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ORIGINAL ARTICLE

Complications After Surgical Repair of Congenital Heart Disease in Infants. An Experience From Tertiary Care Center

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Abstract

Objectives: **This study aimed to describe the incidence and spectrum of postoperative complications in infants who underwent their first cardiac surgery for the repair of congenital heart diseases.**

Methods: **This is a single-center retrospective study. Data of infants admitted to King Faisal Specialist Hospital & Research Center; Jeddah; Saudi Arabia, from January 2015 to December 2019 who underwent the first cardiac procedure for congenital heart disease at an age of less than 3 months, were analyzed. The primary outcome is the prevalence and spectrum of postoperative complications during hospitalization. Data were analyzed by using descriptive and analytical statistics using SAS software version 9.4.**

Results: **Data of 130 procedures were analyzed. The most frequent procedure performed was the Norwood procedure (31.5%), aortic coarctation repair (13.8%), arterial switch operation (13%), and Blalock-Taussig and central shunts (10%). The overall postprocedural complications were reported in 96 (73.8%) of the procedures. The most frequent complications were prolonged postoperative mechanical ventilation (27%), pleural effusion (21%), excessive bleeding (19%), cardiac arrest (18%), and systemic infections (18%).**

Conclusion: **Cardiac surgery for congenital heart disease in young infants has a substantial risk for postoperative complications. The high incidence of these complications in these cases makes necessary attention to prove the outcomes in the cardiac centers.**

Keywords: Postoperative complications, Cardiac procedures, Congenital heart disease, Infants

1. Introduction

Congenital heart defects (CHDs) are one of the most common forms of congenital malformations in the world. Incidence of CHDs is rising steadily and recently reported about 12–14 cases per 1000 live births, worldwide [1]. In Saudi Arabia, the incidence of all forms of CHDs is ranging between 2.1 and 10.7 per 1000 live births, and approximately 5.4/1000 live births for severe forms [2]. Depending on the type and severity of CHD, about half of these patients undergo either corrective or palliative surgeries during their infancy, make them at high risk for the development of several postoperative complications (POCs) [3]. Besides, many associated factors such as low birth weight, immaturity of many organs, and genetic syndromes, can affect the success of surgery in young patients [4]. Therefore, healthcare centers have used several risk stratification systems to determine the risks and difficulty levels of pediatric cardiac surgeries. Aristotle's Basic Complexity score

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and Risk Adjustment in Congenital Heart Surgery (RACHS-1) are most commonly used for this purpose. Traditionally, particular attention is given to the RACHS-1 model, which was created by a team consisting of 11 pediatric cardiologists and pediatric cardiac surgeons from Boston Children's Hospital [5]. The validity of this model has been well described in the literature [5,6].

There are several POCs of cardiac surgery involving cardiovascular and non-cardiovascular systems. Cardiovascular POCs are common and included cardiac arrest, arrhythmias, and low cardiac output. Non-cardiovascular POCs may be pulmonary/thoracic, infections, gastrointestinal, hepatic, neurological, hematological, or renal complications, as well as multi-organ dysfunction syndrome [7]. The occurrence of these complications may extend the in-hospital postoperative length of stay (POLOS), raise the cost to the healthcare system, and increase risk of the mortality [8,9]. Anticipating these potential complications may allow the delivery of the best medical and surgical care and minimizing the morbidity and mortality rates in vulnerable patients [10,11].

To the best of our knowledge, there are limited data concerning the incidence of complications after cardiac surgery in infants in Saudi Arabia. Therefore, this study aimed to describe the prevalence of POCs in infants undergoing cardiac surgery at age of ≤3 months and to evaluate the association of these complications with the prolonged POLOS, prolonged postoperative mechanical ventilation (POMV), and in-hospital mortality rate.

2. Materials and methods

2.1. Study design and population

This is a retrospective study conducted at King Faisal Specialist Hospital & Research Center-Jeddah (KFSH&RC-J), Jeddah; Saudi Arabia. A 500-bed tertiary specialist hospital, KFSH&RC-J is located in western province of Saudi Arabia. Annually, the center performed about 400 adults and pediatric heart surgeries, including open heart and closed heart procedures with outcomes that are among the best in the nation. All infants less than 90 days old who were diagnosed with CHD and admitted between January 2015 and December 2019 to neonatal or cardiac intensive care units and underwent their first cardiac procedure (corrective or palliative), which is classified in the RACHS-1 risk stratification system, were eligible for analysis.

The clinical data were collected from the electronic medical database of KFSHRC-J. The demographic, preoperative risk factors, primary diagnosis of CHD, the appropriate perioperative and operative data, documented POCs, and the number of deaths within the first 30 days after surgery; or before hospital discharge for the index hospitalization; were collected and reported in specified data collection forms (for more details see appendix 1). The final diagnosis of CHD was considered as those made based on echocardiography and/or cardiac catheterization. Documented POCs were grouped into cardiovascular or non-cardiovascular events. Non-cardiovascular complications were also categorized into one of the following subgroups: pulmonary/thoracic; renal and electrolytes; neurological; gastrointestinal; hematological; thromboembolic; infectious; general complications and unplanned procedure or cardiac catheterization. This study was approved by the research ethics committee of KFSH&RC-J (IRB no. 2019-54, PED-J/614/40). The written informed consent was waived by the institutional review board.

Abbreviations and acronyms

ACC	Aortic Cross-Clamp
CHD	Congenital Heart Defects
CI	Confidence Intervals
CPB	Cardio-Pulmonary Bypass
HCA	Hypothermic Circulatory Arrest
IQR	Interquartile Range
KFSH&RC-J	King Faisal Specialist Hospital & Research Center-Jeddah
LCOS	Low Cardiac Output Syndrome
OR	Odds Ratio
POC	Postoperative Complications
POLOS	Postoperative Length Of Stay
POMV	Postoperative Mechanical Ventilation
RACHS-1	Risk Adjustment in Congenital Heart Surgery-1
RVOT	Right Ventricular Outflow Tract
SD	Standard Deviation
TAPVC	Total Anomalous Pulmonary Veins Connection

2.2. Study outcomes and definitions

The primary outcome is the incidence of POCs during the hospitalization period. POCs were considered present if any one or more of the 50 predefined events (listed in appendix 2) occurred during or after the surgery during the index patient's hospitalization. The potential complications were predefined as showed in appendix 2. The secondary outcomes were the association of the POCs with the prolonged POLOS, prolonged POMV, and 30-day postoperative death. POLOS was defined as the number of days from the date of the procedure to the date of discharge and was determined for all patients including those who died in the hospital. POLOS considered as prolonged when it is > 14 days. “We calculated duration of POMV by adding the length of each episode of mechanical ventilation after the index procedure. The registry includes the exact start and stop time of each mechanical ventilation episode in the intensive care units, including episodes in the cardiac intensive care unit and other critical care areas. Patients who were still receiving MV on day 7 after the procedure were counted with prolonged POMV group. In-hospital mortality is defined as any death occurring in the hospital during the same admission regardless of the cause [12]. The 30-day postoperative mortality is defined as any death occurring within 30 days after the indexed cardiac procedure regardless of the cause [12].

2.3. Statistical analysis

All data were entered into SAS software version 9.4 for statistical analysis (SAS Inc. USA). Patient characteristics and outcomes were summarized and separated into two groups based on the presence of the POCs. Data were expressed as mean and standard deviation (SD), while the median and interquartile range (IQR) were used in the presence of skewness. The frequency of the particular POC is calculated as the ratio of that event to the total number of the cases. POLOS and POMV were dichotomized to designate two groups; normal and prolonged. The postoperative mortalities were also dichotomized to yes or no. Between-group differences were assessed using the Student's t-test or the non-parametric Wilcoxon Sign test. The Pearson Chi-square test and Fisher's exact test were used to looking at associations between categorical variables and the presence of the POCs. Odds Ratio (OR) and 95% confidence intervals (95% CI) were generated using the frequency procedure. Missing data were omitted from analyses. A *p*-value <0.05 was considered statistically significant throughout all analyses.

3. Results

3.1. Baseline characteristics

During the 5-years study period, 167 infants were hospitalized for cardiac procedures. Thirty-seven cases did not meet the inclusion criteria, and data of the remaining 130 cases were analyzed. The median operative age was 26.5 (IQR: 30.0) days. Patients who suffered complications had a higher incidence of preoperative resolved systemic infections (86% versus 14%; p = 0.04). Otherwise, there were no significant differences between the complicated and noncomplicated group. Patient characteristics and pre-procedure risk factors are compared and showed in Table 1.

Concerning the clinical diagnosis, the most common cardiac defects were hypoplastic left heart syndrome (25%), followed by aortic arch anomalies and transposition of the great arteries (16% for each). Shone complex, pulmonary atresia, total anomalous pulmonary venous connection, and tetralogy of Fallot variants constituted 20% of cases (5% for each one). Other anomalies, i.e., hypoplastic right ventricle, truncus arteriosus, left ventricle outlet tract obstruction, patent ductus arteriosus, and Ebstein's anomalies comprised the remaining (23%). In terms of the surgical procedure, the most frequent procedure performed was the Norwood procedure (31.5%; $n = 41$), followed by aortic coarctation repair (13.8%; $n = 18$), an arterial switch operation (13%; $n = 17$); see Fig. 1.

During procedures, all patients were intubated and supported by mechanical ventilation. The majority of procedures were open-heart surgery (97.6%; $n = 127$), with a mean RACHS-1 score of 4 points. The operative characteristics of the procedures are shown in Table 2.

3.2. Primary outcome

Among all patients, the incidence of all POCs was 73.8% (95% CI: 65–81; n = 96). The total complication events in the cardiovascular system were 81 (in 51 cases), and the non-cardiovascular events were 219 (in 90 cases). Among all patients, the most frequent complications were prolonged POMV (26.9%), followed by pleural effusion including chylothorax requiring drainage (20.8%), excessive bleeding requiring transfusion or surgical exploration (19.2%), cardiac arrest (17.7%), systemic infections (17.7%), and significant cardiac arrhythmias (16.9%). Table 3 shows the incidence of all postoperative complications in our subjects.

3.3. Secondary outcomes

Patients with complications required a longer POMV time: 6 versus 4 (IQR: 4.0 versus 3) days; with a significant statistical difference; “$P = 0.02$”. Thirty-five (27%; 95% CI: 19–35) patients had prolonged POMV (>7 days); all of them were categorized into the complicated group. The median time of POLOS for all patients was 27.5 (IQR: 29) days, and was 32 versus 21 days; for the complicated and noncomplicated group respectively; “$P = 0.06$”. POLOS was prolonged in 81% of complicated cases versus 76% of the non-complicated group; “p = 0.55”. The overall in-hospital deaths occurred

Table 1. Patient characteristics and pre-operative risk factors separated by the occurrence of the complications.

Characteristics	All patients (n = 130)	Postoperative Complications		
		Yes	No	P. Value
Current age in months, mean (SD)	33.8 (19)	32.2 (19.8)	38.5 (15.6)	0.094
Operative age in days, median (IQR)	26.5 (30.0)	26.5 (25.0)	27.0 (47.0)	0.41
[a]Birth WT in kg, mean (SD)	2.7 (0.65)	2.78 (0.6)	2.74 (0.73)	0.81
Operative WT in kg, mean (SD)	2.9 (0.7)	2.92 (0.6)	2.93 (0.67)	0.96
Gender Male, n (%)	74 (57)	56	18	0.58
Born remote to surgical center, n (%)	118 (91)	85	33	0.18
Any risk factor, n (%)	122 (94)	91	31	0.45
Prematurity (Gestational age ≤36 wks), n (%)	25 (19)	18	7	0.82
Procedure age ≤30 days, n (%)	74 (57)	55	19	0.88
Procedure weight <2500 g, n (%)	23 (18)	17	6	0.99
Major Genetic Syndromes, n (%)	9 (6.9)	7	2	1.00
Non-syndromic anomalies, n (%)	22 (17)	17	5	0.69
[b]Pre-op respiratory support, n (%)	40 (31)	31	9	0.53
Single ventricular heart, n (%)	50 (38)	40	10	0.21
Myocardial dysfunction, n (%)	3 (2.3)	3	0	0.57
Preprocedural CPR, n (%)	4 (3.0)	3	1	1.00
[c]Resolved systemic infections, n (%)	37 (28)	32	5	0.04
[d]Neurological abnormalities, n (%)	16 (12)	12	4	1.00
Endocrine disorders, n (%)	8 (6.1)	5	3	0.43
Gastrointestinal/Hepatic abnormalities, n (%)	5 (3.8)	4	1	1.00
[e]Hematological abnormalities, n (%)	6 (4.6)	4	2	0.65
Electrolytes/renal dysfunction, n (%)	6 (4.6)	5	1	1.00

Abbreviations:, IQR; Interquartile range, SD; Standard deviation, WT; Weight.

[a] Number of patients was 126.

[b] Patient in invasive or noninvasive respiratory support before surgery till the time of surgery.

[c] Sepsis, systemic inflammatory response syndrome, septic shock, Urinary tract infection, or pneumonia.

[d] Neurological deficit, teratoma, seizures, subdural hematoma, intraventricular hemorrhage, hypoxic ischemic encephalopathy, intracranial calcifications, hypotonia.

[e] Anemia, thrombocytopenia, thrombosis.

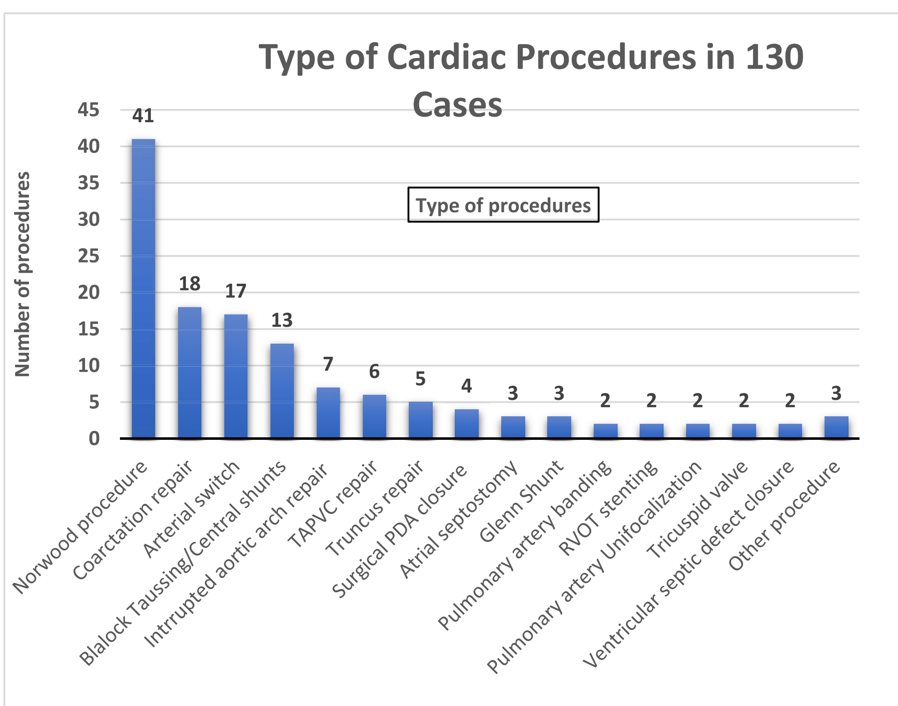

Fig. 1. Number and type of surgical procedures for repair of congenital heart defects performed in 130 infants aged less than 90 days. RVOT: right ventricular outflow tract; TAPVD: total anomalous pulmonary vein drainage.

Table 2. Operative characteristics separated by the occurrence of complications.

Operative characteristics	All patients (n = 130)	Postoperative complications		
		Yes	No	P. Value[a]
Non-elective procedure, n (%)	19 (14.6)	17	2	0.15
RACHS category: ≤ 3 (n, %)	44 (34)	28	16	–
RACHS category: > 3 (n, %)	86 (66)	68	18	0.06
Use of CPB (n, %)	111 (85)	85	26	0.09
CBP in min, median (IQR)	101 (72.7)	102 (73)	83.5 (70.5)	0.18
Use ACC, n (%)	95 (73)	71	24	0.7
ACC time in min, median (IQR)	69 (48.5)	66 (40)	72.5 (49.5)	0.98
Use of HCA, n (%)	41 (31.5)	31	10	0.76
HCA time in min, median (IQR)	26 (25)	26 (23)	25 (21)	0.77
Re-intubation, n (%)	25 (19)	18	7	0.81

Abbreviations: ACC; aortic cross-clamp, CPB; cardiopulmonary bypass, HCA; hypothermic circulatory arrest, RACHS; risk adjustment for congenital heart surgery score.
[a] Compared complicated vs noncomplicated group.

in 17 (13%, 95% CI: 7–20) cases, while the 30-day death in 12 (9.2%; 95% CI: 4.8–15). Patients with complications had a higher overall in-hospital death (16 versus 1; $p < 0.05$). All patients who died within 30 days of procedures have experienced some complication(s). Presence of POCs found to be significantly associated with prolonged POMV [odds ratio 3.18 (95% CI: 1.13–8.97); $p = 0.02$], and 30-day deaths (p = 0.035) but not with prolonged POLOS. The presence of isolated cardiac or noncardiac complication(s) was also not associated with any one of our measured secondary outcomes; see Table 4.

4. Discussion

In this single -center study, we evaluated POCs after cardiac surgery for CHD in infants aged less than 90 days and we found that POCs are common present and associated with significant 30 days mortality. As expected, the incidences of POCs in our vulnerable patients are reasonable and consistent with findings of several large multi-center studies. It comes to our knowledge that this study is one of the first studies to evaluate the incidence of complications after cardiac operations in young infants in Saudi Arabia.

Table 3. Incidence of the postoperative complications following 130 cardiac procedures.

Type of complications	n (%)	Type of complications	n (%)
Mechanical Ventilation >7 days	35 (26.9)	Vocal cord dysfunction/stridor/ Laryngomalacia	10 (7.7)
Chylothorax/pleural effusion[a]	27 (20.8)	Surgical site infection/dehiscence	10 (7.7)
Excessive bleeding[b]	25 (19.2)	Neurologic disorders	8 (6.2)
Cardiac arrest	23 (17.7)	Renal and electrolytes disturbance	8 (6.2)
Systemic infections	23 (17.7)	Multiple Organ Dysfunction Syndrome, Disseminated Intravascular Coagulation, and metabolic acidosis	8 (6.2)
Arrhythmia[c]	22 (16.9)	Pneumothorax required evacuation	6 (4.6)
Post-op extracorporeal membrane oxygenation	14 (10.8)	Hepatic and Gastrointestinal tract	6 (4.6)
Unplanned cardiac catheterization or re-operation	12 (9.2)	Ischemia and thromboembolism	5 (3.8)
Paralyzed diaphragm	11 (8.5)	Anemia and thrombocytopenia	4 (3.1)
Persistent LCOS >72 h after procedure	10 (7.7)	Hypo/hyperglycemia	4 (3.1)
Lung collapse/atelectasis	10 (7.7)	Pulmonary hemorrhage	3 (2.3)
Pulmonary Hypertension (−/+ crisis)	10 (7.7)	Others[d]	6 (4.6)

Abbreviations: LCOS; low cardiac output syndrome.
[a] Pleural effusion Required drainage.
[b] Required transfusion or surgical exploration.
[c] Required drug/cardioversion/pacemaker therapy.
[d] Other complication include: Tracheostomy 2, Laparotomy 1, Diaphragmatic plication 1, Chyloperitonium 1, Surgical herniation 1.

Table 4. Postoperative complications and associated secondary outcomes.

Type of complications	Prolonged POLOS		Prolonged POMV		30-day death	
	OR (95% CI)	P-value	*OR (95% CI)*	P-value	*OR (95% CI)*	P-value
Any Complications (yes, vs no)	1.33 (0.52−3.43)	0.54	3.18 (1.13−8.97)	0.02	Not calculated	0.035
Only Cardiac Complications (yes, vs no)	0.39 (0.09−1.74)	0.19	0.77 (0.15−3.97)	1.00	3.73 (0.66−21.0)	0.1601
Only noncardiac Complications (yes vs no)	1.56 (0.60−4.06)	0.35	0.66 (0.29−1.49)	0.31	0.35 (0.07−1.67)	0.2156

Abbreviations: OR (95%CI); odds ratio (95% confidence interval), POLOS; post-operative length of stay, POMV; postoperative mechanical ventilation.

Despite majority of our cohort had one or more important risk factors for higher postoperative mortality and/or morbidity of the neonatal cardiac surgeries, our observed rates were consistent with the literature. However, the majority of literature was conducted in developed countries. In comparison to data in developed countries, our observed prevalence is relatively higher than that reported in neonates (29.2%) [13] and older pediatric patients (11.9%−43.4%) [7,8,11,14]. The higher rate in our study may be attributed to several reasons. Firstly, the majority of our patients were younger than 30 days in concomitant with smaller operative weight. Secondly, the majority of our subjects experienced complex lesions that necessitated complex surgeries. Thirdly, we enrolled large numbers of complications that were infrequently accounted for in other similar studies. These observations had been confirmed previously. For instance, Brown et al. [15] evaluated the incidence of selected morbidities for 3090 consecutive pediatric cardiac surgery in the United Kingdom and found that the adjusted odds ratio of morbidity was 5.2 higher in neonates when compared with children, while the complex heart diseases (e.g. HLHS) had 2.14 higher mortality than low complexity (e.g. atrial septal defect); "$p < 0.001$". Similarly, Xien Zeng et al. [16] noted that patients who were younger, lighter, or had cyanotic lesions experienced higher POCs. Regardless, our finding still close to that reported by other authors. For example, a large multicentered study enrolled 2557 neonates who underwent Norwood procedure in the United States reported that 75% of these cases suffered at least one POC [17].

The most frequent complications in our subjects were prolonged POMV and pleural effusion including chylothorax. These findings are consistent with many reported studies. Hornik et al. [17], confirmed that prolonged POMV support was required in 21.6%, while pleural effusion in 12.0%. Murni et al. [18] revealed also that 14.8% of 257 enrolled patients had pleural effusion.

Excessive postoperative bleeding that required transfusion or surgical re-exploration occurred in 19.2% of our patients. A recent review in the United States reported that 38%−74% of pediatric patients undergoing cardiac surgery needed blood transfusion [19]. Furthermore, a nested case−control study showed that 33% of included Mexican pediatric patients developed significant bleeding in the first six hours after the cardiac surgery [20]. However, bleeding requiring reoperation was found only on 8.0% of large cohort by Hornik et al. [17]. The lower incidence in this later study may result from the non-counting of patients who required blood transfusion without reoperation.

Infectious complications after cardiac surgery still also a common issue. In high-income countries, the prevalence of bacteremia varied from 1.5% to 10.2% [21]. Whereases in low-to middle-income countries, the postoperative bloodstream infection occurred in 7%−21% of the cases [22,23], and the surgical site infection in 12.7% [22]. These data are similar to our findings.

The most prevalent cardiac events in our study were post-operative cardiac arrest and significant cardiac arrhythmia required therapy. Similar results have been documented by Hornik et al. [17] and Murni et al. [18], while a higher (43.5%) rate had been observed by Alp H et al. [24].

Based on many factors; such as the complexity of the cases; the association of other comorbidities; and the nature of the cardiac surgery; the mortality rate after cardiac surgery in infants differs markedly among centers [25]. We reported higher in-hospital death and 30-day mortality rate than those reported in two large studies (<5%) in United States and United Kingdom [26,27]. Nonetheless, some studies have reported similar or even higher mortality levels than ours [22,28,29].

In a retrospective observational study, Agarwal et al. [8] found that the POCs in pediatric cardiac surgery was associated with longer mechanical ventilation, hospital stays, and increased mortality. Our finding is partially in agreement with the finding of Agarwal et al., where we did not observe any correlation with prolonged POLOS. However, few studies had confirmed a significant association between complication and prolonged POLOS [30]. Lack of this association in our study may be attributed to our small sample size and definition of prolonged POLOS.

This study has several limitations that must be acknowledged. First, the nature of the study is retrospective which raises potential misclassification bias. Second, it reflects the experience of a single center and local practice patterns, thence, it is not possible to generalize our findings. Third, it has a small sample size compared to several previously published studies. Despite these shortcomings, based on a high level of public interest in the outcomes of pediatric cardiac surgery, our paper can provide clues for future areas of research in cardiac surgery and perioperative strategies to minimized POCs in these particular patients; considering the unique characteristics of the local population. Our data may also aid in counseling families, provide an overview on the balance between the risks and benefits of surgery, and offer multiple potential targets for quality improvement.

5. Conclusion

Cardiac surgery for CHDs in young infants has a substantial risk for several POCs involving the cardiovascular system and other organs. This higher incidence makes necessary attention to the potential complications and their treatment after surgery. This study represents preliminary work to improve the outcomes of these patients in Saudi Arabia.

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Conflict of interest

All authors declare no conflict of interest and no personal circumstances that may be inappropriately influencing the representation or interpretation of research results.

Authors' contribution

Farrukh Javed: Conception, Literature review, Methodology, Writer-original draft, Visualization, Project administration.

Nabil Abdulrahman Aleysae: Conception, Literature review, Methodology, Analysis, Writer-original draft, Visualization, Project administration.

Abdulmajid Yahya Al-Mahbosh: Writing- review & editing, Visualization, Project administration.

Amal Ali Zubani: Conception, Methodology, Investigation, Writing- review & editing, Supervision.

Ali Mohammed Atash: Investigation, Data collection, Writing- review & editing.

Hanan Bin Salem: Investigation, Data collection, Writing- review & editing.

Mohamed Abdallah: Investigation, Data collection, Writing- review & editing.

Omaima Alkhatib: Investigation, Data collection, Writing- review & editing.

Ashraf Abu-Adas: Literature review, Investigation, Data collection, Writing- review & editing.

Maymoona Abdelmouz Hrays: Literature review, Investigation, Data collection, Writing- review & editing.

Nawal Ali Alqarni: Investigation, Data collection, Writing- review & editing.

Alla Felemban: Literature review, Investigation, Data collection, Writing- review & editing.

Saad Abdullah Alsaedi: Conception, Methodology, Writing- review & editing, Supervision.

Ahmed Abdullah Jamjoom: Methodology, Writing- review & editing, Supervision, Project administration.

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