Scientific Journal of University of Benghazi

SJUOB (2026) 39 (1) Medical Sciences: Madany, et.al. 45 – 52
www.sjuob.uob.edu.ly

The Predictive Value of Normothermic Cardiopulmonary Bypass Protocol for Early Neurological Complications: A Dual-Center Study in Benghazi.

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DOI: 10.37376/sjuob.v39i1 | Received:15/03/2026 | Accepted:12/05/2026 | Publishing: 30/06/2026

ABSTRACT

The early neurological complications (ENCs), including stroke, seizure, hemiparesis, and delirium, represent a major cause of morbidity in patients who undergo cardiac surgeries for congenital heart disease (CHD), as the immaturity of the central nervous system (CNS) in infants and small children increases the risk of brain insult during cardiac surgeries. Intra-operative risk factors of neurological complications include cerebral air embolism, longer duration of cardiopulmonary bypass (CPB) time, degree of hypothermia, and the strategy of brain neuroprotection to control cerebral perfusion to reduce these risks. This study aims to evaluate the incidence of ENCs and compare outcomes of different hypothermic protocols utilized by three surgical teams. Methods: We conducted a retrospective review of 380 patients undergoing cardiac surgery by three surgical teams, utilizing different hypothermic protocols. Data were analyzed to determine the ENC risks, including age, cardiac complexity, bypass time, and intraoperative temperature. The frequency of (ENCs) was 3.4%. Variation was observed between the surgical teams ($p = 0.036$). The normothermic protocol team had the highest rate of ENCs (7.7 %), while the other teams had 2.2 % and 1.9%. The normothermic protocol revealed an increased risk of (ENCs) by 2.4 times compared to other teams, which highlights the importance of neuroprotection of hypothermia control during cardiac surgery in centers with limited continuous neurological monitoring.

KEYWORDS: Early Neurological Complications (ENCs), cardiac surgery, Libya.

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 ISSN: Online 2790-1637, Print 2790-1629
National Library of Libya, Legal number: 154/2018

1. INTRODUCTION

One of the most common birth defects is congenital heart disease (CHD), with an incidence of 0.8% to 1.3% in every live birth neonate. With improvement in cardiac surgery services, including intraoperative and intensive care unit (ICU) care, Survival rates of patients with CHD, including those with complex lesions, have significantly improved along with a decline in mortality rates[7]. There is an emphasis on reduced morbidity and enhancement of long-term outcomes; neurological complications of cardiac surgery result in a significant effect on the quality of life of patients [14,15.] (ENCs) occurring in post-cardiac surgeries of patients with CHD included convulsion, stroke, and delirium, which may contribute to a long-term neurodevelopmental deficit; their incidence was between 2 and 50%, as reported in previously published studies [2, 12]. The infants and small children are more susceptible to brain ischemia and neurologic insult during cardiac surgeries [1]. The degree of hypothermia and duration of cardiopulmonary bypass (CPB) time, aortic clamp time, and cerebral air embolism contributed to the intraoperative risk of ENCs, whereas mechanical ventilator and low cardiac output were associated with increased postoperative stroke and delirium [4, 11]. In comparison with an increasing number of multicenter research studies on ENCs in other countries that have advances in their healthcare facilities, perioperative management, surgical practices, and postoperative care, we still have a considerable gap in local data regarding early neurological complications in post- cardiac surgery in patients with CHD.

This study aims to evaluate the incidence of ENCs and compare outcomes of normothermic, moderate, and deep hypothermia protocols as utilized by three surgical teams in two hospitals in Benghazi.

2. METHODOLOGY

A retrospective observational study was conducted at the Benghazi Cardiac Center and Benghazi Medical Center to evaluate the incidence, types of ENCs, and risk factors in 380 patients who underwent cardiac surgery for congenital heart disease between 2020 and 2025. Patients who suffer from Severe preoperative neurological conditions were excluded from this study. Data were collected from patients' medical records. The demographic variables included gender, age, and patients' addresses. Congenital heart diseases are divided into two Groups based on anatomical cardiac defects: Acyanotic and cyanotic CHD. The intraoperative data included the degree of hypothermia during cardiopulmonary bypass time(CPB), cardiopulmonary bypass time (CPBT), aortic cross-clamp time (ACCT), cardiac surgeries, including open and closed cardiac surgeries, ENCs, including convulsion, hemiparesis, and delirium, that occurred before patients' discharge or within 30 days of surgery. Temperature during cardiopulmonary bypass (CPB) was monitored via the nasopharyngeal route and classified into three protocols: normothermic (36.0–37.0°C), moderate hypothermic (32.0–34.0°C), and deep hypothermic (28.0–32.0°C), These temperature ranges were routinely used in the participating centers. The data were analyzed using IBM SPSS Statistics version 27, including the Pearson Chi-square test, the independent samples t-test, and the Mann-Whitney U test. P-value < 0.05, Odds Ratios (ORs), and 95% Confidence Intervals (CIs) were used to determine risk factors for ENCs.

3. ETHICAL CONSIDERATIONS

This study is a retrospective descriptive observation study conducted using anonymized medical data, with official approval from the heads of the departments at Benghazi Medical Center and Benghazi Cardiac Center. Given the non-interventional nature of the study and the absence of direct patient contact, the requirement for informed consent was waived.

 ISSN: Online 2790-1637, Print 2790-1629
National Library of Libya, Legal number: 154/2018

4. RESULTS

(66.6%) of the patients were in the child age group, followed by infants (31.2%), while adolescents and young adults constituted (2.1%). 53.2 % were male, 46.8 % were female. 86.6% of patients are from Benghazi and Eastern Region,48.4% of the patients had intermediate hypothermia during bypass. Table.1

Table 1. Clinical Characteristics and Demographics of patients (N = 380).

Age Group	Frequency (n)	(%)
Age		
Infants	119	31.2%
Children	253	66.6%
Adolescents/Adults	8	2.1%
Sex		
Male	202	53.2 %
Female	178	46.8 %
Address (Region)		
Benghazi & Eastern Region	330	86.6%
Other Regions (South/West)	50	13.1 %
Surgical Team		
Normothermic Team	91	23.6%
Intermediate hypothermic Team	184	48.4%
Deep hypothermic Team	105	27.6%

23.9% of patients had genetic syndromes; 20 % of patients had Down syndrome. For CHD, 69% were Acyanotic; VSD was the most common defect (44.2%), and 31% had cyanotic defects, and TOF was the most common defect (44%).Table.2

Table 2. Clinical and Genetic Profile (N=380)

Patients Clinical profile	Frequency (n)	%
Genetic Syndromes		
Normal (Non-syndromic)	289	76 %
Down Syndrome	76	20 %
Williams Syndrome	7	1.8%
Other Syndromes*	8	2.1%
Classification of CHD		
Acyanotic CHD	262	69%
Cyanotic CHD (CCHD)	118	31%
Acyanotic CHD		
Ventricular Septal Defect (VSD)	116	44.2%
Atrial Septal Defect (ASD)	51	19.2%

 ISSN: Online 2790-1637, Print 2790-1629
National Library of Libya, Legal number: 154/2018

Atrioventricular Canal (AVC) Defects	38	14.5%
Aortic stenosis (AS), Coarctation of Aorta (COA), Patent ductus (PDA)	57	21.8%
Common Cyanotic CHD (CCHD)		
Tetralogy of Fallot (TOF)	51	43.2 %
Single Ventricle Physiology	25	21.2%
Pulmonary Stenosis/Atresia	11	9.3%
Transpostion Great Artery(TGA) & Double outlet right ventricle(DORV)	16	13.5%
Others	15	12.7%

The incidence of (ENCs) complications was 3.4% (n=13). Convulsions were the most prevalent manifestation, occurring in 2.1% of the total operated patients, followed by delirium (0.8%) and hemiparesis (0. 5%).Table.3

Table 3. Early Neurological Complications (ENCs) (N = 380)

ECNs	Frequency (n)	(%)
Complications	13	3.4%
Type of Complication		
Convulsions	8	2.1 %
Delirium	3	0.8 %
Hemiparesis (Stroke)	2	0.5%
No CNS Complications	367	96.6 %
Total	**380**	**100%**

The highest operation performed in 2024 (n=127). No significant association was found between the year of surgery and the occurrence of ENCs (p = 0.587).

Table 4. Year of Operation

Year of Operation	Total, n (%)	ENCs, n (%)	P-value
2021	42 (11.0%)	1 (2.4%)	
2022	78 (20.5%)	4 (5.1%)	
2023	63 (16.6%)	3 (4.8%)	0.0.587
2024	127 (33.4%)	2 (1.6%)	
2025	70 (18.4%)	3 (4.3%)	
Total	380 (100%)	13 (3.4%)	

The normothermic team had the shortest bypass and cross-clamp durations compared to other teams ($p < 0.05$); however, the highest ENC rate occurred in the patient operated by the normothermic team (7.7%, $p = 0.037$). Table 5

Table 5.Comparison of Operative Parameters and Neurological Outcomes between Surgical Teams:

Team	NT Team (n=91)	IH Team (n=184)	DH Team (n=105)	p-value
ENCs Rate, n (%)	7 (7.7 %)	4 (2.4%)	2 (1.9%)	0.037*
Odds Ratio (OR)	2.4	1.00	--	
95% Confidence Interval (CI)	1.054 – 5.667	--	--	
Operative Parameters				
Bypass Time (min)				
Mean (SD)	2.81 (1.05)	3.31 (1.27)	2.86 (1.25)	0.001*
Mean Rank	171.3	211.7	168.7	
Cross-clamp Time (min)				
Mean (SD)	1.71 (0.60)	2.05 (0.75)	1.89 (0.68)	0.001*
Mean Rank	161.10	207.26	184.96	
Normothermic Bypass, %	100%	23.5%	19.0%	< 0.001*

NT (Normothermic), IH (Intermediate hypothermic), DH (Deep hypothermic). CPB mean (Mean: 1=less than 30min,2=30-60min,3=60-90 min,4= more than 90min.Cross-clamp times mean (1=less 25min,2=more than 25min). IH (Reference Group)

The normothermic team's protocol was the sole independent predictor of ENC (OR: 2.4, 95% CI: 1.054 – 5.667, p = 0.037). while patient age, lesion type, and bypass duration were not associated with increased neurological risk (p > 0.05) -Table 6.

Table 6. Predictors Risk Factors for Neurological Complications:

Predictive variable	Odds Ratio (OR)	95% Confidence Interval	P-value
Patient Age	1.34	0.95 – 1.89	0.086
Bypass Duration	01.02	0.58 – 1.80	0.929
Cross-clamp Time	1.34	0.47 – 3.84	0.575
Congenital Heart Defect	1.51	0.44 – 5.12	0.506

5. DISCUSSION

We focused on early neurological complications following cardiac surgery for CHD. There was a wide range in age groups from infancy to adulthood, according to the type of CHD and the availability of the surgical teams' mission schedule. Neurological complications included stroke, seizure, hemiparesis, and delirium, as the immaturity of the central nervous system (CNS) in infants and small children increases the risk of brain insult during cardiac surgeries, compared to findings in other studies, where the most affected was the infant age group as reported by Melnychenko. and Yılmaz et al.[14,16]. At the same time, in our setting, there was no association between age and ENCs, indicating that the higher proportion of young patients at high risk did not affect the outcomes in our setting, brain growth is most rapid during the first year of life. Head circumference increases by 12 cm from birth to one year (35 cm to 47 cm), but only 8 cm from two to 18 years (49 cm to 57 cm). Since our study found no association between age and neurological complications, the corrective cardiac surgery for congenital heart disease should be performed as early as possible to protect brain development and prevent complications, including cyanotic spells. The peak of surgeries was in 2024 (33.3%); the year of surgery was not associated with an increased rate of ENCs, suggesting that the higher complication rates observed with some protocols remained consistent over time and were not the result of a particular year of poor performance.

Down syndrome (DS) was observed in 20 % of patients; the result of our analysis suggested the presence of a syndrome was not an independent predictor of early neurological complications (ENCS). This finding is crucial and not aligned with other studies by Starr et al and Bashir et al[1,7] demonstrated associations between DS and ENCs, as it supports the hypothesis that the observed neurological morbidity was primarily due to surgical protocols rather than preexisting genetic susceptibility. According to the types of CHD operated on in this study, 31% of patients had cyanotic CHD, mainly Tetralogy of Fallot (43.2%) and other complex CHD, and this spectrum of CHD needs advanced management during cardiac surgeries and manipulation of cardiopulmonary bypass (CPB). Despite the complexity of this type of CHD, there is no significant difference in ENCs rates between Acyanotic and cyanotic CHD groups ($p = 0.506$). This observation is consistent with the results of Shams-Malkara et al [2], suggesting that when uniform neuroprotection is applied, the anatomical complexities of the defect become secondary compared to the effectiveness of the cooling strategy. The high prevalence of ventricular septal defects (44.2%) and atrial septal defects (19.2%) provided a solid basis for comparing surgical performance. In these relatively routine procedures, the high complication rate recorded by the normothermic protocol becomes even more striking. This suggests that even in low-risk morphological repairs, neglecting cooling exposes the developing brain to unnecessary risks, which is consistent with what Starr et al. [1] and Raj et al[9]. reported regarding long-term neurodevelopmental outcomes in children with heart disease. ENCs rate in this conducted study was 3.4 %, which is consistent with findings reported in previous pediatric cardiac surgery literature. Starr et al.[1] and Hobara et al.[8] reported that seizures were the most common sign of early brain insult in the early recovery phase after cardiac surgery; our finding regarding postoperative seizures is consistent with previous studies. While the most severe focal deficits, such as hemiplegia, were (0.5%), the presence of delirium was observed in (0.8%) of patients, this is consistent with previous studies conducted by Schumann et al.[4] and Wolf et al.[10], who reported that postoperative delirium is an ENC and may affect long-term cognitive outcomes. The low rate of hemiplegia compared to convulsions suggests that many cases may be related to reversible metabol-

 ISSN: Online 2790-1637, Print 2790-1629
National Library of Libya, Legal number: 154/2018

ic disturbances Lin Set et al [6] and Silva et al.[12] suggested that even transient neurological events during the neonatal and childhood periods affect long-term neurodevelopment outcomes, necessitating strict neuroprotective strategies. In this study, our analysis supports that normothermic protocol during cardiac surgery was a predictor for ENCs. The normothermic protocol team had the highest rate of NECs at 7.7 %, compared with the moderate hypothermic team (2.4%) and the deep hypothermic team (1.9 %). Particularly, the normothermic protocol revealed shorter bypass and aortic clamp times in comparison with the corresponding groups. Our observations focus on the significant variation in neurological outcomes between the three different surgical teams, which is described as the "Efficiency-Protection Paradox." The normothermic team showed the shortest median bypass and cross-clamp times, respectively, revealing a high surgical speed; however, this procedural velocity was not transformed into brain protection during surgery. On the contrary, they exhibited the highest rate of ENCs (%, a frequency nearly 2.4 times that of the Deep hypothermic protocol team (p=0.037), our data indicate that for vulnerable pediatric brains, metabolic suppression through cooling is a more decisive determinant of outcome than the speed of surgery. Under normothermia, cerebral metabolic rate for oxygen (CMRO2) remains at its physiological peak, offering no 'buffer' against micro-emboli or extracorporeal circulation-associated systemic inflammatory response syndrome (SIRS)[2,3,8]. This result reinforces what Staar et al.[1] and Shayan et al.[13] have demonstrated, that the 'thermal shield' provided by cooling constitutes a strong neurological defense that effectively eliminates the risks associated with prolonged bypass periods.

Our analyses showed that the normothermia protocol was a strong risk factor for ENCs (odds ratio: 2.4, p=0.037), supporting the assertion by Shams-Molkara et al.[2] that neuroprotection standards should not be compromised for expedited surgery. Furthermore, the high incidence of postoperative seizures in the normothermic protocol group most likely indicates acute cerebral stress that could have been minimized through moderate to deep hypothermia, which raises the threshold for neuronal injury during critical stages of cardiac repair.[10,11]

6. LIMITATIONS

Due to a lack of availability of postoperative neuroimaging (MRI/CT) in some cases and continuous EEG monitoring, diagnosis depended mainly on clinical manifestations of ENCs, which might have resulted in an underestimation of "silent" or subclinical brain injuries in this study.

7. CONCLUSIONS AND RECOMMENDATIONS

The normothermic cardiopulmonary protocol with shorter bypass times was a predictor of increased risk of early neurological complications (ENCs) in the post-cardiac intensive care unit. The optimization of temperature management strategies is strongly recommended, with at least moderate hypothermia required during cardiopulmonary bypass, to provide adequate brain protection during cardiac surgery. This highlights the importance of neuroprotection of hypothermia control in centers with limited continuous neurological monitoring. This study focuses mainly on early neurological complications; future studies are needed to assess the long-term neurodevelopmental effects of these protocols on the brains of operated patients.

FINANCIAL SUPPORT AND SPONSORSHIP:

Nil

CONFLICTS OF INTEREST:

There are no conflicts of interest

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