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Research Article

Risk Stratification in Pediatric Cardiac Catheterization Using the CRISP Score: A Cross-Sectional Study in Indonesia

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ABSTRACT

Background: Cardiac catheterization is an essential procedure in managing pediatric congenital heart disease, providing a less invasive alternative to thoracotomy. However, adverse events remain a concern, especially in high-risk patients. The CRISP (Cardiac Risk in Pediatric) score, developed by the Congenital Cardiac Intervention Study Consortium (CCISC), predicts serious adverse events (SAEs) in pediatric cardiac catheterization. Despite its reliability, CRISP has not been implemented in Indonesia. This study evaluates its predictive ability at Dr. Wahidin Sudirohusodo Hospital, Makassar.

Methods: A prospective cross-sectional study was conducted from November 2024 to January 2025. Pediatric patients (<18 years) undergoing elective cardiac catheterization were assigned CRISP scores pre-procedure, and adverse events were recorded. The relationship between CRISP categories and SAE incidence was analyzed.

Results: Among 70 patients, the majority of patients were categorized as CRISP I (67.1%), followed by CRISP II (21.4%), CRISP III (5.7%), and CRISP IV (5.7%), with no CRISP V cases. There were 6 cases (8.6%) of serious adverse events identified, consisting of 4 cases (5.71%) of cardiac arrest and 2 cases (2.89%) of bleeding. A significant correlation was found between higher CRISP risk categories and SAE incidence ($p < 0.001$). SAEs occurred exclusively in CRISP III (50% incidence) and CRISP IV (100% incidence) patients.

Conclusion: The CRISP score effectively stratifies risk in pediatric cardiac catheterization. Higher CRISP categories correlate with increased SAE incidence, supporting its predictive validity. Routine CRISP implementation could enhance pre-procedural planning, risk mitigation, and patient safety in Indonesia. Further studies with larger sample sizes are recommended.

Introduction

Cardiac catheterization plays a crucial role in managing pediatric patients with congenital heart disease, offering a less invasive alternative to thoracotomy and reducing the risks associated with cardiopulmonary bypass (CPB). By eliminating the potential adverse effects of CPB and significantly shortening hospital stays, this procedure has become an essential component of pediatric cardiac care. In recent years, the field has evolved rapidly, with a growing focus on innovative therapeutic approaches that expand non-surgical treatment options, prolong the interval before surgery is needed, and in some cases, even replace open-heart surgery altogether [1-2].

Despite advancements in technology and the high success rate of pediatric cardiac catheterization, adverse

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events still occur in a small percentage of cases. The risk of morbidity and mortality in pediatric/congenital cardiac catheterization laboratories (PCCL) is second only to that in cardiac operating rooms, with unexpected events (UE) reported in 10–11% of cases [3]. Procedure-related complications are estimated to occur in 12.14% of cases, with arrhythmias and hypotension being the most frequently observed [1]. Additionally, complications arising from venipuncture, catheter manipulation, device malfunction, and anesthesia occur in approximately 4–10% of pediatric catheterization procedures. Severe complications, including death, emergency surgery, extracorporeal membrane oxygenation (ECMO) use, prolonged intensive care unit (ICU) stays, and unplanned tracheal intubation, are rare, affecting fewer than 1% of cases. Notably, studies have found a higher incidence of major complications in patients under general anesthesia compared to those receiving sedation [4]. Given these risks, a standardized preoperative assessment tool is needed to predict serious adverse events in pediatric cardiac catheterization.

To address this, the Congenital Cardiac Intervention Study Consortium (CCISC) introduced the CRISP (Cardiac Risk in Pediatric) scoring system in 2015. This validated tool consists of a 21-item questionnaire designed to estimate the likelihood of serious adverse events (SAEs) related to the procedure. The CRISP score has proven to be an effective predictor of SAEs, demonstrating good discriminatory ability with an area under the curve (AUC) of 0.71 (95% CI: 0.66–0.91; $p < 0.008$) [5]. Another multivariate analysis further supported its predictive value, reporting an AUC of 0.741 [6]. By implementing the CRISP score, healthcare providers can better prepare equipment, personnel, and support services before procedures to mitigate the risk of SAEs.

Aim

Although previous studies have demonstrated the predictive value of the CRISP score, several limitations remain. Most existing research has been conducted in high-resource settings, with limited generalizability to different healthcare systems or populations. Additionally, the majority of studies have focused on Western populations, which may differ significantly in terms of demographic, clinical, and procedural characteristics compared to patients in other regions. These gaps highlight the need for further evaluation of the CRISP score in diverse clinical environments. To date, there are no published reports on the use or outcomes of CRISP implementation in Indonesia. Given these limitations and the potential influence of local population characteristics, this study aims to evaluate the effectiveness of the CRISP score in predicting serious adverse events among pediatric cardiac patients undergoing catheterization at the Pediatric Cardiac Center in Makassar, Indonesia.

Methods

Study Design

This study was conducted after obtaining ethical approval from the Ethics Committee for Biomedical Research on Humans, Faculty of Medicine, Hasanuddin University (No: 520/UN4.6.4.5.31/ PP36/2A24). This is a cross-sectional study conducted at Dr. Wahidin Sudirohusodo General Hospital from November 2024 to January 2025.

Participants

Sample inclusion criteria included pediatric patients (<18 years) who underwent pediatric cardiac catheterization (elective surgery) and were willing to participate in the study, as confirmed by the signing of informed consent by the patient's parents/legal guardian. Patients lost to follow-up were excluded from this study. All patients registered in the research period were included as research samples.

Variables and Statistical Method

The variables evaluated in this study included demographic characteristics, clinical diagnoses, the incidence of SAEs, and CRISP scores based on the Nykanen scoring system. A serious adverse event was defined as any complication resulting in mortality, permanent morbidity, the need for additional interventions, or a prolonged hospital stay. Specific conditions classified as SAEs were categorized according to criteria established in the study by Nykanen et al. [6].

All data were collected through direct observation. The dataset was then processed using SPSS version 26. Univariate analysis was performed to describe the characteristics of the study population, while appropriate statistical tests (either parametric or nonparametric) were applied to assess the significance of relationships between variables. A p-value of <0.05 was considered statistically significant.

Results

(Table 1) shows the demographic characteristics of 70 pediatric patients who underwent cardiac catheterization. During the observation period, there were 6 cases of serious adverse events (Table 2). Therefore, the incidence of serious adverse events in pediatric cardiac patients undergoing cardiac catheterization was 8.6%. We found that most of the patients who experienced serious adverse events had cardiac arrest (4 patients), and 2 patients experienced bleeding. We also found that 4 out of 6 patients who experienced adverse events were at high risk because they were less than 30 days old. Most of the patients (4 out of 6) had a CRISP III risk category, while the other 2 patients had a CRISP IV category.

We found that the majority of pediatric cardiac patients (67.1%) had a CRISP I risk category. CRISP II risk category was found in 21.4%, CRISP III in 5.7%, and CRISP IV in 5.7%. No samples were found to have a CRISP V risk category (Table 3).

In this study, SAEs occurred in patients with CRISP III and IV risk categories. It was found that 50% of patients with CRISP III and 100% of patients with CRISP IV experienced SAE. There is a significant relationship between CRISP category risk and the incidence of SAE in pediatric cardiac patients undergoing catheterization. The higher the CRISP risk category, the higher the risk of patients experiencing SAE ($p < 0.001$) (Table 3).

Discussion

In this study, the incidence of serious adverse events was 8.6%. Among the 6 cases of SAE, there were 4 cases (5.71%) of cardiac arrest and 2 cases (2.89%) of bleeding. The results of this study tend to be higher than those reported in other studies. Jayram et al. (2022) reported 1.9% cases of major adverse events in pediatric cardiac catheterization procedures [7]. A similar finding was reported by Nykanen (2015), who found a 4.9% incidence of major adverse events [6]. The same study also reported a mortality rate of 0.08% and a rebleeding rate requiring transfusion of 0.13%. Additionally, Tokel (2018) documented a 1.4% mortality rate following catheterization [8].

Table 1-Sample characteristics

Characteristics	Frequency (n)	Percentage (%)
Sex		
Male	40	57.1
Female	30	42.9
Body Weight		
>5 kg	66	94.3
2.5 - 5.0 kg	3	4.3
<2.5 kg	1	1.4
Age		
>1 year	61	87.1
30 days - 1 year	5	7.1
<30 days	4	5.7
Type of procedure		
Diagnostic	53	75.7
Intervention	0	0
Hybrid	17	24.3

Table 2- Profile of patients who experience serious adverse events

No	Sex	Age	Weight	Pre-Catheterization Diagnosis	CRSIP Score	Adverse event
1.	Male	8 months	8.0 kg	DORV + PS	8 (CRISP 3)	Cardiac arrest
2.	Male	3 days	3.7 kg	TGA + PDA	12 (CRISP 4)	Cardiac arrest
3.	Female	16 days	2.7 kg	TOF	14 (CRISP 4)	Cardiac arrest
4.	Female	9 years	17.0 kg	ASD + TR + PH	9 (CRISP 3)	Cardiac arrest
5.	Female	10 days	2.7 kg	TOF + PS + AT	13 (CRISP 4)	Massive bleeding
6.	Female	18 days	2.4 kg	AVSD + PS	14 (CRISP 4)	Unstable hemodynamics, (epinephrine continued) Bleeding

Legend = DORV: Double outlet right ventricle, PS: pulmonary stenosis; TGA: transposition of the great artery; PDA: patent ductus arteriosus; TOF: tetralogy of fallot; ASD: atrial septal defect; TR : tricuspid regurgitation; PH: Pulmonary hipertension; AVSD: Atrioventricular Septal Defect

Table 3- Relationship Between CRISP Score and Adverse Events

CRISP Risk Category	n (%)	Incidents of Serious Adverse Events		P value
		No n (%)	Yes n (%)	
CRISP I	47 (67.1%)	47 (100%)	0 (0%)	<0.001[a]
CRISP II	15 (21.4%)	15 (100%)	0 (0%)	
CRISP III	4 (5.7%)	2 (50%)	2 (50%)	
CRISP IV	4 (5.7%)	0 (0%)	4 (100%)	
CRISP V	0	0 (0%)	0 (0%)	

(a) Chi-square test

Further analysis showed that 4 out of 6 patients who experienced serious adverse events were at high risk, being <30 days old and weighing <5 kg. Younger age and lower body weight have been reported to be significant poor predictive indicators in pediatric cardiac catheterization ($p<0.001$). Age <30 days has been reported to have a serious adverse event incidence of up to 12%. In contrast, the incidence of serious adverse events in children <5 kg is reported to be as high as 23% [6]. Pediatric cardiac catheterization is a complex procedure associated with higher risks, particularly in younger patients and those with low body weight. One major factor contributing to the increased incidence of complications in these patients is hemodynamic instability due to their underdeveloped physiological systems. Smaller vascular structures in low-weight children pose challenges in achieving safe and effective vascular access, increasing the risk of vascular injury or thrombosis- especially when catheters larger than the vessel size are used [9].

Infants and children of low body weight have a different hemodynamic response. In some cases, their cardiovascular system is less able to compensate for sudden changes in blood pressure or volume during catheterization, which can lead to systemic hypotension or arrhythmias [10-11]. They are also at higher risk for respiratory complications during sedation or anesthesia, including hypoxemia and hypercapnia, which can cause cardiovascular instability [10, 12]. In addition, low body weight also affects the pharmacokinetics of anesthetic agents, making them more susceptible to the effects of anesthesia. This increased susceptibility can lead to prolonged sedation, respiratory depression, and cardiovascular instability, increasing the risk of adverse effects during and after the procedure [10].

Younger patients, especially neonates and infants, have immature organ systems that are at risk of not tolerating the physiological pressures of catheterization as well as older children. This immaturity can lead to complications such as arrhythmias and systemic hypotension due to inadequate myocardial performance or autonomic dysregulation [11].

This study found that 67.1% of patients were categorized as CRISP I, followed by 21.4% in CRISP II, 5.7% in CRISP III, and 5.7% in CRISP IV, with no cases falling into CRISP V. Comparatively, a study in Turkey by Gerçeker (2022) reported that the majority of patients were classified as CRISP II (50.1%), while CRISP I accounted for 20.8%, CRISP III for 25.3%, CRISP IV for 3.3%, and CRISP V for 0.5% [13].

A significant relationship was found between CRISP score and SAE incidence ($p < 0.001$), confirming that higher CRISP risk categories correlate with increased adverse event rates in pediatric cardiac catheterization. SAEs occurred exclusively in patients classified as CRISP III and IV, with 50% of CRISP III patients and 100% of CRISP IV patients experiencing adverse events. These findings align with a study by Hill (2018), which reported SAE rates of 1.5% in CRISP I, 2.5% in CRISP II, 4.8% in CRISP III, 11.2% in CRISP IV, and 24.1% in CRISP V [14]. Gerçeker (2022) also reported similar findings, emphasizing that a higher CRISP score corresponds to a greater risk of adverse events ($p < 0.01$) [13]. These results support the CRISP score's reliability in predicting procedural risks in pediatric cardiac catheterization.

The outcome of cardiac catheterization in pediatric patients needs to be continuously evaluated as, these procedures are constantly evolving and improving. Determination of risk factors will help to anticipate adverse events, which will guide the preparation of rescue procedures, the organization of catheterization laboratories, and the improvement of patient safety systems. The CRISP score is a stronger predictor, confirmed by the agreed AUC measurement, and can be used to plan and prepare the equipment, personnel, and support available before the procedure is performed. Nykanen et al. demonstrated that the CRISP-20 score is a valid predictor of serious adverse events. The CRISP-20 score provides an easily calculated estimate of the patient's risk of experiencing an SAE [6, 8, 13].

The increased risk of adverse events in low-weight pediatric patients is influenced by multiple factors, including hemodynamic challenges, physiological sensitivity, and developmental vulnerabilities. Understanding these mechanisms is critical for optimizing procedural approaches and enhancing patient safety. Improved monitoring and individualized techniques may help reduce the risks associated with pediatric cardiac catheterization.

Implementing CRISP scoring can also improve patient counseling and informed consent, providing families with a clearer understanding of procedural risks. Strategies to minimize preventable complications- such as alternative vascular access methods, improved anesthesia management, careful catheter manipulation, and pre-procedure hemodynamic stabilization—can help enhance patient safety [8]. Additionally, avoiding arterial access when possible and using more refined vascular tools may lower the risk of vascular injury.

Some limitations of this study include the relatively small sample size and the lack of assessment of operator-related factors, which may influence procedural outcomes. Future research with a larger sample size is needed to provide a more comprehensive analysis of potential complications in pediatric cardiac catheterization.

Conclusion

In conclusion, this study found an 8.6% incidence of SAE among pediatric cardiac patients undergoing

catheterization at Dr. Wahidin Sudirohusodo Hospital, with the majority classified as CRISP I. A significant association was observed between CRISP scores and adverse events, confirming that higher CRISP risk categories correspond to an increased likelihood of SAE occurrence.

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