Prevalence and Short-Term Outcomes of Postprocedural Complete Heart Block in Congenital Heart Disease Correction in Children

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Received 7 January 2024; Accepted 20 October 2024

Abstract

Background: *Complete heart block (CHB) is a known complication of congenital heart disease (CHD) corrections in children. However, data on the prevalence and short-term outcomes of postprocedural CHB in this population are scarce.*

Objectives: *This study aimed to investigate the prevalence and short-term outcomes of postprocedural CHB in pediatric patients undergoing surgical or transcatheter procedures to correct CHD.*

Method: *A retrospective cohort study was conducted on pediatric patients under 18 years old who underwent CHD corrections between March 2019 and April 2020 at a tertiary cardiac center in Isfahan, Iran. Patients with a history of arrhythmia or heart block before surgery were excluded. The medical records of these patients were reviewed to identify cases of postprocedural CHB. The prevalence, risk factors, and short-term outcomes of postprocedural CHB were analyzed.*

Result: *This study involved 840 patients with a mean age of 3.4 ± 4.3 years, with 47.8% being male. CHB was identified in 22 patients (2.6%) during the postprocedural period, with a prevalence of 0.6% in the transcatheter group and 4.7% in the surgical group. Patients with postprocedural CHB were younger than non-CHB patients. The most common CHDs were patent ductus arteriosus and ventricular septal defect (VSD). Univariate and multivariate regression analyses showed that the type of procedure (surgical method) and the type of CHD (VSD) correlated with postprocedural CHB. Patients who developed postprocedural CHB had a longer mean stay in the pediatric cardiac critical care unit than non-CHB patients. The postoperative in-hospital mortality rate was 5.2%, with no correlation between CHB occurrence and in-hospital mortality.*

Conclusion: *The findings highlight the importance of attentive monitoring for postprocedural CHB, particularly in younger patients, to facilitate timely intervention and improve outcomes. Further research is warranted to explore the long-term complications and risk factors associated with postprocedural CHB in this patient population.*

J Teh Univ Heart Ctr 2024;19(S1):17-23

This paper should be cited as: Mahdavi C, Sabri MR, Ahmadi A, Ghaderian M, Bigdelian H, Dehghan B, et al. Prevalence and Short-Term Outcomes of Postprocedural Complete Heart Block in Congenital Heart Disease Correction in Children. J Teh Univ Heart Ctr 2024;19(S1):17-23. DOI: 10.18502/jthc.v19is1.18475

Keywords: Complete heart block; Congenital heart disease; Pediatric; Postprocedural; Surgical correction

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DOI: 10.18502/jthc.v19is1.18475

Introduction

Congenital heart disease (CHD) is the most common essential congenital abnormality, with an estimated prevalence of approximately 9 cases per 1000 live births.[1, 2] Interventions are frequently required for dealing with CHD to enhance the overall well-being and long-term prognosis of affected pediatric patients.[3] The advancement of pediatric healthcare in the last decades has resulted in a notable improvement in survival rates among patients diagnosed with CHD.[4, 5] Additionally, improvements in diagnostic methods, catheter-based procedures, and various surgical advancements have contributed to the progress.[6, 7] Still, there are potential risks associated with these interventions, and complete heart block (CHB) is a widely recognized conduction-related complication after surgical procedures in pediatric patients, including those undergoing cardiac procedures for CHD.[8] The available research indicates a range of 0.05% to 6% incidence during the postoperative phase.[8–12]

Postoperative arrhythmias can result from pathological processes as well as patient- and surgery-related factors, such as CHD complexity, myocardial incisions that can directly traumatize the atrioventricular node and conducting system, and the occurrence of localized edema or inflammation that can cause fibrotic tissue.[13, 14] The majority of these conditions are transient, although they can lead to significant adverse outcomes.[15] It is critical to establish an accurate diagnosis and monitor the prevalence of CHB following open-heart surgery to improve surgical techniques, determine when temporary pacemakers (TPMs) and permanent pacemakers (PPMs) are required, and decrease unfavorable outcomes. Pediatric surgeons and cardiologists should be informed of the prevalence of CHB and employ the most recent techniques to reduce postoperative complications.

Our primary aim was to determine the incidence of CHB following CHD-related cardiac interventions at our institution. Moreover, we investigated the in-hospital prognosis and risk factors associated with the development of postprocedural CHB in children who have undergone CHD interventions.

Methods

Study design and population

A retrospective analysis was conducted at the pediatric cardiac department of Chamran Hospital in Isfahan, Iran. This study involved pediatric patients under 18 years old with CHD diagnosis who received surgical or transcatheter procedures to correct CHD. The study was conducted from March 2019 through April 2020. Patients with a history of arrhythmia or heart block before surgery were excluded. The research obtained ethical clearance from the Ethics Committee of Isfahan University of Medical Science (Ethical number: IR.MUI.MED.REC.1400.745), adhering to the ethical guidelines outlined in the Declaration of Helsinki. Due to the retrospective nature of this study, informed consent was waived. Patient information was coded and anonymized to ensure that it remained confidential.

Data collection

Demographic and perioperative clinical parameters were retrieved from hospital records. These data included age, gender, the type of CHD, and the type of surgical procedure. A standardized data collection sheet was employed to minimize information bias. Following the surgical procedure, consistent electrocardiographic and hemodynamic monitoring of all patients was conducted within the pediatric cardiac critical care unit (PCCU). Additionally, postoperative ECGs were examined for all patients involved in the study, following the established protocols of normal clinical practice. Standard ECG tracings were initially evaluated by a pediatric cardiologist and then by an electrophysiologist to confirm the diagnosis of CHB. To distinguish between transient and permanent CHB, a period of about 10 to 14 days was considered for CHB recovery in transient ones.

Outcome assessment

The primary outcome of interest was the prevalence of transient and permanent postprocedural CHB in children undergoing CHD correction. Secondary outcomes included the need for temporary or permanent pacing, the length of PCCU stay, in-hospital mortality, and the risk factors associated with postprocedural CHB.

Statistical Analysis

The data in the study were presented in terms of frequencies and percentages for categorical variables and mean ± standard deviation (SD) for continuous variables. The Shapiro-Wilk test was employed to assess the normality of all continuous variables. The χ^2 or Fisher exact test was utilized for categorical variables in descriptive statistics, while the independent samples t-test or the Mann-Whitney U test was employed for continuous variables. A univariate analysis (binary logistic regression) was performed between each demographic and clinical variable and CHB occurrence to identify the potential predictors of postprocedural CHB. Subsequently, all these variables were included in a multiple logistic regression model to control for potential confounders and ensure that the associations observed were not simply due to the influence of other variables. The results of the binary logistic regression model are presented as the odds ratio (OR) with a 95% confidence interval (CI). Statistical significance was defined as P-values<0.05. IBM SPSS Statistics, version 26.0 (IBM Corp, Armonk, NY, USA), was used for all statistical analyses.

Results

A total of 870 patients underwent transcatheter or surgical procedures during the study period. Of them, 840 patients were included in the study (Figure 1). The mean age of the study population was 3.4 ± 4.3 years, and 47.8% were male. CHB was determined in 22 patients (2.6%) in the

postprocedural period. A total of 471 patients underwent the transcatheter procedure, and 369 patients underwent surgery. The prevalence of CHB in the transcatheter and surgical groups was 0.6% and 4.7%, respectively. Patients with postprocedural CHB were younger than those who did not suffer from this complication, and this difference was statistically significant (mean ± SD: 1.91 ± 2.65 vs 3.45 ± 4.33 y; P = 0.014). The prevalence of postprocedural CHB after CHD correction in pediatric patients younger than 2 years old was 3.4% (17 of 488 patients), and this prevalence was 1.4% (5 of 351 patients) in those older than 2 years (P = 0.066). Concerning CHD classification as cyanotic and acyanotic, the frequency of cyanotic diseases was higher in the CHB group than in the non-CHB group, and this difference tended to be significant (31.8% vs 22.8%; P = 0.054). The most common CHD in the study was patent ductus arteriosus (PDA). Whereas all PDA patients in the CHB group were comorbid with other CHDs, none of the patients in the CHB group had isolated PDA. Furthermore, the frequency of VSD was higher in patients with CHB than in the non-CHB group (63.6% vs 34.3%; P = 0.005). Additionally, 40.9% of patients with CHB also had both VSD and PDA defects. Table 1 shows the baseline characteristics of the studied patients.

Univariate and then multivariate binary logistic regression analyses were performed to determine the independent predictors of postprocedural CHB (Table 2). Univariate regression analyses showed that the type of procedure (surgical method) and the type of CHD (VSD) correlated with the incidence of postprocedural CHB, and these factors remained significant after multivariate regression (surgical method**:** univariate OR: 8.49, 95% CI: 2.49 to 28.92; P = 0.001 and multivariate OR: 6.45, 95% CI: 1.72 to 24.08; P = 0.006 and VSD: univariate OR: 3.33, 95% CI: 1.38 to 8.03; P = 0.007 and multivariate OR: 3.45, 95% CI: 1.25 to 9.48; P = 0.01).

All patients with permanent CHB were female. However, a comparison of demographic and clinical characteristics between patients with transient and permanent CHB revealed no significant differences in age, type of CHD, or type of surgical procedure (Table 3). Fourteen patients had transient CHB, and 8 had permanent CHB that required PPM implantation (Table 4). CHB occurred at a median (IQR) duration of 0.5 (0–1.25) days after the procedure. In cases of transient CHB, the duration of TPM use was 5 ± 4.04 days. The mean length of stay in the PCCU was higher in the CHB group than in the non-CHB group, with the difference constituting statistical significance (mean±SD: 11.18 ± 12.07 vs 3.75 ± 6.85 d; P < 0.001, mean difference: 7.42, 95% CI: 4.44 to 10.41). Still, there was no difference in the length of PCCU stay between the permanent and transient CHB groups. The postoperative in-hospital mortality rate in the study population was 5.2%. In addition, the rate of in-hospital mortality in the CHB group was 9%, and no correlation was found between the occurrence of CHB and in-hospital mortality (P = 0.41).

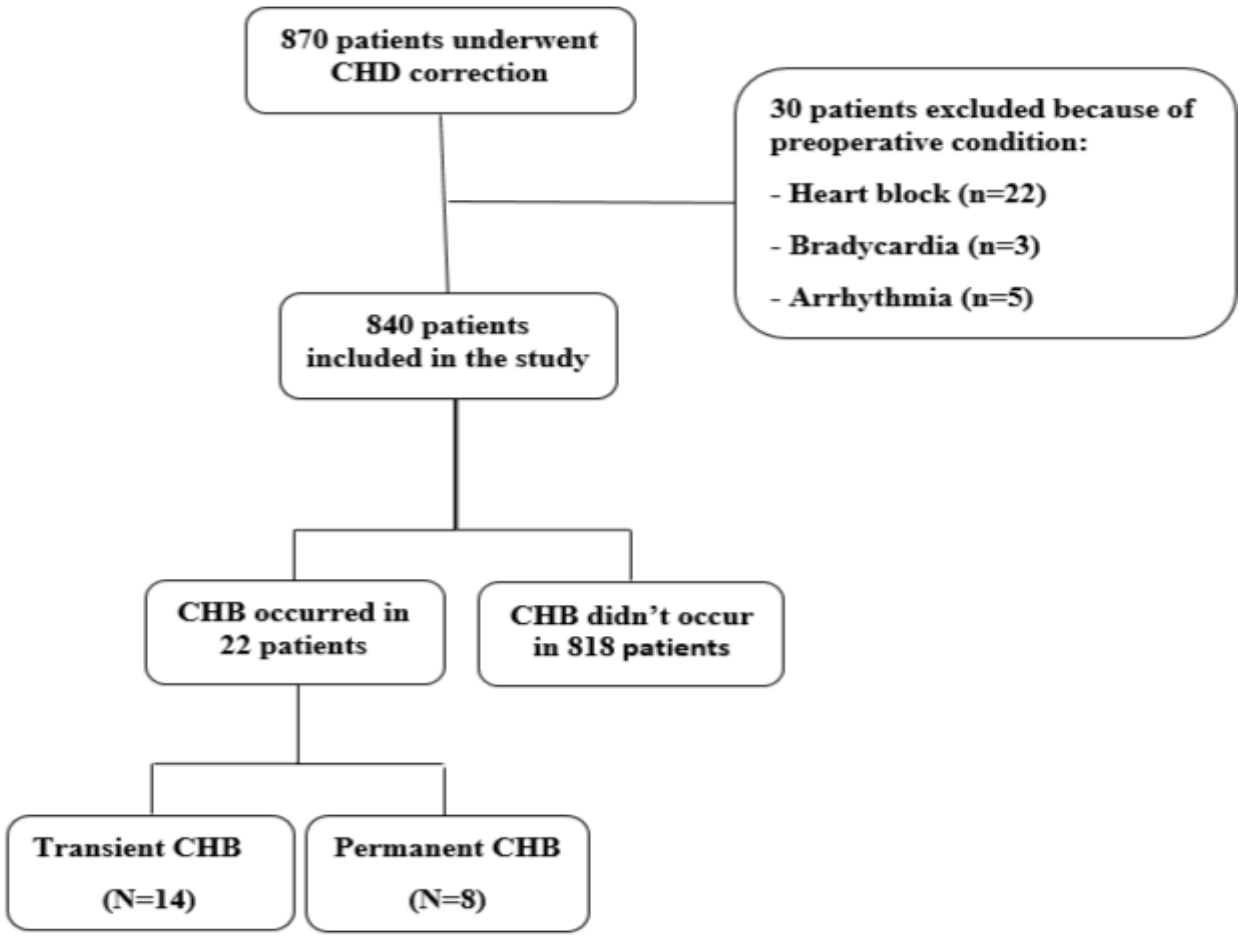


Figure 1. The image illustrates the flow diagram of the studied patients.

Table 1. Baseline and postoperative characteristics concerning the incidence of postoperative CHB

Variables	Total (N = 840)	CHB (N = 22)	Non-CHB (N = 818)	P-value [2]
Age	3.41±4.3	1.91±2.65	3.45±4.33	0.014*
Gender (male)	402(47.8%)	8(36.3%)	394(48.1%)	0.27
Type of Procedure				
Transcatheter	471(56.07%)	3(13.6%)	468(57.2%)	0.001>*
Surgery	369(43.9%)	19(86.3%)	394(48.1%)	
Type of CHD				
Cyanotic	194(23.09%)	7(31.8%)	187(22.8%)	0.054
Acyanotic	635(75.5%)	15(68.1%)	619(75.6%)	
Other #	11(1.3%)	0(0.00%)	11(1.3%)	
VSD	296(35,2%)	14(63.6%)	281(34.3%)	0.005*
ASD	245(29.1%)	7(31.1%)	238(29.09%)	0.78
AVSD	30(3.5%)	2(9.09%)	28(3.4%)	0.18
PDA	405(48.2%)	16(72.7%)	389(47.5%)	0.02*
TGA	65(7.7%)	3(13.6%)	62(7.5%)	0.24
TOF	104(12.3%)	4(18.1%)	100(12.2%)	0.28
Length of PCCU stay	3.95±7.12	11.18±12.07	3.75±6.85	0.001>*
Postoperative in-hospital mortality	44(5.2%)	2(9.09%)	42(5.1%)	0.41

CHB, Complete heart block; CHD, Congenital heart disease; VSD, Ventricular septal defect; ASD, Atrial septal defect; AVSD, Atrioventricular septal defect; PDA, Patent ductus arteriosus; TGA, Transposition of the great arteries; TOF, Tetralogy of Fallot; PCCU, Pediatric critical care unit
*Significant difference at the 0.05 level.
Other: eg, dilated cardiomyopathy, cardiac tumor, congenital stenosis of the aortic valve, and arteriovenous fistula

Table 2. Univariate and multivariate logistic regression analyses to determine independent predictors of postprocedural CHB in pediatric patients with CHD

Variables	Univariate			Multivariate		
	OR	CI	P-value	OR	CI	P-value
Age	0.89	0.77-1.02	0.10	0.95	0.82-1.11	0.56
Gender (male)	0.61	0.25-1.47	0.27	0.52	0.21-1.30	0.16
Type of surgery (surgical method)	8.49	2.49-28.92	0.001*	6.45	1.72-24.08	0.006*
Type of CHD (cyanotic)	1.57	0.63-3.91	0.33	5.22	0.07-390	0.45
VSD	3.33	1.38-8.03	0.007*	3.45	1.25-9.48	0.01*
ASD	1.13	0.45-2.81	0.78	1.73	0.64-4.63	0.27
AVSD	2.81	0.62-12.63	0.17	4.05	0.74-22.08	0.10
PDA	2.92	1.13-7.55	0.02*	1.21	0.37-3.91	0.75
TGA	1.92	0.55-6.66	0.30	7.19	0.09-527	0.36
TOF	1.59	0.52-4.79	0.40	13.11	0.17-974	0.24

CHB, Complete heart block; CHD, Congenital heart disease; VSD, Ventricular septal defect; ASD, Atrial septal defect; AVSD, Atrioventricular septal defect; PDA, Patent ductus arteriosus; TGA, Transposition of the great arteries; TOF, Tetralogy of Fallot

Table 3. Comparison of baseline characteristics and postoperative outcomes regarding transient and permanent CHB

Variables	Transient CHB (N = 14)	Permanent CHB (N = 8)	Mean difference (95% CI)	P-value
Age	2.21±3.04	1.38±1.84	-0.83 (-3.32 – 1.64)	0.48
Gender (male)	8(57.1%)	0(0.00%)	-	0.009*
Type of surgery				
Transcatheter	11(78.5%)	8(100%)	-	0.23
Open	3(21.4%)	0(0.00%)	-	
Type of CHD				
Cyanotic	4(28.5%)	3 (37.5%)	-	0.51
Acyanotic	10(71.4%)	5(62.5%)	-	
VSD	10(71.4%)	4(50%)	-	0.29
ASD	4(28.5%)	3(37.5%)	-	0.51
AVSD	1(7.1%)	1(12.5%)	-	0.60
PDA	9(64.2%)	7(87.5%)	-	0.25
TGA	3(41.4%)	0(0.00%)	-	0.23
TOF	1(7.1%)	3(37.5%)	-	0.11
Time from the procedure to CHB occurrence	2.14±6.32	2.00±3.33	-0.14 (-5.19 – 4.91)	0.94
TPM duration	4.07±3.66	9.33±3.05	5.26 (0.39 – 10.13)	0.036*
Length of PCCU stay	9.79±14.51	13.63±5.95	3.83 (-7.46 - 15.14)	0.48
Postoperative in-hospital mortality	0(0.0%)	2(25%)	-	0.39

CHB, Complete heart block; CHD, Congenital heart disease; VSD, Ventricular septal defect; ASD, Atrial septal defect; AVSD, Atrioventricular septal defect; PDA, Patent ductus arteriosus; TGA, Transposition of the great arteries; TOF, Tetralogy of Fallot; TPM, Temporary pacemaker; PCCU, Pediatric critical care unit
*Significant difference at the 0.05 level.

Table 4. Demographic and clinical characteristics of each patient

Patients	Gender	Age (y)	Type of Procedure	Type of CHB	Type of CHD	CHD	Time from the Procedure to CHB Occurrence	Type of Pacemaker	TPM Duration	In-Hospital Outcome
1	Male	2	Surgical	transient CHB	Acyanotic	VSD/ PDA	0	TPM	2	alive
2	Male	<1	Transcatheter	transient CHB	Cyanotic	ASD/ PDA/ TGA	0	TPM	9	die
3	Female	1	Surgical	permanent CHB	Cyanotic	PDA/ TOF	0	PPM	-	alive
4	Female	<1	Surgical	transient CHB	Acyanotic	VSD	0	TPM	10	alive
5	Male	2	Surgical	transient CHB	Acyanotic	VSD	0	TPM	2	alive
6	Male	2	Transcatheter	transient CHB	Acyanotic	VSD/ ASD	0	Medical treatment	0	alive
7	Female	<1	Transcatheter	transient CHB	Acyanotic	Other	0	TPM	0	die
8	Female	11	Surgical	transient CHB	Cyanotic	VSD/ TGA	0	TPM	2	alive
9	Female	3	Surgical	permanent CHB	Acyanotic	VSD	0	PPM	-	alive
10	Female	<1	Surgical	permanent CHB	Acyanotic	ASD/ PDA	0	PPM	-	alive
11	Female	1	Surgical	transient CHB	Cyanotic	VSD /PDA/ TGA	0	TPM	1	alive
12	Female	5	Surgical	permanent CHB	Cyanotic	PDA/ TOF	1	PPM	-	alive
13	Male	<1	Surgical	transient CHB	Acyanotic	ASD/ AVSD/ PDA	1	TPM	8	alive
14	Female	1	Surgical	transient CHB	Cyanotic	PDA/TOF	1	TPM	2	alive
15	Female	5	Surgical	transient CHB	Acyanotic	VSD / ASD /PDA	1	TPM	5	alive
16	Male	2	Surgical	transient CHB	Acyanotic	VSD /PDA	1	TPM	2	alive
17	Female	<1	Surgical	permanent CHB	Acyanotic	VSD /PDA	1	both	12	alive
18	Female	2	Surgical	permanent CHB	Cyanotic	VSD /PDA/TOF	2	both	6	alive
19	Male	5	Surgical	transient CHB	Acyanotic	VSD /PDA	2	TPM	4	alive
20	Female	<1	Surgical	permanent CHB	Acyanotic	VSD /ASD / PDA	2	PPM	10	alive
21	Female	<1	Surgical	permanent CHB	Acyanotic	ASD /AVSD /PDA	10	PPM	-	alive
22	Male	<1	Surgical	transient CHB	Acyanotic	VSD /PDA	24	TPM	10	alive

CHB, Complete heart block; CHD, Congenital heart disease; VSD, Ventricular septal defect; ASD, Atrial septal defect; AVSD, Atrioventricular septal defect; PDA, Patent ductus arteriosus; TGA, Transposition of the great arteries; TOF, Tetralogy of Fallot; TPM, Temporary pacemaker; PPM, Permanent pacemaker

Discussion

In this retrospective study, the postprocedural prevalence of CHB independently of the CHD correction in pediatric patients was 2.6%, with 60% being transient CHB and the remaining 40% classified as permanent CHB. The study population's in-hospital outcome investigation revealed that although CHB was linked to longer PCCU stays in patients, no correlation was discovered between postprocedural CHB and in-hospital mortality.

Surgical repair operations have been observed to boost the long-term prognosis of pediatric patients diagnosed with CHD. It must be kept in mind, nevertheless, that these procedures are not without risks. One of the most common postoperative complications is cardiac arrhythmia. In the literature, one-third of the cases of postoperative arrhythmias following CHD correction are CHB.[16]

The present study revealed a prevalence of 4.7% for post-surgical CHB in pediatric patients with CHD. In previous investigations, the incidence of these complications has similarly been observed to range from 2% to 6%.[8, 9,17–19] In a study conducted by Jeffery et al,[4] annual assessments over 10 years, from 2000 through 2009, involving 16,105 pediatric patients under 24 months of age who underwent repair of ventricular septal defect, atrioventricular canal, and tetralogy of Fallot revealed that 4.1%, 7.7%, and 3.7% of these patients developed postprocedural CHB, respectively. The incidence of postprocedural CHB was between 4.5% and 5.2% during 4 time points. Furthermore, there was no significant change over time in the frequency of postprocedural CHB between patients undergoing repair of VSD, atrioventricular canal, and tetralogy of Fallot.

In another study involving 6333 children between 0 and 21 years of age who underwent cardiac surgery for CHD

between 2010 and 2019, 2% of the studied cases developed post-surgical CHD.

In our study, out of 471 patients who underwent transcatheter corrective intervention, CHB occurred in 3 cases diagnosed with ASD/PDA/transposition of the great arteries, VSD/ASD, and aortic stenosis/pulmonary stenosis/pulmonary insufficiency. While our study found a lower incidence of CHB in patients who underwent transcatheter intervention compared with patients who underwent surgical repair, there have been reports of an increased incidence of CHB following transcatheter procedures in other research.[20–22]

Although early correction of CHD in children has been associated with a reduction in mortality rates in recent decades, the likelihood of postoperative complications may increase with age in these patients. In the current study, early CHD correction was associated with an increased risk of CHB occurrence. Besides being younger, previous studies have identified a correlation between VSD, particularly cases involving the perimembranous region, and an increased risk of CHB development following CHD repair. This association has been documented in the existing literature. Murray et al[18] conducted a study to examine the impact of phenotypic and genotypic characteristics on children who underwent corrective intervention for CHD. They identified several independent predictors of CHB occurrence following an intervention, such as VSD closure, preoperative digoxin exposure, duration of aortic cross-clamping, and the presence of the GJA5 polymorphism. Edwin et al[23] observed that the presence of VSD, either in isolation or as a component of conotruncal anomalies, was identified as a significant anatomical risk factor for CHB.

However, studies that identify the electrophysiologic sites of CHB following open-heart surgery remain limited. Identifying the incidence of early and delayed atrioventricular block after surgical and transcatheter closure of VSDs is potentially important because it can be a point of comparison for new techniques such as transcatheter VSD device closure.[21]

Romer et al[8] conducted a multicenter registry-based study involving 15,901 patients who underwent surgical correction of CHD and reported that the incidence of atrioventricular block was 2.7%. Similar to our findings, in this study, the average length of hospitalization in patients with transient atrioventricular block and those with PPM implantation was longer than that in other patients. Nonetheless, contrary to our results, in this study, in-hospital mortality in the PPM group was 3 times higher. Additionally, in the transient atrioventricular block group, it was almost twice that of patients in whom atrioventricular block did not occur.

In our study, 86% of patients who underwent TPM implantation had a resolution within 10 days or less. According to the study by Madani et al,[9] the likelihood of recovery following PPM implantation increases with advancing age and higher body weight. In this study, 91% of the cases were resolved by the 10th postprocedural day. Consistent with these findings, guidelines suggest that a PPM be placed for post-surgical heart block after 7 to 10 days as a Class I indication.[15, 24]

Our study has certain limitations that need to be acknowledged. Firstly, the study was observational in nature and nonrandomized, which may have influenced the results. Secondly, the study relied on retrospective chart reviews and medical records, which may have led to incomplete data. Additionally, the study was conducted at a single center, and the findings may not apply to other centers or populations. The impact of factors such as autonomic tone, growth, and age on PR interval and electrophysiologic measurements was not evaluated through dynamic ECG tracings. Moreover, the study did not account for various factors that could affect the development of CHB, such as genetic polymorphisms and QRS escape rhythm morphology. The lack of detail regarding decision-making around PPM placement further limits the evaluation. Lastly, long-term atrioventricular nodal conduction assessment was not included, which may have led to an underestimation of the incidence of postprocedural CHB. These limitations may restrict the applicability of the study's results to a broader population or different healthcare settings. The lack of randomization and incomplete data collection could introduce bias and affect the reliability of the conclusions drawn from the study. The failure to account for various influencing factors and the lack of evaluation of long-term outcomes may lead to an incomplete understanding of the development and management of postoperative arrhythmias. Therefore, it is essential to interpret the study findings with caution and consider these limitations when applying the results to clinical practice or future research. Future research is needed to identify predictive factors and improve management protocols for patients with CHB to reduce morbidity and mortality associated with postoperative arrhythmia.

Conclusion

The prevalence of CHB in children following CHD correction was 2.6%. Pediatric patients undergoing CHD reconstructive surgery, particularly at a younger age, should be closely monitored for this potential postoperative complication. While postprocedural CHB does not appear to worsen short-term mortality, it is associated with an increased length of stay in the PCCU. Future studies should explore the relationship between CHB occurrence and long-term outcomes.

Ethical approval and consent to participate

The research obtained ethical clearance from the Ethics Committee of Isfahan University of Medical Sciences, adhering to the ethical guidelines outlined in the Declaration of Helsinki (ethics code: IR.MUI.MED.REC.1400.745). Due to the retrospective nature of this study, informed consent was waived. Patient information was coded and anonymized to ensure that it remained confidential.

Acknowledgments

We extend our heartfelt gratitude to all the participants involved in this study.

Conflict of Interest

The authors have no competing interests.

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