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Validation of the Turkish Version of the Catheterization Risk Score for Pediatrics

ORIGINAL INVESTIGATION

ABSTRACT

Background: The aim of this study was to perform a validity analysis of the Turkish version of the Catheterization Risk Score for Pediatrics.

Methods: The study sample consisted of 419 pediatric patients who underwent cardiac catheterization. Patient risk factors and outcomes were collected using the revised (r) Catheterization Risk Score for Pediatric score (21 points) and Catheterization Risk Score for Pediatric score-20 point (Nykanen score). The serious adverse events and non-serious adverse event complications that occurred during and after the procedure were recorded. The revised Catheterization Risk Score for Pediatrics and Catheterization Risk Score for Pediatrics score-20 points were administered by pediatric cardiologists. The content validity index was calculated based on expert opinions. Chi-square, correlation, and regression analyses were used.

Results: The mean age of the pediatric patients was 4.5 ± 4.8 years. Of the patients, 50.1% were male (n = 210) and 85% (n = 356) had acyanotic heart disease. The patients' Catheterization Risk Score for Pediatrics score-20 point and revised Catheterization Risk Score for Pediatrics score were 5.9 ± 2.5 (range, 3-16) and 4.0 ± 2.5 (range, 0-16), respectively. Serious adverse events developed in 10.7% (n = 45) of the patients and were found to be related with patient status/timing of catheterization, age, weight, respiratory status, and American Society of Anesthesiologist scores ($P < .05$). Significant positive correlations were found between the incidence of serious adverse events and total revised Catheterization Risk Score for Pediatrics score (21 points), total Catheterization Risk Score for Pediatrics score-20 point, and American Society of Anesthesiologist score ($P < .01$).

Conclusion: The revised Catheterization Risk Score for Pediatrics score (21 points) and Catheterization Risk Score for Pediatrics score-20 point are valid tools for predicting pre-procedural risk in the Turkish population.

Keywords: Pediatrics, cardiac catheterization, adverse event, risk score, validation

INTRODUCTION

Despite advances in the non-invasive evaluation of patients with congenital heart disease (CHD), cardiac catheterization remains essential for studying the heart structure and hemodynamics with the advancement of interventional procedures. Changes in catheterization techniques, equipment, procedures, patient selection, and pre-procedural medical management have resulted in improvements in catheterization-related morbidity and mortality rates. Studies on the risk factors for cardiac catheterization in children are limited. Multi- or single-center retrospective cohort studies are available.[1] Bergersen et al[2] defined adverse events and risk adjustment and developed the multivariate Catheterization for Congenital Heart Disease Adjustment for Risk Method model to predict adverse events in patients with CHD.[2] In the study by Nykanen et al[3] data from the Comprehensive Continuous Integrated System of Care between 2008 and 2013 were used to validate the Catheterization Risk Score for Pediatrics (CRISP). The CRISP score estimates the risk of procedure-related serious adverse events (SAEs).[3] Hill et al[4] also validated the CRISP. They re-fitted the original CRISP model and developed the revised (r) CRISP. The rCRISP score showed a risk prediction ability similar to original CRISP score. The timing of catheterization, pre-catheterization airway status,

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and American Society of Anesthesiologists (ASA) score did not provide significant data.[4]

In this study, we aimed to perform a validity analysis of the CRISP score by comparing the predicted risk based on our observed incidence of adverse events and based on the CRISP score in patients indicated to undergo catheterization procedures within a 2-year period.

METHODS

Study Design and Population

This is a single-center validity study. In the first phase of the research, back and forward translations of the rCRISP score (21 points) and the original CRISP score-20 point (Nykanen score) were made. The scores were finalized after obtaining expert opinions and consensus on the translations.

These scales were used in pediatric patients who underwent catheterization. A total of 419 patients who underwent catheterization at the cardiac catheterization unit between July 2018 and July 2020 were included in the study. Cardiac catheterization procedures were divided into diagnostic and interventional groups. The diagnostic procedures were transcatheter procedures performed only to confirm a diagnosis or as hemodynamic studies, in which no intervention was made in the patient, such as transcatheter therapies. The interventional operations performed were aortic valvuloplasty, pulmonary valvuloplasty, balloon atrial septostomy, aortic coarctation angioplasty, patent ductus arteriosus (PDA) closure, secundum atrial septal defect (ASD) closure, ventricular septal defect (VSD) closure, stenting for aortic coarctation or peripheral pulmonary stenosis, and pacemaker implantation. The CRISP score-20 point and rCRISP score (21 points) were calculated for all patients before the procedure. Serious adverse events and non-SAE complications that occurred during and after the procedure were recorded. This study was approved by the hospital's clinical Ethics Committee (approval number: 2018/217 and June 28, 2018). Written informed consent was obtained from each parent.

Study Definitions

Patient risk factors and outcomes were collected using the rCRISP score (21 points) and CRISP score-20 points (Nykanen score). The scores were used to predict SAE risk from cardiac catheterization. The CRISP score-20 point consisted of 10 variables developed on the basis of the consensus opinions of pediatric cardiologists. Each variable was classified into 3 levels of perceived increasing risk.[3] Hill et al[4] validated the CRISP score-20 point and found that with minor modifications (rCRISP score), it performed well in pre-procedural risk prediction. They re-defined physiologic sub-scores and procedure types. Compared with the CRISP score-20 point, the rCRISP score showed a similar risk prediction ability.[4]

Catheterization Risk Score for Pediatrics Score-20 Point (Nykanen Score)

A 10-component scoring system was developed on the basis of expert consensus. It includes patient status/timing of catheterization (X1), age (X2), weight (X3), inotropic support (X4), respiratory status (X5), systemic illness/failure (X6), ASA score (X7), physiological category (X8), pre-catheterization diagnosis (X9), and procedure risk category (X10).[3]

Revised Catheterization Risk Score for Pediatrics Score (21 Point)

Each variable was classified into 3 levels. The rCRISP score includes patient age (X2), weight (X3), inotropic support (X4), systemic illness/organ failure (X6), physiological category (X8), pre-catheterization diagnosis (X9), procedure category (X10), and procedure type (X11).[4]

Validity Analysis

The scales were finalized after obtaining expert opinions and consensus on the translations. For the rCRISP score (21 points) and CRISP score-20 point (Nykanen score), the translation–back translation method was used, and the content validity index (CVI) was calculated. The translated and original versions were evaluated by 8 pediatric cardiologists, who scored the items between 1 and 4 points (1=not suitable, 2=needs much correction, 3=needs little correction, and 4=very appropriate). The CVI value was 1.00 for all risk factors. The content validity for the CRISP scores was analyzed using Kendall's W. There was no statistically significant difference between the experts' opinions (Kendall's W: 0.573; $P=.104$). To evaluate the validity of the CRISP score, the consistency of the rCRISP and CRISP score-20 point between 2 pediatric cardiologists was assessed. The rCRISP and CRISP score-20 point were applied by the 2 pediatric cardiologists to the same patient. The kappa coefficient was calculated to determine inter-rater agreement. The CRISP scores had a kappa coefficient of 1.00 between the 2 pediatric cardiologists for all risk score items. This proficient level of consistency showed that the CRISP is valid for the Turkish population.

The CRISP score-20 point and rCRISP scores were applied to 419 patients. The total scores and items of the scores were compared with each other using Kendall's Tau-B correlation analysis. The CRISP score-20 point and rCRISP scores had similar content, and the differences in scores obtained from 2 scores were also tested with the Paired sample *t*-test.

The patients' characteristics and the development of SAEs were evaluated using a chi-square analysis. The relationship between the incidence of SAEs and the risk category based

HIGHLIGHTS

- Serious adverse event (SAE) developed in 10.7% (n=45) of the patients.
- The patients' SAE incidence correlated with total revised Catheterization Risk Score for Pediatrics (rCRISP) score (21 point), total CRISP Score-20 point, and American Society of Anesthesiologist score.
- Patient's age, respiratory status, systemic illness/failure, physiologic and procedure category, pre-catheterization diagnosis, and procedure type predicted 67% of SAE.
- The rCRISP score (21 points) and CRISP Score-20 points are valid tools for Turkish population.

on the CRISP score was evaluated using correlation analysis. The correlations of the incidence of SAEs with the total CRISP score-20 point (Nykanen score), total rCRISP score, and ASA score were evaluated.

Linear regression was used for predictive validity between total CRISP score and SAEs. The regression analysis was performed to identify the patients' procedural characteristics that could explain the incidence of SAEs. Mean, standard deviation, and percentage distribution data were used to express the descriptive variables. The Statistical Package for the Social Sciences 22.0 Microsoft for Windows program (IBM Corp; Armonk, NY, USA) was used in the analysis. The results were evaluated at a 95% CI, and those with P values < .05 were considered significant.

RESULTS

Patient Characteristics

The mean age of the patients was 4.5 ± 4.8 years (range, 1 day-21 years). Of the patients, 50.1% were male (n=210), and 85% (n=356) had acyanotic heart disease and 15% (n=63) had cyanotic heart disease. The heart disease was PDA in 20.8% (n=87) of the patients, VSD in 20% (n=84), ASD in 17.2% (n=72), pulmonary stenosis in 9.3% (n=39), aortic coarctation in 6% (n=25), double outlet right ventricle in 5% (n=21), tetralogy of Fallot in 4.1% (n=17), aortic stenosis in 3.8% (n=16), pulmonary atresia in 2.1% (n=9), peripheral pulmonary stenosis in 1.9% (n=8), subaortic stenosis in 1.4% (n=6), supravalvular aortic stenosis in 1.2% (n=5), atrioventricular septal defect in 1% (n=4), total anomalous pulmonary venous drainage in 1% (n=4), transposition of the great arteries in 0.7% (n=3), tricuspid atresia in 0.7% (n=3), truncus arteriosus in 0.7% (n=3), hypoplastic left heart in 0.5% (n=2), and other diseases in 2.2% (n=11).

Genetic disease was found in 8.8% (n=37) of the patients. Down syndrome (4.3%, n=18), Williams syndrome (1%, n=4), Noonan syndrome (0.7%, n=3), and other genetic diseases were the most common. Of the patients, 3.3% (n=14) received prostaglandin E1 before the procedure.

Catheterization Risk Score for Pediatrics Scores

An elective procedure was performed in 85% (n=356) of the patients, of whom 67.3% (n=282) were aged < 1 year, 60.6% (n=254) weighed > 10 kg, and 93.6% (n=392) did not receive inotropic support before the procedure. Of the patients, 84.2% (n=353) did not receive airway support, 90.7% (n=380) had no systemic disease, and 80.2% (n=336) had an ASA score of 3. The assessments of the patients were as follows: physiological category 1 in 90.5% of the patients, pre-catheterization diagnosis 1 in 69% (n=289), procedure risk category 1 in 80% (n=335), and interventional procedure type in 64% (n=268).

When the total scores and sub-dimensions of the scores were compared with each other, there was a correlation between sub-dimensions and total CRISP scores (Kendall's Tau-B=0.121-1.000, P < .01), excluding the procedure risk category (Table 1) (n=419). A weak correlation was found between the procedure risk category (X10) and the physiological Category (X8) (r=0.115, P=0.016) and pre-catheterization diagnosis (X9) (r=0.131, P < .01). A moderate correlation was found between the procedure risk category (X10) and rCRISP scores (r=.575, P < .01), and CRISP score-20 point (r=.326, P < .01). The CRISP score-20 point had similar content validity with the rCRISP-21 point score adapted to Turkish.

The average CRISP score-20 point was 5.9 ± 2.5, and the average rCRISP score was 4.0 ± 2.5. There was no statistically significant difference in scores obtained from paired samples (t=20.475, P < .01).

The SAE explained 7% of total CRISP score-20 point (F=1.193, P < .01). There was a positive correlation (β=1.192, P < .01) between SAE and total CRISP score-20 point. The SAE explained 38% of total rCRISP-21 point (F=262.681, P < .01). There was a positive correlation (β=0.854, P < .01) between SAE and total rCRISP-21 point.

Development of Serious Averse Events

Serious adverse events developed in 10.7% (n=45) of the patients. The patients often developed arrhythmia (n=15, 3.6%), cardiac arrest (n=9, 2.1%), airway compromise (n=5, 1.2%), pulmonary compromise (n=3, 0.7%), device migration (n=3, 0.7%), pericardial effusion (n=2, 0.5%), and vascular injury (n=2, 0.5%). Atrioventricular block (n=7), nodal rhythm (n=3), and supraventricular tachycardia (n=5) were frequently found in the patients with arrhythmia. The patients with airway compromise (inappropriate extubation, bronchospasm, etc.) were admitted to the intensive care unit and provided with mechanical ventilator support. Pulmonary hypertensive crisis was detected in 1 patient with pulmonary compromise, and pulmonary edema was detected in the other 2 patients. In a patient with device migration, the stent applied for coarctation migrated to the abdominal aorta, so the patient underwent repeated angiography to correct the placement of the stent. In the device procedure for the other patient with VSD, the device migrated to the pulmonary artery and was removed with the help of a snare. In the device procedure in the other patient with PDA, the device that migrated to the pulmonary artery was removed with a snare. In the VSD device procedure, surgical ventricular repair and surgical pericardial effusion evacuation were performed after the right ventricle was perforated during the delivery of the catheter. Cardiac tamponade developed owing to perforation caused by the Amplatzer wire during the balloon valvuloplasty procedure for critical pulmonary stenosis. The fluid was drained surgically. In 2 patients with vascular injury, vascular repair was performed by the pediatric cardiovascular surgery team because of damage to the vessel wall during sheath placement.

When the patients' characteristics were compared according to the development of SAEs, the development of SAEs was found to be related to patient status/timing of catheterization, age, weight, respiratory status, and ASA score (P < .05). Serious adverse events were more common in the patients aged < 30 days, in those weighing < 2.5 kg, and in those with emergent/urgent catheterization. The patients who did not receive airway support had lower incidence rates of SAEs than those with airway support. Seven patients died after the procedures.

Table 1. Kendall's Tau–B Correlations

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1	X1																				
2	X2	0.418**																			
3	X3	0.333**	0.790**																		
4	X4	0.357**	0.331**	0.270**																	
5	X5	0.556**	0.554**	0.471**	0.482**																
6	X6	0.464**	0.387**	0.319**	0.750**	0.472**															
7	X7	0.308**	0.306**	0.296**	0.306**	0.357**	0.329**														
8	X8	0.154**	0.133**	0.141**	0.216**	0.219**	0.124*	0.275**													
9	X9	0.236**	0.128**	0.121*	0.113*	0.195**	0.098*	0.226**	0.302**												
10	X10	0.083	0.029	0.004	0.034	0.128**	0.042	0.134**	0.115*	0.131**											
11	CRISP-20 point	0.287**	0.433**	0.331**	0.214**	0.381**	0.263**	0.260**	0.062	0.181**	0.525**										
12	X2	0.418**	1.000**	0.790**	0.331**	0.554**	0.387**	0.306**	0.133**	0.128**	0.029	0.433**									
13	X3	0.333**	0.790**	1.000**	0.270**	0.471**	0.319**	0.296**	0.141**	0.121*	0.004	0.331**	0.790**								
14	X4	0.357**	0.331**	0.270**	1.000**	0.482**	0.750**	0.306**	0.216**	0.113*	0.034	0.214**	0.331**	0.270**							
15	X6	0.464**	0.387**	0.319**	0.750**	0.472**	1.000**	0.329**	0.124*	0.098*	0.042	0.263**	0.387**	0.319**	0.750**						
16	X8	0.154**	0.133**	0.141**	0.216**	0.219**	.124*	0.275**	1.000**	0.302**	0.115*	0.062	0.133**	0.141**	0.216**	0.124*					
17	X9	0.236**	0.128**	0.121*	0.113*	0.195**	0.098*	0.226**	0.302**	1.000**	0.131**	0.181**	0.128**	0.121*	0.113*	0.098*	0.302**				
18	X10	0.083	0.029	0.004	0.134	0.128**	0.042	0.134**	0.115**	0.131**	1.000**	0.525**	0.029	0.004	0.034	0.042	0.115*	0.131**			
19	X11	0.112*	0.157**	0.215**	0.127**	0.071	0.084	0.149**	0.363**	0.368**	0.354**	0.410**	0.157**	0.215**	0.127**	0.084	0.363**	0.368**	0.354**		
20	rCRISP score	0.490**	0.611**	0.614**	0.345**	0.514**	0.403**	0.524**	0.294**	0.412**	0.326**	0.486**	0.611**	0.614**	0.345**	0.403**	0.294**	0.412**	0.326**	0.210*	

*$P \leq .05$; **$P \leq .01$

CRISP, Catheterization Risk Score for Pediatrics; rCRISP, revised Catheterization Risk Score for Pediatrics.

Table 2. CRISP Score Point Assignment and Chi-Square Analysis of SAE by Patient/Procedural Characteristics

Patient Clinical Characteristics	The CRISP Score-20 Point	The rCRISP Score-21 Point	n (%)	SAE (%)	*P*
Patient status/timing (X1)					
Elective	0		356 (85.0)	28 (7.9)	<.001
Emergency/urgent	1		46 (11.0)	16 (34.8)	
Post-operative	2		17 (4.1)	1 (5.9)	
Age (X2)					
>1 year	0	0	282 (67.3)	22 (7.8)	<.001
30 days-1 year	1	2	110 (26.3)	11 (10.0)	
<30 days	2	2	27 (6.4)	12 (44.0)	
Weight (X3)					
> 10 kg />5 kg*	0	0	254 (60.6)	20 (7.9)	.003
2.5-10 kg/2.5-5 kg*	1	2	158 (37.7)	22 (13.9)	
<2.5 kg	2	2	7 (1.7)	3 (42.9)	
Inotropic support (X4)					
None	0	0	392 (93.6)	40 (10.2)	.151
Yes—stable	1	0	27 (6.4)	5 (18.5)	
Yes—unstable or ECMO	2	2	-(-)	-(-)	
Respiratory status (X5)					
Own airway	0		353 (84.2)	26 (7.4)	<.001
Stable on ventilator or known difficult/unusual airway	1		62 (14.8)	18 (29.0)	
Respiratory failure on mechanical ventilation	2		4 (1.0)	1 (25.0)	
Systemic illness/failure (X6)					
none	0	0	380 (90.7)	37 (9.7)	.089
Medically controlled or 1 organ system failure	1	0	36 (8.6)	7 (19.4)	
Uncontrolled or >1 organ system failure	2	3	3 (0.7)	1 (33.3)	
ASA score (X7)					
1 or 2	0		55 (13.1)	5 (9.1)	.001
3	1		336 (80.2)	31 (9.2)	
4 or 5	2		28 (6.7)	9 (32.1)	
Physiologic category (X8)					
Category 1	0	0	379 (90.5)	38 (10.0)	.228
Category 2	1	1	37 (8.8)	6 (16.2)	
Category 3	2	4	3 (0.7)	1 (33.3)	
Pre-catheterization diagnosis (X9)					
Category 1	0	0	289 (69.0)	27 (60.0)	.377
Category 2	1	2	124 (29.6)	17 (37.8)	
Category 3	2	2	6 (1.4)	1 (16.7)	
Procedure risk category (X10)					
Category 1	0	0	335 (80.0)	31 (9.3)	.093
Category 2	1	1	38 (9.1)	5 (13.2)	
Category 3	2	3	46 (11.0)	9 (19.6)	
Procedure type (X11)					
Diagnostic		0	151 (36.0)	17 (11.3)	.458
Interventional		3	268 (64.0)		
Hybrid		3	-		
				28 (10.4)	
	M ± SD (min-max) 5.9 ± 2.5 (3-16)	**M ± SD (min-max)** 4.0 ± 2.5 (0-16)	419 (100.0)	45 (10.7)	

CRISP, Catheterization Risk Score for Pediatrics; SAE, serious adverse events; SD, standard deviation; ASA, American Society of Anesthesiologists.

Table 3. Incidence of Serious Adverse Events (SAE) by Proposed Risk Category

Risk Category	CRISP Score (21 point)	n (%)	SAE (%) 1 / 2.6 / 6.2 / 14.4 /36.8
CRISP 1	0-2	87 (20.8)	81 (93.1) / 6 (6.9) / - / - / -
CRISP 2	3-5	210 (50.1)	1 (0.5) / 208 (99.0) / 1 (0.5) /- / -
CRISP 3	6-9	106 (25.3)	-/3 (2.8) / 103 (97.2) / - / -
CRISP 4	10-14	14 (3.3)	- / - /1 (7.1) / 13 (92.9) / -
CRISP 5	≥15	2 (0.5)	- / - / - / - / 2 (100.0)
Total		419	82 (19.6) / 217 (51.8) / 105 (25.1) / 13 (3.1) / 2 (0.5)

CRISP, Catheterization Risk Score for Pediatrics.

No significant difference in SAE development status was found when the patients were compared according to inotropic support, systemic illness/failure, pre-catheterization diagnosis, physiological and procedural risk categories, and procedure type ($P > .05$). Although unstable patients or patients receiving extracorporeal membrane oxygenation more frequently received inotropic support than stable patients, the difference between the groups was not significant. Serious adverse events were more common in the patients with uncontrolled or multi-organ system failure, pre-catheterization diagnosis category 2, physiological category 3, and procedural risk category 3 (Table 2).

Incidence of Serious Adverse Events

The incidence rates of SAEs according to CRISP risk category were as follows: 1 in 93.1% (n = 81) of the patients with CRISP category 1 (87%, n = 87), 2.6 in 99% (n = 208) of the patients with CRISP category 2 (50.1%, n = 210), 6.2 in 97.2% (n = 103) of the patients with CRISP category 3 (25.3%, n = 106), 14.4 in 92.9% (n = 13) of the patients in the CRISP category 4 (3.3%,

Table 4. Serious Adverse Events According to the CRISP Risk Category

	n (%)	CRISP Risk Category 1 / 2 / 3 / 4 / 5
Arrhythmia, hemodynamically unstable, requiring pharmacologic intervention	15 (3.6)	2 (13.3) / 7 (46.7) / 5 (33.3) / 1 (6.7) /-
Cardiac arrest, unexpected, within 24 hours of procedure	9 (2.1)	-/ 3 (33.3) / 2 (22.2) / 3 (33.3) / 1 (11.1)
Airway compromise, unanticipated	5 (1.2)	-/ 4 (80.0) 1 (20.0) / - / -
Pulmonary compromise (pulmonary hemorrhage/hemoptysis or pulmonary edema	3 (0.7)	2 (66.7) / 1 (33.3) / - / - / -
Device migration requiring open surgical removal, removal via cut down, or transcatheter retrieval	3 (0.7)	-/ 1 (33.3) / 2 (66.7) / -/ -
Pericardial effusion requiring surgical intervention or pericardial drainage	2 (0.5)	-/ - / 2 (100.0) /- /-
Vascular injury (i.e., dissection, intimal tear, aneurysm) requiring surgical, or transcatheter intervention	2 (0.5)	-/ 2 (100.0) / - / - / -
Anaphylactic reaction	1 (0.2)	-/ 1 (100.0) / - / - / -
Brachial plexus injury	1 (0.2)	-/ - / 1 (100.0) / - / -
Device migration, post-procedure	1 (0.2)	-/ - / 1 (100.0) / - / -
Retroperitoneal hematoma	1 (0.2)	-/ - / 1 (100.0) / - / -
Second organ system injury requiring extended hospitalization or therapeutic intervention	1 (0.2)	-/ - / 1 (100.0) / - / -
Unanticipated escalation of hemodynamic support, CPS/ECMO	1 (0.2)	-/ - / 1 (100.0) / - / -
None	374 (89.3)	
Total	419 (100.0)	

CRISP, Catheterization Risk Score for Pediatrics; CPS, cardiopulmonary support; ECMO, extracorporeal membrane oxygenation.

Table 5. Correlation of SAE Incidence, Total CRISP Score-20 Point (Nykanen Score), Total rCRISP Score-21 Point, and ASA Score

	Incidence of SAE	Total rCRISP Score-21 Point	Total CRISP Score-20 Point	ASA Score
Incidence of SAE	1			
Total CRISP score-21 point	0.861**	1		
Total CRISP score-20 point (Nykanen score)	0.621**	0.708**	1	
ASA score	0.309**	0.337	0.625**	1

SAE, serious adverse event; CRISP, Catheterization Risk Score for Pediatrics; rCRISP, revised Catheterization Risk Score for Pediatrics.

**$P < .001$.

Table 6. Clinical Characteristics Predicting the Incidence of SAE

	Incidence of SAE				
	Model 1				
	Unstandardized Beta	Standard Error	Standardized Beta β	*t*	*P*
Patient status/timing (X1)	−0.213	0.243	−0.029	−0.879	.380
Age (X2)	1.537	0.289	0.264	5.310	.000
Weight (X3)	−0.551	0.303	−0.082	−1.818	.070
Inotropic support (X4)	0.224	0.634	0.016	0.353	.725
Respiratory status (X5)	1.461	0.364	0.165	4.010	.000
Systemic illness/failure (X6)	3.098	0.481	0.284	6.446	.000
ASA Score (X7)	−0.066	0.265	−0.008	−0.250	.803
Physiologic category (X8)	2.133	0.346	0.198	6.162	.000
Pre-catheterization Diagnosis (X9)	1.294	0.228	0.183	5.668	.000
Procedure risk category (X10)	1.878	0.168	0.351	11.201	.000
Procedure type (X11)	2.756	0.256	0.376	10.771	.000
R		**0.822**			
***R*²**		**0.675**			
F		**76.914**			
P		**<.001**			

SAE, serious adverse event.

n=14), and 36.8 in all the patients with CRISP category 5 (0.5%, n=2; Table 3). A significant correlation was found between the incidence of SAEs and the CRISP risk category ($X^2=1.573$, $P<.01$).

Of the patients with SAEs (10.7%, n=45), 3.6% (n=15) had arrhythmia and were hemodynamically unstable, requiring pharmacological interventions. The other SAEs are presented in Table 4. Of the patients who developed arrhythmia (46.7%, n=7), those who were hemodynamically unstable, and requiring pharmacological intervention had a CRISP score of 2. The CRISP score of 33.3% (n=3) of the patients who had an unexpected cardiac arrest within 24 hours of the procedure was 4. Most other SAEs developed in the patients with CRISP scores of 2 and 3 (Table 3). The incidence of SAEs showed positive correlations with the total rCRISP, total CRISP score-20 point, and ASA scores ($P<.01$; Table 5).

The logistic regression analysis results showed that age (X2), respiratory status (X5), systemic illness/failure (X6), physiological category (X8), pre-catheterization diagnosis (X9), procedure category (X10), and procedure type (X11) predicted 67% of SAEs (Table 6).

DISCUSSION

Nyakanen et al[3] have proven that the CRISP score-20 point is a valid predictor of SAEs. The CRISP score-20 point provides an easily calculable estimate of a patient's risk of developing SAEs. A comparison of the CRISP score, which is a robust estimator, with other risk assessment tools by other centers will contribute to the existing literature. Not all variables in the CRISP scoring system may be considered an equal predictor of the incidence of SAEs. Patient status/timing of catheterization, respiratory status, and ASA score may not contribute decisively to the CRISP score. Centers should also consider the determinants they deem important. We used both CRISP scores in our study.

The rCRISP score is based on 8 risk factors, patient status/timing of catheterization, respiratory status, and ASA score, but unlike CRISP score-20 point, it includes procedure type. In this study, the 8-variable rCRISP and 10-variable CRISP score-20 point were calculated for each patient. The patients' total CRISP score-20 point and rCRISP score were 5.9 ± 2.5 and 4.0 ± 2.5, respectively. Serious adverse events developed in 10.7% of the patients. Şahin and Meşe[5] found that the overall incidence of SAEs was 9.18%. The incidence rate of SAEs in our study was similar to those reported in previous studies.[1,2,6]

Our aim in this study was to compare the incidence rates of SAEs according to patient characteristics and to determine whether the CRISP score is an accurate predictor of SAEs. Nyakanen et al[3] found a relationship between the development of SAEs and all patient characteristics included in the CRISP-20 point scoring system. In our study, no significant differences in the incidence rates of SAEs were found when the patients were compared according to inotropic support, systemic illness/failure, pre-catheterization diagnosis, physiological and procedural risk categories, and procedure type. Hill et al[4] also found no significant differences in the incidence of SAEs according to age, inotropic support, and respiratory status. Phillips et al[7] found that patient age, weight, sex, and procedure type did not impact the risk of developing complications.

Nyakanen et al[3] found that CRISP score-20 point had an observed SAE risk of 1%, 2.6%, 6.2%, 14.4%, and 36.8%. In this study, a significant relationship was found between the

incidence of SAEs and the CRISP risk category. Similarly, we found that the incidence rate of SAEs increased as the CRISP category increased.

In our study, 3.6% (n = 15) of the patients developed arrhythmia and were hemodynamically unstable, requiring pharmacological interventions. Hill et al[4] found that 0.87% of their patients had hemodynamic instability requiring chest compressions or inotropic support. Yılmazer et al[8] found that the most common complications were arterial thrombosis, which required intervention. Meanwhile, Mori et al[9] found that the most common complication was arrhythmia.

In this study, the incidence of SAEs correlated with the patients' total rCRISP score, total CRISP score-20 point, and ASA scores. Patient age (X2), respiratory status (X5), systemic illness/failure (X6), physiological category (X8), pre-catheterization diagnosis (X9), procedure category (X10), and procedure type (X11) predicted 67% of the SAEs. The CRISP scoring system is a valuable tool in pre-procedural counseling for pediatric patients.[10] O'Callaghan et al[11] also validated the CRISP score in 5 congenital disease centers.

Although the incidence rate of SAEs was quite low in this study, we found that patients' clinical characteristics are particularly important in determining the incidence of SAEs. We found that 6 of the 8 variables of the rCRISP score, excluding weight (X3) and inotropic support (X4), were highly effective in predicting the incidence of SAEs.

We conclude that the CRISP score is a valid tool for predicting the incidence of SAEs. Future studies should use the validated CRISP scoring system. The rCRISP score is preferable for ease of use.

Study Limitations

This study has several limitations. It was conducted in 1 center, where the incidence rate of SAEs was comparable with those in more than 1 center. Both the revised and original CRISP scoring systems were used in this study. The effects of variables such as ASA score, procedure type, and time of SAE onset could be elucidated more clearly by including patients who underwent catheter angiography in different centers.

CONCLUSIONS

In conclusion, our data show that the rCRISP score and CRISP score-20 point can be used as valid tools for preprocedural risk prediction. The CRISP score focused on SAEs, and several CRISP components predicted the incidence of SAEs. In this study, we determined that CRISP score is a valid tool for SAE risk assessment in the Turkish population.

Ethics Committee Approval: This study was approved by the hospital's (Buca Gynaecology and Pediatrics Hospital, İzmir Dr. Behçet Uz Children's Hospital) Clinical Ethics Committee (approval number: 2018/217 and June 28, 2018).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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