, and 110 (65.1%) had acyanotic congenital heart disease. One patient (0.6%) had normal cardiac catheterization. One hundred and nine procedures (64.5%) were diagnostic, and 60 procedures (35.5%) were therapeutic. Ninety-seven patients (57.4%) were under 1 year of age, while 72 (42.6%) were over 1 year old.

The total complication rate was 12.9% in cases under one year of age, compared to 5% in cases aged one year and older. The overall complication rate was 11.3% in cyanotic congenital heart disease, compared to 6.7% in acyanotic congenital heart disease.

The overall complication rate was 6.9% in diagnostic cardiac catheterization, while it was 8.7% in therapeutic cardiac catheterization. The total complication rate was 10.9% in cases with a weight less than 10 kg, whereas it was 5.1% in cases weighing 10 kg or more.

Dysrhythmia was detected in 41 (1.8%) cases. Tachycardia developed in 13 cases (0.57%), and complete Atrioventricular (A-V) block in 12 cases (0.52%). Dysrhythmia was most frequently observed in 5 isolated VSD (12.2%), in 4 (9.8%) transposition of great arteries (TGA), and in 4 (9.8%) complex cardiac pathologies.

Respiratory arrest occurred in 16 patients (0.7%) during cardiac catheterization. Respiratory arrest was most frequently observed in TGA (31.3%) and pulmonary stenosis (18.8%).

Cyanotic spells were observed in eight cases. Four of them have tetralogy of Fallot, two have tricuspid atresia, one has complex cardiac pathology, and one has double outlet right ventricle.

Convulsions developed in five cases, cerebral infarct and convulsions in two, transient loss of strength in one case, and hemiparesis in one case. Neurological complications were most frequently observed in cases of isolated CoA or with PDA and VSD (44.4%).

Endocarditis occurred in three patients (1.7%) following the closure of PDA with ADO and after diagnostic cardiac catheterization procedures were performed for conditions such as double outlet right ventricle and CoA.

Chest pain developed in the patient with normal cardiac catheterization (0.6%), who was operated on because of a coronary A-V fistula. Cardiac perforation occurred in one case (0.6%) with pulmonary atresia.

Femoral veins were used for right heart catheterization; femoral arteries were used for left heart catheterization. The most commonly used sheath in patients with complications was 5F (84%). The right femoral vein was the most common used vascular access site in 106 procedures, while the left femoral artery was the fewest vasculer access site with just 30 procedures. Vascular complications were most frequently detected in isolated PDA (18.5%) and TOF (14.8%). Vascular events were found to develop in 32 patients (59.3%) under 1 year of age and in 39 patients (72.2%) weighing under 10 kg. There was no significant difference in the development of vascular complications between patients under and over 1 year of age. Similarly, when patients under 10 kg were compared with patients over 10 kg, the difference was not statistically significant ($p>0.05$).

General anesthesia was applied for ASD and VSD closure procedures. Sedation and superficial anesthesia were applied to all other cases. The most common complication in patients undergoing superficial anesthesia was arrhythmia (23.9%). The most common complication was device migration in patients undergoing general anesthesia (40%).

Statistically significant difference was observed between the type of procedure and anesthesia used when comparing minor and major complications.

The distribution of complications is shown in **Table 1**, and the characteristics of the cases that developed complications and died within the first 24 hours are shown in **Table 2**. Comparison of the variables in patients with complications is shown in **Table 3**.

Management of the Complications

Low molecular weight heparin was given to cases that developed thrombosis. Thrombectomy was performed in one case with TAG. Heparin infusion was administered to patients with circulatory disorders until the clinical vascular symptoms improved. Antiaggregant treatment was given subsequently. The symptoms of cyanotic spells improved with supportive treatment.

After the ASD closing procedure, the device was in the right ventricle in one case, in the aortic arch in one case, and in the pulmonary artery in two cases. The device that migrated to the aorta was captured with a snare catheter

Table 1. *Distribution of complications*

Complication	Major	Minor	Total (%)
Dysrhythmia	9	32	41 (24.3)
Circulatory disturbance	-	24	24 (14.2)
Fever	-	18	18 (10.7)
Respiratory arrest	16	-	16 (9.5)
Bleeding	-	15	15 (8.9)
Neurological complications	4	5	9 (5.3)
Hematoma	-	8	8 (4.7)
Cyanotic spell	-	8	8 (4.7)
Thrombosis	1	6	7 (4.1)
Device migration	6	-	6 (3.5)
Hemopericardium/ hemothorax	4	-	4 (2.4)
Infective endocarditis	3	-	3 (1.7)
Transient hypertension	-	2	2 (1.2)
Pericardial effusion	-	2	2 (1.2)
Flushing	-	2	2 (1.2)
Cardiac perforation	1	-	1 (0.6)
Larynx spasm	-	1	1 (0.6)
Chest pain	-	1	1 (0.6)
Intimal rupture	1	-	1 (0.6)
Total	**45**	**124**	**169 (100)**

and removed from the femoral artery. The devices that migrated to the right ventricle and pulmonary artery were surgically removed. ASDs were also surgically closed.

One patient developed hemiparesis after undergoing correction of CoA with a stent. Monoparesis continued in the left arm during follow-up. Cranial imaging of the patient who developed transient weakness after ASD closure was normal. Strength recovered without sequelae in the follow-up period.

Three patients with complete A-V block were treated with a temporary pacemaker; one patient was treated with a permanent pacemaker.

All of the patients with respiratory arrest were intubated, and among them, six patients died.

The patient who had cardiac perforation underwent surgery but unfortunately died within the first 24 hours.

Discussion

Since cardiac catheterization procedures are invasive, they also carry associated risks. Complications related to cardiac catheterization are influenced by both patient-dependent and independent risk factors. These risk factors include: age, weight, gender, type of procedure, duration of the procedure and fluoroscopy, the severity of the clinical condition, and the experience of the operator[1].

Uysal[3], Vitiello et al.[4], and Bennet et al.[5] reported complication rates of 5.8%, 8.8%, and 9.3%, respectively. The complication rate was 7.5% in our study, and it is consistent with these findings.

The incidence of major complications was found to be 2.3%, 2%, and 1.76% by Yavaş Abalı et al.[10], Vitiello et al.[4], and Mehta et al.[13], respectively. The incidence of major complications in our study, which was 2% is similar to the literature. The frequency of minor complications was found to be 5.5% in our study, which is lower than these three studies. The complication rates were 15.2%, 9.2%, and 7.7%, respectively, in these studies.

Bennett et al.[5] reported the frequency of complications to be 9.3% in diagnostic procedures and 11.6% in therapeutic procedures. The overall frequency of complications was 6.9% in diagnostic procedures and 8.7% in therapeutic procedures in our study.

Uysal[3] reported that the complication rate in patients undergoing catheterization due to cyanotic congenital heart disease was 1.7 times that of the acyanotic group. Similar rates were observed in our study.

Complications such as thrombosis, pseudoaneurysm, dissection, laceration, arteriovenous fistula, bleeding, infection, and distal embolization may occur at the vascular site due to cardiac catheterization[14,15]. The incidence of vascular complications has been shown to be higher in therapeutic procedures, using sheaths larger than 4F in patients weighing less than 4 kg and/or under one month of age[16,17]. Also, longer duration of cardiac catheterization procedures, unplanned access sites, younger age, and smaller body weight are associated with an increased risk of complications[18]. Bansal et al.[19] reported that patients younger than 8 months, and weighing less than 7 kg were found to have a high risk of femoral artery thrombosis due to catheterization.

Table 2. *Characteristics of the cases that developed complications and died within the first 24 hours*

Case	Year	Gender	Diagnosis	Complication
1	9 day-old	M	CoA+VSD	Bradycardia and convulsion
2	20 day-old	F	Pulmonary stenosis	Cardiac arrest
3	7 month-old	F	TGA+PS+VSD+PDA	Respiratory arrest
4	22 day-old	M	TGA	Respiratory arrest
5	16 day-old	M	Pulmonary atresia	Cardiac perforation
6	8 day-old	M	CoA+AS+PDA	A-V block

VSD; Ventricular septal defect, TGA; Transposition of the great arteries, PS; Pulmonary stenosis, PDA; Patent ductus arteriosus, AS; Aortic stenosis, CoA; Coarctation of the aorta, A-V; Atrioventricular

Table 3. *Comparison of the variables in patients with complications*

Variable		Major complication	Minor complication	p
Gender (Female/Male)	**n** **%**	(16/29) (35.5/64.5)	(58/66) (46.8/53.2)	0.194^{x2}
Age	**Median (25-75p)**	5 month (27 day-6.5 years)	6 month (2 month-4years)	0.394^{m}
Weight (kg)	**Median (25-75p)**	5.8 (3.6-17.7)	6.7 (4.6-14.3)	0.502^{m}
Therapeutic/diagnostic	**n** **%**	26/19 (57.8/42.2)	34/90 (27.4/72.6)	**0.000**^{x2}
Cyanotic/acyanotic	**n**	18/27	40/83	0.553^{x2}
Under one year's/over one years	**n** **%**	28/17 (62.2/37.8)	69/55 (55.6/44.4)	0.445^{x2}
Under 10 kg/over 10 kg	**n** **%**	29/16 (64.4/35.6)	82/42 (66.1-33.9)	0.838^{x2}
Superficial/general anesthesia	**n** **%**	39/6 (86.7/13.3)	120/4 (96.8/3.2)	**0.014**^{x2}

χ2; Chi-square test, m; Mann-Whitney U test

50 IU/kg heparin was administered in diagnostic procedures when using venous access; whereas 100 IU/kg heparin was used in therapeutic procedures and administered during arterial access in our study. Despite the use of systemic anticoagulation and the improved techniques and equipment, vascular complications continue to be frequent. In our study, a total of 54 vascular events were observed, including circulatory disorders in 24 patients, bleeding in 15 patients, hematoma in 8 patients, and thrombosis in 7 patients. Vascular events were found to develop in 32 patients (59.3%) under 1 year of age and 39 patients (72.2%) under 10 kg. There was no difference between patients under 1 year of age and over 1 year of age. Similarly, the difference was not statistically significant below and above the 10 kg threshold ($p>0.05$).

Arrhythmias were observed in 41 procedures (1.8%) in our study, which is lower than the studies of Kasar et al.[7] (7%) and Doğan et al.[20] (6.7%). This lower frequency of arrhythmias may be attributed to the fact that transient tachycardia and bradycardia were not included in the reports.

Neurological complications such as convulsions, hemiplegia, intracranial hemorrhage, extrapyramidal side effects, visual and hearing impairments, and brachial plexus injury have been reported[21]. The frequency of neurological complications is reported to be 0.36-6.6%[3,6,10]. Neurological complications, consistent with the literature, were observed in 9 (0.39%) procedures in our study, including convulsions, cerebral infarction, and transient muscle weakness.

Some of the reasons complications develop more frequently in children under 1 year of age and under 10 kg include limited intervention area due to smaller body size, increased hemodynamic instability, complicated heart diseases, and the tendency of critically ill patients to be younger and of lower weight and age.

Yilmazer et al.[22] suggested that younger children (<1 year of age) may experience more complications during cardiac catheterization. Bergersen et al.[23] found that young age (<1 year) is a risk factor for adverse events and is considered independently in the catheterization for congenital heart disease adjustment for risk method. The total complication rate was 12.9% in cases under one year of age, while it was 5% in cases aged one year and older in our study.

Rhodes et al.[24] showed that patient weight <5 kg is a significant risk factor for complications irrespective of the type of procedure performed. Backes et al.[25] reported that the risk of adverse events during cardiac catheterization of infants increases with lower weight. They showed that death occurred more frequently in the subjects weighing less than 2 kg. The total complication rate was 10.9% in cases with a weight less than 10 kg, whereas it was 5.1% in cases weighing 10 kg or more in our study.

Yilmazer and Meşe[26] reported a 10-month-old girl with infective endocarditis who underwent PDA closure with an ADO. She was admitted to the hospital with tachypnoea, fatigue and fever. Fever occurred in our patients after cardiac catheterization; vegetation was detected in the first echocardiographic evaluation. Therefore, catheterization-related infective endocarditis was considered.

Cardiac perforation is a rare complication that can be fatal. McCrossan et al.[27] reported cardiac perforation in 50 out of 36,986 patients (0.14%). They showed that the risk of cardiac perforation is higher in younger patients who undergo emergency and/or interventional procedures. Cardiac perforation occurred in a 16-day-old baby with pulmonary atresia, in our study. Despite surgical intervention, the patient died.

Study Limitations

This study has some limitations. The study was designed as a retrospective, single-center study. This study did not include long-term longitudinal follow-up data on the patients. There is a need for prospective studies in which factors that may reduce the incidence of complications and outcomes of patients are also evaluated. The other limitation of our study is that we do not have any data on the duration of the cardiac catheterization procedure.

Conclusion

The impact of improvements in catheterization techniques, equipment, procedures, patient selection, and preprocedural medical management on catheterization-related morbidity and mortality rates is well known. Retrospective studies focusing on risk factors and complications will provide guidance for prospective studies.

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*This study was prepared using data obtained from a pediatrics thesis in 2010 (Retrospective evaluation of the cases and cardiac catheterization/angiocardiography procedures which were performed in Pediatric Cardiology Department, Medical Faculty of Erciyes University).

Ethics

Ethics Committee Approval: The study was conducted in accordance with the Declaration of Helsinki and good clinical practice ethics. The study was approved by the Ethics Committee of Kayseri City Hospital (date: 26.11.2024, approval number: 252/2024).

Footnotes

Informed Consent: Because the study was designed retrospectively no written informed consent form was obtained from the patients.

Author Contributions: Soylu Üstkoyuncu P: Concept, Design, Data Collection or Processing, Analysis or Interpretation, Literature Search, Writing; Üzüm K: Surgical and Medical Practices, Concept, Design, Data Collection or Processing, Literature Search; Narin N: Surgical and Medical Practices, Design; Baykan A: Surgical and Medical Practices, Concept, Design; Onan SH: Surgical and Medical Practices, Data Collection or Processing; Sezer S: Surgical and Medical Practices, Data Collection or Processing.

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