Original Article

Pediatric Cardiac Surgery Complications and the Risk Factors: A Single-Center Study

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Received 06 February 2023; Accepted 12 January 2024

Abstract

Background: *This study aimed to determine postoperative cardiac and noncardiac complications and their association with the use of cardiopulmonary bypass (CPB), surgical outcomes (length of hospital and ICU stays), dependence on mechanical ventilation, and mortality.*

Methods: *This retrospective cross-sectional study was conducted on pediatric patients aged 0 to 18 who underwent open or closed cardiac surgery over a 1-year period. The use of CPB support, CPB duration, cardiac surgery complexity according to the risk-adjusted classification for congenital heart surgery (RACHS-1), and demographics were examined as potential risk factors associated with an increased number of postoperative complications. The study was performed at the Children's Medical Center, a teaching hospital affiliated with Tehran University of Medical Sciences in Iran.*

Results: *A total of 283 surgeries were included in our study. Seventy-six (26.9%) of the study population experienced at least 1 complication. Our analysis revealed that increased CPB durations were associated with higher odds of cardiac complications, with an odds ratio of 1.02 (P=0.002). Moreover, higher RACHS-1 levels were significantly associated with greater numbers of cardiac and noncardiac complications. Additionally, prolonged mechanical ventilation and open-heart surgery intensive care unit (OH-ICU) stays were significantly associated with cardiac and noncardiac complications. Our logistic regression analysis found no association between demographic and clinical risk factors, the number of complications, and mortality.*

Conclusion: *Postoperative complications occurred in 27% of pediatric heart surgeries. Prolonged mechanical ventilation and OH-ICU stays were significantly associated with cardiac and noncardiac complications. However, no significant association was found between postoperative complications and mortality.*

J Teh Univ Heart Ctr 2024;19(2):124-131

This paper should be cited as: Mirzaaghayan M, Vahdati Z, Nematian H, Memarian S, Heidari M, Askari MH, et al. Pediatric Cardiac Surgery Complications and the Risk Factors: A Single-Center Study. J Teh Univ Heart Ctr 2024;19(2):124-131.

Keywords: *Cardiovascular diseases; Heart defects, congenital*

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Introduction

Congenital heart disease (CHD) is the leading cause of birth defects in infants and the primary cause of infant mortality resulting from birth defects.[1, 2] Additionally, while 8 out of every 1000 live births are affected by congenital heart disorders globally, this figure has been reported in developing Asian countries to be as high as 22 per 1000 children.[3, 4] Despite advances in medical science, CHD remains a significant challenge in childhood, particularly in developing countries, and is associated with substantial morbidity and mortality in these children. Furthermore, CHD is linked with numerous long-term consequences, such as pulmonary hypertension, endocarditis, aortic-related outcomes, heart failure, and arrhythmia. Even when patients survive infancy, they face a continued risk of mortality. As the most common cause of death in children, CHD accounts for 34% of mortality cases, with a mortality rate of 9.7 deaths per 1000 individuals between the ages of 1 to 20, and 3.5 deaths per 100 infants under 1 year of age.[5]

Treatment for most congenital heart defects involves complex surgical procedures, catheter-based interventions, and specialized medical care.[6] Approximately 25% of affected children require catheterization or surgery during their first year of life.[7] Nonetheless, up to one-third of congenital heart surgeries may encounter complications, increasing the risk of mortality in these patients.[6] Following pediatric cardiac surgery, postoperative cardiac and extracardiac complications significantly impact mortality, hospitalization, costs, and quality of life.[8] Complications and their association with outcomes are challenging to measure but can enable comparisons between different centers. Recognizing, documenting, and investigating the factors influencing the occurrence of complications is crucial in determining treatment duration, costs, and clinical outcomes.[6] Several studies have examined the relationship between complications from pediatric heart surgeries and outcomes. All open-heart surgeries are associated with cardiopulmonary bypass (CPB) complications, including inadequate organ or tissue perfusion, activation of systemic inflammatory response, air or particle embolization, and bleeding.[9] Some studies investigating postoperative complications in pediatric heart surgery patients and their association with CPB have demonstrated that longer CPB durations are linked to increased complication severity and mortality.[10] Classifying risk factors in heart surgery is challenging due to the diverse range of CHD, the limited number of cases for each heart defect, and the high complexity of the cases. The risk-adjusted classification for congenital heart surgery (RACHS-1) is a measure that predicts outcomes of pediatric heart surgery, such as mortality and quality of care.[11] Furthermore, the duration of mechanical ventilation and hospitalization in the ICU and the hospital can be assessed as surgical outcomes, which have been studied in relation to surgical centers under the concept of failure to rescue.[12-14] Given the significance of cardiac surgery complications in children and their association with outcomes, this study aimed to determine postoperative cardiac and noncardiac complications in children who have undergone cardiac surgery and the relationship of these complications with the use of CPB. Additional objectives included investigating the association of these complications with surgical outcomes, such as length of hospital and ICU stays, dependence on mechanical ventilation, and mortality.

Methods

This study received full approval from the Institutional Research Ethics Committee of the School of Medicine at Tehran University of Medical Sciences (IR.TUMS.CHMC.REC.1399.039; 2020-05-30). All research was conducted following the ethical standards established by the 1964 Declaration of Helsinki and its subsequent amendments. Written informed consent was acquired from the patients' legally authorized representatives.

This retrospective cross-sectional study was conducted at the Children's Medical Center, a tertiary hospital affiliated with Tehran University of Medical Sciences, and received approval from the Institutional Research Ethics Committee of the School of Medicine at Tehran University of Medical Sciences. The inclusion criteria were as follows: pediatric patients aged 0 to 18 years who had undergone open or closed cardiac surgery from April 1, 2016, through March 31, 2017. The exclusion criteria included severe internal diseases, previous surgical site infection, and patients not admitted to the open-heart surgery intensive care unit (OH-ICU) for postoperative care or those who experienced mortality in the operating room. Data collection was performed by extracting clinical information and outcomes from hospital databases and patient records. This study aimed to identify postoperative complications in patients admitted to the OH-ICU and investigate the factors influencing these complications in children. The presence or occurrence of complications was defined as the occurrence of at least 1 of the 14 predefined complications (based on the consensus definitions provided by the Multi-Societal Database Committee for Congenital and Pediatric Heart Disease) in the OH-ICU. The 14 complications were categorized into 8 groups based on the primary affected body systems. Most statistical analyses of postoperative complications were classified under 2 broad categories: cardiac (5 items) and noncardiac complications (9 items) [Appendix 1].[15] Renal and endocrinological complications were not evaluated in this study. The clinical outcomes assessed included the duration of mechanical ventilation, length of stay in the OH-ICU and hospital, and mortality rate. This study investigated the following risk factors associated with an increased number of postoperative complications: the use of CPB support, CPB time, complexity of cardiac surgery according to RACHS-1, pre-existing anomalies, and demographic factors, including age, sex, and weight.

After the establishment of standard monitoring, inhalational induction of anesthesia was performed using spontaneous breathing through the Mapleson D breathing system. Sevoflurane 8% and 100% oxygen were administered for induction. Following the establishment of peripheral venous access, 2 mg/kg of ketamine, 5–15 µg/kg of fentanyl, and 0.1 mg/kg of cisatracurium were injected. A cuffed or uncuffed tracheal tube, appropriate for the patient's age, was used for intubation. Upon the completion of tracheal intubation, the patients were connected to a mechanical ventilator with a tidal volume of 7–8 mL/kg, and the respiratory rate was adjusted to maintain an end-tidal CO2 between 30 mm Hg and 35 mm Hg. Subsequent to the intubation and initiation of mechanical ventilation, arterial and central venous catheters were inserted, allowing for the invasive monitoring of arterial and central venous pressures. Anesthesia was maintained using 0.03–0.1 µg/kg/minute of midazolam, 0.25–1.5 mg/kg/h, and 1–2 µg/kg/min of cisatracurium. An arterial blood sample was collected for the analysis of arterial blood gases and electrolytes. Prior to CPB initiation, 400 IU/kg of heparin was administered, and a minimum activated clotting time of 480 seconds was required to commence CPB.

Standard monitoring was established, including bicaval cannulation of the right atrium, and CPB was initiated using a Stöckert S5 roller pump. The CPB machine was connected to a membrane oxygenator (CAPIOX FX 05 Tremo medical 87 USA), with the extracorporeal circuit primed using 150–250 mL of lactated Ringer's solution, 10 mg of heparin, 1 mg/kg of furosemide, 0.5 g of $MgSO_4$, and 100 mL of red blood cells. The pump flow rate during CPB was maintained at 100–150 mL/kg/min, with rectal temperature (after cardiac arrest) ranging from 30 °C to 34 °C. An anterograde crystalloid cardioplegic solution was used for all the patients while maintaining an activated clotting time above 480 seconds during bypass. Following aortic cross-clamping, pulsatile flow perfusion was initiated with frequencies according to group settings (30, 60, or 100 beats/minute, or non-pulsatile control), base flow at 30%, and pulse width set at 30%. Fluid levels were closely monitored during CPB, and hemodynamic parameters were recorded at 3-minute intervals. Mean arterial pressure was maintained between 25 mm Hg and 60 mm Hg, with epinephrine administered as needed for hypotension (20 mm Hg). Lactated Ringer's solution was added to the reservoir to replace fluid loss as indicated by the fluid gauge. After the removal of the aortic cross-clamp, cardiac reperfusion was initiated, and upon achieving adequate contractility, the pulsatile flow perfusion was discontinued. The patients were gradually rewarmed to a nasopharyngeal temperature of 36.0 °C and a rectal temperature of 34 °C. Upon the termination of extracorporeal circulation, 4 mg/kg of protamine was administered for heparin neutralization.

Data analysis was performed using SPSS 22.0 software (SPSS Inc, Chicago, IL, USA). Continuous data were presented as medians and interquartile ranges, while categorical data were presented as counts and percentages. The Mann-Whitney U-test was conducted to compare continuous variables between the 2 groups. The χ^2 or Fisher exact test was employed to analyze frequencies. Proportional odds logistic regression analysis was performed to investigate the risk factors associated with increased cardiac and extracardiac complications. Linear regression analysis was utilized to assess the relationship between the duration of mechanical ventilation and the length of OH-ICU stay in relation to postoperative complications, adjusting for relevant confounders. Proportional odds logistic regression analysis was used to evaluate the association between mortality, complications, and risk factors while accounting for relevant confounders.

Results

In a 1-year study of pediatric cardiac surgery involving patients under 18 years of age, 311 surgeries were performed, with 283 patients included in our analysis. Of these 283 surgeries, 241 (85.2%) were conducted with CPB support, while 42 (14.8%) were performed without CPB support.

Table 1 presents the demographic data and risk factors of the study population based on the use of CPB. Our univariate analysis revealed that patients undergoing surgery without CPB support were significantly younger and had lower body weights than those who received CPB support (Table 1). The average age of the CPB group was approximately 1 year, while the non-CPB group had an average age of 3 months, which also correlated with lower average weights in the latter group. Furthermore, fewer patients in the non-CPB group had pre-existing abnormalities. The study population comprised 58% boys and 42% girls.

Among the 283 patients in the study population, 76 (26.9%) experienced at least 1 complication. Of the 241 patients who received CPB support, 67 (27.8%) developed 1 or more complications. Among the 42 patients who underwent surgery without CPB support, 9 (21.4%) experienced at least 1 postoperative complication. Table 2 presents the descriptive statistics for the 14 postoperative complications evaluated in our study, categorized by CPB support (Table 2).

Our logistic regression analysis did not provide sufficient evidence to demonstrate significant differences in the incidence of cardiac or noncardiac complications between

Table 1. Demographics and risk factors of the study population

Risk Factors	CPB Support		P
	Yes (n=241)	No (n=42)	
Age (d)	570.00 (180.00 - 1596.50)	112.50 (23.00 - 533.75)	< 0.001
Weight (kg)	10.000 (5.600 - 15.250)	4.750 (3.075 - 9.350)	< 0.001
Sex			
Male	137 (56.8)	27 (64.3)	0.367
Female	104 (43.2)	15 (35.7)	0.367
Previous anomaly (yes)	28 (11.6)	6 (14.3)	0.624
RACHS-1 category			
1	19 (7.9)	14 (33.3)	< 0.001
2	134 (55.6)	13 (31.0)	0.004
3	75 (31.1)	10 (23.8)	0.369
4	13 (5.4)	2 (4.8)	0.611
Unclassified	0 (0.0)	3 (7.1)	0.003
CPB time (min)	115.00 (76.00 - 162.50)	NA	—

Data are presented as medians (interquartile ranges) or absolute numbers (%), with the P value determined using the Mann-Whitney U or Fisher exact test.
RACHS-1, Risk-adjusted classification for congenital heart surgery, version 1; CPB, Cardiopulmonary bypass; NA, Not applicable

Table 2. Postoperative cardiac and noncardiac complications

Complications	CPB Support	
	Yes (n=241)	No (n=42)
Cardiac, total	56 (23.2)	10 (23.8)
Cardiopulmonary resuscitation	8 (3.3)	1 (2.4)
Arrhythmia	20 (8.3)	3 (7.1)
Reoperation	8 (3.3)	3 (7.1)
Low cardiac output status	18 (7.5)	1 (2.4)
Use of permanent pacemakers	2 (0.8)	2 (4.8)
Noncardiac, total	33 (13.7)	5 (11.9)
Neurologic	13 (5.4)	2 (4.8)
Seizures or focal neurologic deficit	4 (1.7)	2 (4.8)
Abnormal neuroimaging findings	9 (3.7)	0 (0)
Respiratory	6 (2.5)	0 (0)
Pulmonary edema	2 (0.8)	0 (0)
Paralyzed diaphragm	4 (1.7)	0 (0)
Gastrointestinal complications	7 (2.9)	0 (0)
Infectious	6 (2.5)	2 (4.8)
Pneumonia	2 (0.8)	1 (2.4)
Sternal wound infection	3 (1.2)	1 (2.4)
Suspected infection/bacteremia	1 (0.4)	0 (0)
Hematologic	1 (0.4)	1 (2.4)
Bleeding requiring chest re-exploration	1 (0.4)	1 (2.4)
Cardiac complications/patient		
0	191 (79.3)	36 (85.7)
1	46 (19.1)	6 (14.3)
>1	4 (1.7)	1 (2.4)
Extracardiac complications/patient		
0	213 (88.4)	38 (90.5)
1	25 (10.4)	3 (7.1)
>1	4 (1.7)	1 (2.4)
Total complications/patient		
0	174 (72.2)	33 (78.6)
1	49 (20.3)	7 (16.7)
>1	18 (7.5)	2 (4.8)

Data are presented as absolute numbers (%).

cardiac surgeries performed with and without CPB support after adjusting for age, sex, pre-existing abnormalities, and RACHS-1 levels (Table 3). Nevertheless, the model accounted for only 0.2% (Nagelkerke R2) of the variance in complication incidence for both groups with and without CPB support.

For the 241 cardiac surgeries performed with CPB, Table 4 presents the results of the risk factor evaluation for cardiac and extracardiac complications. Proportional odds logistic regression analysis was conducted to assess the association between demographic and clinical risk factors and cardiac and noncardiac complications. The analysis revealed that an increase in CPB time was significantly associated with increased odds of cardiac complications, with an odds ratio of 1.02 (P=0.002). Higher RACHS-1 levels were also found to be significantly associated with a greater number of cardiac and noncardiac complications. Moreover, the odds of cardiac complications in male patients were 2.24 times (95% CI, 1.07 to 4.68) greater than in female patients, a statistically significant finding (P=0.04). For the comparison of complication risks across RACHS-1 categories, each category was treated as an ordinal variable and compared with RACHS-1 category 1. Table 5 presents the results of the risk factor evaluation and their association with postoperative complications for CPB patients in relation to the duration of mechanical ventilation and OH-ICU stay. Cardiac and noncardiac complications were significantly associated with extended periods of mechanical ventilation and OH-ICU stay. Furthermore, the analysis demonstrated that longer CPB durations were significantly associated with prolonged OH-ICU stays after adjustments for relevant covariates (Table 5). For the 42 patients who underwent surgeries without CPB support, cardiac and noncardiac complications were significantly associated with prolonged mechanical ventilation and OH-ICU stays ($F(2.39)=37.06$ and $F(2.39)=41.90$; $P<0.01$ for both) compared with patients with no complications.

Nine patients passed away: 7 from the group that received CPB support and 2 from the group that underwent surgery without CPB support. The presence of postoperative complications was not significantly associated with mortality. For the 241 surgeries performed using CPB and

Table 3. Logistic regression analysis of the incidence of cardiac and noncardiac complications between cardiac surgeries performed with and without CPB support

	CPB Support				
Outcome	Yes (n=241)	No (n=42)	OR	95% CI	P*
Cardiac complications	50 (20.5)	7 (16.7)	0.764	0.320 – 1.822	0.544
Noncardiac complications	29 (12)	4 (9.5)	0.770	0.256 – 2.314	0.641

Data presented as absolute numbers (%).
Risk factors were adjusted for analysis, including age, sex, previous anomaly, and RACHS-1.
RACHS-1, Risk-adjusted classification for congenital heart surgery, version 1; CPB, Cardiopulmonary bypass

Table 4. Proportional odds logistic regression analysis of risk factors for patients with CPB for cardiac and non-cardiac complications

	Cardiac Complications		Extracardiac Complications	
Risk Factors	OR (95% CI)	P	OR (95% CI)	P
Age (d)	1.00 (0.89- 1.12)	0.46	1.01 (0.95 - 1.21)	0.73
Sex (male vs female)	2.24 (1.07 – 4.68)	0.04	1.59 (0.67 - 3.76)	0.29
Previous anomaly (yes vs no)	1.41 (0.48 – 4.11)	0.53	0.37 (0.08 – 1.79)	0.219
RACHS-1 category		0.003*		0.04*
2	1.66 (1.19 – 14.53)		1.63 (0.17 – 15.28)	
3	4.77 (1.54 – 42.13)		0.37 (0.04 – 3.53)	
4	10.88 (1.88 – 133.90)		2.12 (0.08 – 52.11)	
CPB time (min)	1.02 (1.01 – 1.04)	0.002	1.00 (0.981 – 1.023)	0.857

RACHS-1, Risk-adjusted classification for congenital heart surgery, version 1; CPB, Cardiopulmonary bypass
*RACHS-1 levels were analyzed as categorical variables, and the P value was calculated comparing each category with RACHS-1 categories 1.

Table 5. Logistic regression analysis of CPB parameters and cardiac and noncardiac complications with mechanical ventilation and OH-ICU stay duration

	Mechanical ventilation duration		OH-ICU Stay Duration	
Risk Factors	Ratio of geometric mean (95% CI)	P	Ratio of geometric mean (95% CI)	P
Cardiac complication	2.59 (2.76 – 5.42)	< 0.001	3.70 (1.39 – 6.01)	0.002
Non-cardiac complication	5.09 (3.14 – 6.03)	< 0.001	5.07 (2.38 – 7.76)	0.001
RACHS-1 category	1.27 (0.16 – 2.69)	0.36	1.01 (0.99 – 1.04)	0.18
CPB time (min)	1.17 (0.89 – 1.31)	0.06	1.58 (1.08 – 3.17)	0.02

RACHS-1, Risk-adjusted classification for congenital heart surgery, version 1; CPB, Cardiopulmonary bypass; OH-ICU, Open-heart surgery intensive care unit

42 surgeries without CPB, the logistic regression analysis revealed no significant associations between demographic and clinical risk factors, the total number of cardiac and noncardiac complications, and mortality.

Discussion

Our study on postoperative complications after pediatric cardiac surgeries and their related factors indicated that approximately 27% of children in this study experienced at least 1 postoperative complication. Although these complications occurred in both surgeries with and without CPB, a higher incidence of complications was observed following the use of CPB. Moreover, our analysis revealed that increased CPB durations were associated with increased odds of cardiac complications. Cardiac and noncardiac complications were significantly associated with prolonged periods of mechanical ventilation and OH-ICU stays. A study by Benavidez et al[6] proposed a new classification system for defining complications, suggesting that one-third of pediatric heart surgery patients experience complications. Similar studies, such as those conducted by Pasquali et al[13] and Kansy et al,[8] have reported postoperative complication rates ranging from 33% to 39%. The relatively lower complication rate in our study could be attributed to a smaller sample size or more inclusive exclusion criteria. Although this study was conducted in a developing Middle Eastern country, some studies suggest that high-performing cardiac surgery centers with lower mortality rates do not necessarily have fewer postoperative complications. Instead, these centers may have lower mortality rates resulting from complications or a lower failure-to-rescue rate.[13] Another study investigating the relationship between complication rates and center volume found no significant association between the 2 factors, whereas a significant correlation was observed between mortality and center volume.[16]

Our results demonstrated that postoperative complications occurred in both patient groups, with and without CPB, which aligns with the findings of a study by Agarwal et al.[10] However, this finding contradicts other studies suggesting that the use of CPB is associated with increased complications.[8] Although our study did not establish a significant association between CPB use and cardiac or noncardiac complications, the incidence of cardiac complications was higher than noncardiac complications in both groups. This finding differs from that reported by the aforementioned authors,[10] who reported a higher prevalence of extracardiac complications. In our study, arrhythmia was the most prevalent cardiac complication, consistent with a study by Delaney et al,[17] which reported arrhythmia as a common complication in about 15% of pediatric heart surgeries and suggested an increased risk with longer CPB durations. Regarding another cardiac complication, Liberman et al[18] described complete heart block and pacemaker implantation as a rare complication occurring in approximately 1% of cases, which chimes with our findings. In contrast to pulmonary complications being more prevalent in other studies,[10] neurological complications were more commonly observed in our study when examining noncardiac complications.

Our analysis revealed no significant association between age, sex, or the presence of previous anomalies with cardiac and noncardiac complications, with the exception of female sex, which was associated with cardiac complications. The incidence of complications based on CPB was further investigated by considering variables such as age, weight, sex, previous anomalies, and RACHS-1 levels (Table 4).

A higher RACHS-1 score, which indicates the severity of the cardiac anomaly, has been associated with increased cardiac and non-cardiac complications in this study, like other studies that have proposed the RACHS-1 score as a predictor of morbidity and mortality.[19, 20] In addition, the increase in CBP time has been described as a risk factor for cardiac complications. The same as other studies have described the increase in CBP time as a factor affecting the prognosis and occurrence of complications of cardiac surgery in children.[21, 22] This issue can be explained by the fact that some high-risk patients may require long cardiopulmonary bypass times with a short duration of cross-clamping, such as surgical procedures that focus more on the right heart.

We found that complications were significantly associated with extended periods of mechanical ventilation and OH-ICU stays, which aligns with findings reported in other studies.[23, 24] Our study identified postoperative complications and RACHS-1 levels as factors influencing the duration of mechanical ventilation and OH-ICU stays, consistent with previous research investigating predictors of prolonged mechanical ventilation.[12, 25, 26]

The crude postoperative mortality rate was 3% (9 out of 283 patients). Reported mortality rates in other studies have ranged from 2.2% to 14%.[21, 22] In our study, mortality rates in both groups were not significantly associated with any risk factors, possibly due to the small number of mortality cases relative to the sample size. Previous studies have demonstrated an independent association between increased CPB durations and postoperative mortality, as well as the influence of increasing age and decreasing left ventricular ejection fraction on patient mortality.[21]

This study has several notable limitations. First, it is a single-center retrospective study with a relatively small sample size in the non-CPB group, which may limit the ability to detect risk factors predictive of complications or mortality. Additionally, the retrospective nature of the study precluded the evaluation of various factors, such as variations in CPB techniques, anesthesia, and human factors, necessitating further research to establish causal relationships. Second, the study did not investigate the relationship between the type of surgery, underlying diseases, and different complications or mortality rates. Third, some complications mentioned in previous studies, such as renal and endocrine complications, were not examined. Fourth, the impact of aortic cross-clamp time—a risk factor for cardiac surgery complications in various studies—was not investigated, despite evidence suggesting a significant relationship between increased aortic clamp time and cardiac complications.[21, 22] Fifth, the subjective definition and counting of complications in this study may limit its generalizability to other medical centers. Lastly, it was not possible to investigate which specific complication was associated with worse patient outcomes and mortality.

Conclusion

Despite these limitations, our study demonstrated that postoperative cardiac and noncardiac complications affected a significant proportion of pediatric patients undergoing cardiac surgery, impacting outcomes regardless of CPB use. We observed a substantial association between cardiac and noncardiac complications and measured outcomes, including duration of mechanical ventilation and length of ICU stay. However, no significant relationship between these complications and mortality was found in this study. To improve care quality and reduce complications, we emphasize continuous staff training, particularly for nurses, enhancing surgical wound care and hand hygiene practices, optimizing pain and sedation management, and minimizing mechanical ventilation duration. Implementing more precise invasive hemodynamic monitoring may enable better fluid management and medication optimization. We plan to evaluate the effects of these modifications in future research. Further studies are recommended to assess cardiac and noncardiac complications following pediatric cardiac surgery using valid and standardized definitions and criteria, ensuring comparability across different settings and facilitating the establishment of causality.

Acknowledgments

This study was approved and financially supported by Tehran University of Medical Sciences. The authors wish to express their gratitude to the personnel of open-heart surgery intensive care unit at Children’s Medical Center.

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