

## The effect of the duration of the procedure on the risk of complications during pediatric cardiac catheterization

*İşlem süresinin pediatrik kardiyak kateterizasyon sırasındaki komplikasyon riski üzerine etkisi*

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### ABSTRACT

**Background:** This study aims to evaluate the frequency of and associated risk factors for adverse events caused by cardiac catheterization procedures in pediatric patients.

**Methods:** Between January 2009 and January 2012, a total of 599 pediatric patients (320 males, 279 females; mean age 5.4±4.7 years; range, 1 day to 21 years) who underwent cardiac catheterization in our cardiac catheterization laboratory were retrospectively analyzed. Demographic and clinical data of the patients including the duration of the procedure, management of anesthesia, the American Society of Anesthesiologists class, and Catheterization Risk Score for Pediatrics, and procedure-related serious adverse events were recorded.

**Results:** The incidence of procedure-related serious adverse events was 9.18%. Potential risk factors associated with serious adverse events were identified as interventional heart catheterization, high scores obtained from the Catheterization Risk Score for Pediatrics, the use of endotracheal tube in airway control, and prolonged procedural duration.

**Conclusion:** Our study results suggest that prolonged duration of catheterization is a potential risk factor for procedure-related adverse events and the duration of the procedure needs to be included as a variable in the Catheterization Risk Score for Pediatrics scoring system for predicting procedure-related adverse events.

**Keywords:** Adverse event, cardiac catheterization, congenital heart disease.

### ÖZ

**Amaç:** Bu çalışmada çocuk hastalarda kardiyak kateterizasyon işlemlerinin neden olduğu advers olayların sıklığı ve ilişkili risk faktörleri değerlendirildi.

**Çalışma planı:** Ocak 2009 and Ocak 2012 tarihleri arasında kardiyak kateterizasyon laboratuvarımızda kalp kateterizasyonu yapılan toplam 599 çocuk hasta (320 erkek, 279 kız; ort. yaş 5.4±4.7 yıl; dağılım, 1 gün-21 yıl) retrospektif olarak incelendi. İşlem süresi, anestezi yönetimi, Amerikan Anesteziyoloji Derneği sınıfı ve Pediatrik Kateterizasyon Risk Skoru ve işleme bağlı ciddi advers olaylar dahil olmak üzere hastaların demografik ve klinik verileri kaydedildi.

**Bulgular:** İşleme bağlı ciddi advers olay insidansı, %9.18 idi. Ciddi advers olaylar ile ilişkili muhtemel risk faktörleri; girişimsel kardiyak kateterizasyon, Pediatrik Kateterizasyon Risk Skoru'nun yüksek olması, havayolu kontrolü için endotrakeal tüp kullanılması ve uzun işlem süresi olarak belirlendi.

**Sonuç:** Çalışma sonuçlarımız, uzun süreli kateterizasyonun işleme bağlı ciddi advers olaylar için muhtemel bir risk faktörü olduğunu ve işlem süresinin Pediatrik Kateterizasyon Risk Skoru skorlama sistemine bir değişken olarak dahil edilmesi gerektiğini göstermektedir.

**Anahtar sözcükler:** Advers olay, kardiyak kateterizasyon, doğuştan kalp hastalığı.

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Pediatric cardiac catheterization is usually performed for the diagnosis and the interventional treatment of congenital heart diseases or hemodynamic problems.<sup>[1]</sup> However, cardiac catheterization has various potential complications. Previous studies have reported several risk factors associated with the complications during cardiac catheterization procedures.<sup>[2-9]</sup> The Catheterization Risk Score for Pediatrics (CRISP) is commonly used to predict the risk of any serious adverse event (SAE).<sup>[10]</sup> The SAEs include any adverse event causing mortality, permanent morbidity, the need for further interventions, or the prolonged length of stay in the hospital.<sup>[10]</sup> The CRISP evaluates eight variables (i.e., age, body weight, the need for inotropic support, the presence of systemic disease/failure, physiologic category, pre-catheterization diagnosis, procedure risk category, and procedure type) through a web-based CRISP calculator\* (Table 1)<sup>[11]</sup>

In this study, we aimed to evaluate the CRISP for cardiac catheterization procedures in a pediatric heart center and to assess SAEs and associated risk factors in this patient population.

## PATIENTS AND METHODS

This retrospective, cross-sectional study included a total of 599 patients (320 males, 279 females; mean age 5.4±4.7 years; range, 1 day to 21 years) who underwent cardiac catheterization between January 2009 and January 2012. Patients whose medical files could not be accessed were excluded from the study. Demographic

data, the American Society of Anesthesiologists (ASA) class, CRISP, the type of cardiac catheterization, anesthesia management, procedure duration (the duration from percutaneous catheter insertion until removal), and data regarding SAEs were obtained from the anesthesia follow-up forms of the patients. A written informed consent was obtained from each parent. The study protocol was approved by Dr. Behçet Uz Child Disease and Pediatric Surgery Training and Research Hospital Ethics Committee (No. 2017/152). The study was conducted in accordance with the principles of the Declaration of Helsinki.

The catheterization procedures were diagnostic or interventional purposes. All procedures were compared considering hybrid catheterizations as interventional procedures. All catheterization procedures were performed under sedation or inhalational general anesthesia. During sedation analgesia, airway management was provided with a natural unaided airway. During inhalational general anesthesia, airway patency was provided with an endotracheal tube (ETT), a laryngeal mask airway (LMA), or a facial mask. An intramuscular cardiologic cocktail containing pheniramine maleate (45.5 mg/2 mL), chlorpromazine (25 mg/5 mL), and meperidine (100 mg/2 mL) was used at a dose of 0.1 mL/kg (up to maximum 2 mL) for the premedication in patients older than one year of age. All patients underwent non-invasive monitoring including heart rhythm, oxygen saturation (SpO<sub>2</sub>), non-invasive blood pressure (NIBP), and RR interval every 5 min, until they left the catheterization laboratory.

**Table 1. Calculation of the risk score**

Assigned points	0	1	2	3	4
Age (year)	>1		<1		
Weight (kg)	>5		<5		
Inotropic support	None/yes-stable		Yes-unstable/ ECMO		
Systemic illness/organ failure	None/medically controlled/ one organ failure		Uncontrolled/ >1 organ failure		
Physiologic category	Category 1	Category 2		Category 3	
Pre-catheterization diagnosis	Category 1	Category 2/ Category 3			
Procedure risk category	Category 1	Category 2		Category 3	
Procedure type	Diagnostic			Interventional/ hybrid	

ECMO: Extracorporeal membrane oxygenation.

**Table 2. Serious adverse events during diagnostic and interventional catheterization**

Type of complications	Diagnostic catheterization (n)	Interventional catheterization (n)
Arrhythmias requiring pharmacologic intervention*	13	10
Increase in hemodynamic support	2	1
Bronchospasm	11	17
Transient apnea	4	1
Vomiting	2	1
Allergic reactions	1	1
Seizure	1	1
Cardiac arrest	1	-
Death	1	-
Total	36	32

\*: Bradyarrhythmia, left bundle branch block, atrioventricular block, supraventricular tachyarrhythmia, ventricular tachyarrhythmia, ventricular fibrillation, Torsades de pointes.

### Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean  $\pm$  standard deviation (SD), median (min-max), or number and frequency. The normality distribution of variables was assessed by the Kolmogorov-Smirnov test. In the analysis of quantitative data for independent groups, the Mann-Whitney U test was used. The chi-square test or Fischer's exact test was used in the analysis of qualitative data for independent groups. Univariate and multivariate logistic regression analyses were also done. A *p* value of <0.05 was considered statistically significant.

### RESULTS

Of 599 patients, a total of 68 SAEs were reported in 55 patients who underwent cardiac catheterization procedures for diagnostic or interventional purposes. The overall incidence of SAEs was 9.18%.

Arrhythmia was the most common SAE in diagnostic catheterizations, while laryngospasm was the most common SAE during interventional catheterizations. The SAEs were categorized as cardiac events, airway events, vomiting, allergic reactions, seizure, cardiac arrest, and death. Cardiac events in patients having cardiac catheterization included bradyarrhythmia, left bundle branch block, atrioventricular block, supraventricular tachyarrhythmia, ventricular tachyarrhythmia, ventricular fibrillation, Torsades de pointes, and unexpected cardiac arrest. Only one patient (0.16%),

who was critically ill and required inotropic and ventilator support before catheterization, died during cardiac catheterization. Diagnostic cardiac catheterization and balloon angioplasty were planned for this patient. However, this patient died during diagnostic cardiac catheterization. The patient had cardiopulmonary arrest and did not respond to the cardiopulmonary resuscitation for more than 30 min (Table 2).

The airway events such as bronchospasm, transient hypoventilation, and apnea were experienced in patients having cardiac catheterization. Transient hypoventilation and apnea were caused by an LMA shift in two patients and a deepening of sedation-analgesia in six patients. Therefore, these eight patients required bag-mask ventilation and LMA insertion. The distribution of SAEs experienced during diagnostic and interventional catheterizations is shown in Table 2.

In order to further investigate the risk factors of these SAEs, we divided the patients into two groups as those with and without SAEs. A comparison of the characteristics of patients with and without SAEs is shown in Table 3.

Univariate and multivariate analyses revealed three independent risk factors for SAEs: procedure duration (odds ratio [OR]= 1.04, 95% confidence interval [CI]: 1.03-1.06), interventional procedure (OR= 0.21, CI: 0.07-0.56), airway control with endotracheal tube (OR= 6.25, CI: 2.92-13.42) (*p*<0.05) (Table 4).

A comparison of the patients with and without SAEs indicated that a high CRISP score (*p*<0.001),

**Table 3. Demographic and clinical characteristics of patients**

	SAE (+)				SAE (-)				p
	n	%	Mean±SD	Median	n	%	Mean±SD	Median	
Age (month)			33.3±60.7	6.0			39.9±62.5	7.0	0.324*
Sex									0.695†
Female	27	49.1			252	46.3			
Male	28	50.9			292	53.7			
Weight (kg)			19.3±16.0	16.0			19.6±14.5	15.0	0.578†
Accompanying syndroms (Down, Turner, Williams, Eisenmenger)									0.238*
(+)	1	1.8			30	5.5			
(-)	54	98.2			514	94.5			
With cyanosis									0.208*
(+)	10	18.2			141	25.9			
(-)	45	81.8			403	74.1			
Procedure duration (min)			71.7±18.1	70.0			44.1±21.4	40.0	0.000†
Procedure type									
Diagnostic procedure	24	43.6			368	67.6			0.000*
Interventional procedure	25	45.5			157	28.9			0.011*
Hybrid procedure	6	10.9			19	3.5			0.009*
Pre procedure SpO <sub>2</sub>			94.1±5.6	96.0			92.8±6.9	95.0	0.178†
Catheterization type									
Diagnostic procedure	24	43.6			368	67.6			<b>0.000*</b>
PDA device	0	0.0			25	4.6			0.104*
ASD device	24	43.6			39	7.2			<b>0.000*</b>
Ballon atrial septostomy	0	0.0			6	1.1			1.000*
Coarctation angioplasty	1	1.8			24	4.4			0.359*
VSD device	2	3.6			7	1.3			0.197*
Pulmonary balloon valvuloplasty	1	1.8			38	7.0			0.139*
Aortic balloon valvuloplasty	2	3.6			27	5.0			0.662*
Pace maker implantation	1	1.8			9	1.7			1.000*
Pace maker removing	0	0.0			1	0.2			1.000*
Anesthesia management									
Sedation-analgesia	13	23.6			322	59.2			0.000*
Facemask	4	7.3			118	21.7			0.011*
Laryngeal mask airway	5	9.1			41	7.5			0.680*
Endotracheal tube	33	60.0			63	11.6			0.000*
ASA class									0.068*
II	3	5.5			43	7.9			
III	20	36.4			273	50.2			
IV	32	58.2			228	41.9			
CRISP score			5.8±2.8	6.0			4.2±2.9	4.0	0.000†

SAE: Serious adverse event; SD: Standard deviation; PDA: Patent ductus arteriosus; ASD: Atrial septal defect; VSD: Ventricular septal defect; ASA: The American Society of Anesthesiologists; CRISP: Catheterization Risk Score for Pediatrics; \* Chi-square test (Fischer exact); † Mann-Whitney U test.

airway control with ETT (p<0.001), and interventional procedure (p=0.012) were associated with the risk of SAEs. More remarkably, the duration of the procedure was significantly longer in patients with SAEs

(p<0.001). The SAEs occurred in 55 patients, of whom 42 (76.4%) were operated under general anesthesia, and 13 (23.6%) were operated under sedation-analgesia. The rate of SAEs among the patients who underwent

**Table 4. Risk factors for serious adverse events of cardiac catheterization**

	Univariate model			Multivariate model		
	OR	95% CI	<i>p</i>	OR	95% CI	<i>p</i>
CRISP score	1.18	1.08-1.28	0.000			
Procedure duration	1.05	1.03-1.06	0.000	1.04	1.03-1.06	0.000
Diagnostic procedure	0.37	0.21-0.65	0.001			
Interventional procedure	2.05	1.17-3.60	0.012	0.21	0.07-0.56	0.002
Hybrid procedure	3.38	1.29-8.87	0.013			
Endotracheal tube	11.45	6.29-20.87	0.000	6.25	2.92-13.42	0.000

OR: Odds ratio; CI: Confidence interval; CRISP: Catheterization Risk Score for Pediatrics.

**Table 5. Distribution of patients with SAE according CRISP score and risk category**

CRISP score	Risk category	All patients	Patients having complication SAE (n=55)	Patients having complication SAE	Nykanen et al. <sup>[12]</sup>	Nykanen et al. <sup>[12]</sup> SAE (n=665)	Nykanen et al. <sup>[12]</sup> SAE
0 to 2	CRISP 1	218	3	1.37	2969	29	1
3 to 5	CRISP 2	197	22	11.16	6622	171	2.6
6 to 9	CRISP 3	161	25	15.52	3777	235	6.2
10 to 14	CRISP 4	18	3	16.66	1308	188	14.4
15 or more	CRISP 5	5	2	40.00	114	42	36.8

SAE: Serious adverse event; CRISP: Catheterization Risk Score for Pediatrics.

general anesthesia was higher than that of the sedated patients. The rate of airway control with ETT was significantly higher in those with SAEs.

The incidence of SAEs was analyzed in patients categorized in terms of CRISP scores. The rates of SAEs in patients with CRISP Category 1 to Category 5 were 1.37%, 11.16%, 15.52%, 16.66%, and 40%, respectively (Table 5).

## DISCUSSION

Cardiac catheterization in pediatric patients with congenital heart disease has a risk of morbidity and mortality. The reported rates of SAEs range from 6.16 to 11.3%, while mortality rates range from 0.09 to 0.22%.<sup>[2-4,6]</sup> These rates were 9.18% and 0.16%, respectively in our study.

Young age, low body weight, having interventional procedures, the requirement inotropic support during the procedure, accompanying of non-cardiac problems, low peripheral oxygen saturation, and longer procedures have previously been shown to be risk factors for SAEs.<sup>[6,12,20]</sup> In our study, multivariate analysis revealed three independent risk factors: the

duration of the procedure, interventional procedure, airway control with ETT. Lin et al.<sup>[12]</sup> reported the rate of SAEs to be 0.4% in patients with whom the cardiac catheterization took less than 60 min, while the rate increased up to 0.8% in those with the duration of procedure between 60 and 180 min and 1.3% in those with a duration longer than 180 min. The duration of procedure was also demonstrated to be a risk factor by Bergersen et al.<sup>[21]</sup> who reported that the risk of SAEs significantly increased, when the duration of the procedure for cardiac catheterization was longer than 60 min. These authors found that the rate of SAEs was 6% when the duration was less than 60 min; 15% when the duration was between 60 and 120 min; 31% when it was between 120 and 180 min; and 38% when it was longer than 180 min.

The risk of SAEs may increase due to prolonged duration of procedure in interventional catheterization.<sup>[2-4,6,7,12,21,22]</sup> Several studies have demonstrated that SAEs are more frequent during intervention procedures, particularly with aortic valve dilatation, atrial septostomy, and balloon interventions.<sup>[2,4,6,23-26]</sup>

Applying the positive intrathoracic pressure (during ETT) in controlled ventilation induces undesired inferior vena cava compression, which reduces venous return for the preload. The ETT application is, therefore, considered a potential risk factor compared to the face-mask.<sup>[13,18]</sup> Flick et al.<sup>[18]</sup> found that the use of ETT was riskier for the development of laryngospasm. A study focusing on the perioperative morbidity in pediatric anesthesia reported that complications were more frequent in patients who underwent endotracheal intubation.<sup>[13]</sup> Likewise, our findings indicated that the rate of complications was higher in the intubated patients, compared to the patients managed with other airway devices.

The main limitation of our study was its retrospective and single-center design.

In conclusion, the Catheterization Risk Score for Pediatrics accurately predicts procedural risk, and an extended procedure time is a crucial risk factor, irrespective of the type of catheterization (i.e., diagnostic or interventional) or anesthesia. Therefore, time matters in a catheterization laboratory. Nonetheless, multi-center, large-scale, long-term prospective studies are needed to confirm these findings.

#### Declaration of conflicting interests

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