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Research Article

Can Cerebral Oximetry Near-Infrared Spectroscopy Strategy in Hypothermic Cardiopulmonary Bypass in Congenital Cardiac Surgery be Considered an Advanced Nursing Practice?

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ABSTRACT

Background: The importance of cerebral perfusion during congenital cardiac surgery, especially after hypothermic cardiopulmonary bypass (CPB) strategy, has remained a debate. In this study, we evaluated the effect of mild hypothermic CPB strategy on cerebral oximetry near-infrared spectroscopy in congenital heart defects surgery.

Methods: In a randomized prospective study, the pediatrics aged two months and six years with RACHS categories I-Ⅱ for congenital heart defects surgery were randomly divided into normothermic and mild hypothermic CPB groups. The NIRS was measured in all patients via the INVOS ™ cerebral oximetry system. The perfusion and anesthesia strategies during the study were followed as standard methods. A p-value below 0.05 is considered to be a significant level.

Results: Regarding cerebral oximetry, the results showed no significant difference between normothermic and mild hypothermic CPB groups.

Conclusion: It can be concluded that optimizing cerebral oxygen saturation monitoring during congenital cardiac surgery can improve patient outcomes as a protective strategy.

Introduction

Cardiopulmonary bypass (CPB) is indispensable to most cardiac surgeries [1]. Many protective strategies have been introduced to decrease CPB use complications [2]. Nevertheless, none can provide an optimal situation to protect organs from perfusion disturbances [3].

Hypothermic CPB is a protective strategy to diminish the incidence chance of Ischemic- reperfusion injury (I/R

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Injury) [4]. However, the significant consequences of this approach may be neglected [5].
The balance of the cerebral oxygen supply versus oxygen metabolic demand represents cerebral oxygen saturation [6]. Hence, cerebral oximetry Near-infrared spectroscopy (NIRS) is an applied technology for estimating non-invasive systemic oxygen delivery (DO2) adequacy [7]. Although some evidence demonstrates that this index measures cerebral venous oxyhemoglobin saturation and reflects the adequacy of tissue oxygen delivery during cardiac surgery, the accuracy of this technology in hypothermic situations during cardiac surgery is debated [8].

Methods

Study design and Participants:

This study is a single-center, prospective, randomized cohort study. Patients were randomly allocated to receive either normothermic CPB (35-37℃) or mild hypothermic (28-32℃) CPB strategy.

The patients were all of pediatrics between two months and six years old. They underwent cardiopulmonary bypass (CPB) with risk adjustment for congenital heart surgery (RACHS) categories I-II for congenital heart defects surgery from January 2019 to June 2022, at the Department of cardiac surgery, Imam-Reza Hospital, Mashhad, Iran.

Exclusion criteria were congenital heart surgery (RACHS) categories higher than II, critical conditions (severe renal and hepatic failure) before surgery, upper airway congenital anomalies, the history of Cold Agglutinins, Parents/guardians do not provide written informed consent and cardiac surgeries that require deep hypothermic circulatory arrest (18-28℃). Also, drop-out criteria were intraoperative complications and the need for reoperation.

The sample size was 120 patients (60 patients in the mild hypothermic perfusion and 60 patients in the normothermic group) by considering the means of space and hypothesis of the same study [6], 99% confidence level, 80% power, and weaning time in the mild hypothermic and normothermic groups. Finally, a further 10% was added to anticipate drop-out cases. The method of block randomization, after the patients were deemed eligible and informed consent had been obtained from the parents, was used.

A computer using block randomization of four patients created a randomization schedule. The study managers placed the group assignments in sequentially numbered envelopes and arranged the facilities and data collection.

Perfusion Strategy

All the pediatrics received the same perfusion strategy in both groups. The CPB flow in normothermic group patients was maintained at 3.5 L/min/m2 (body surface area), and in mild hypothermic group patients, it was between 2.63 and 3.15 L/min/m2.

Non-pulsatile perfusion with a roller pump was recommended. During CPB, the alpha-stat strategy was administrated to evaluate arterial blood gas. Thus, $PaCO_2$ and PaO_2 were maintained at 35-45mmHg and 150-250 mmHg, respectively.

Anesthesia strategy

The anesthetic induction and maintenance were administrated in the operation room using a standardized protocol in both groups. Also, mild hypothermia and normothermia were monitored via a nasopharyngeal thermometer.

At first, demographic variables (age, gender, and BMI), cyanotic or acyanotic congenital cardiac defects, and the type of cardiac defects were recorded.

The core endpoint of this research was the near-infrared cerebral oximetry measurements by INVOS ™ system (Medtronic, Minneapolis, MN, USA).

Statistical analysis was performed using SPSS software version 26.0 (Chicago, IL, USA). The quantitative results were presented as mean± SD and median (inter-quartile range=IQR) for normal and non-normally distributed data. Categorical data were expressed as frequency (percentage). Normal distribution of the quantitative data was checked using the Shapiro-Wilks test, Q-Q, and Box plots. Independent Student's T-test was used for variables with normal distribution, and the Mann–Whitney test compared non-normal quantitative variables. The homogeneity of categorical variables between the groups was analyzed using the independence Chi-square or Fisher's exact test. After checking relevant assumptions, paired quantitative variables were compared with paired sample t-test or Wilcoxon test. After checking the normality of residuals, in order to investigate the measurement time (repeated measure variable) and interaction of measurement time and categorical group variables, the generalized estimating equation (GEE) method was used. The significance level was considered as $P<0.05$.

Results

In this study, 120 (50% in the normothermic group and 50% in the mild hypothermic group) eligible patients with a mean± age of 18.6±17.6 months who underwent congenital cardiac defects surgery participated. The male patients comprised 54.2% of all of the patients.

1) Baseline characteristics:

The comparison of the demographic variables of the pediatrics is provided in (Table 1).

The two groups in this study had no significant differences in age, BMI index, type of surgery, and cyanosis or acyanotic status ($P>0.05$). Only the gender of the patients was heterogeneous between treatment groups ($p<0.001$).

As the evaluation of the primary outcome, the NIRS evaluation analysis revealed no statistical differences between normothermic CPB and mild hypothermic CPB groups. Nevertheless, the investigation of the effect of the study groups and measurement time on the NIRS variations through Generalized Estimating Equations (GEE) showed that the normothermic group had a more significant effect on the time measurement trend than the mild hypothermic CPB group (p= 0.030).

Table 1- Compares the baseline characteristics between mild hypothermic and normothermic group patients

Variables		Hypothermia group	Normothermia group	P value
Age (mean± SD) Month		19.4±18.3	17.8±16.9	0.629
BMI (mean± SD)		14.3±2.4	14.1±2.7	0.667
Gender; N(%)	Male	43(71.7)	22(36.7)	<0.001*
	Female	17(28.3)	38(63.3)	
Type of Surgery; N(%)	ASD	4(6.7)	6(10)	0.167
	VSD	28(46.7)	36(60)	
	TOF	28(46.7)	18(30)	
Cyanotic disorder; N (%)	Yes	11(18.3)	9(15)	0.624
	No	49(81.7)	51(85)	

*=significant level at p<0.05). (ASD= Atrial Septal Defect, VSD= Ventricular Septal Defects, TOF= Tetralogy of Fallot

Discussion

Currently, systemic hypothermia during CBP among pediatric cardiovascular surgeons is prevalent. Many prefer maintaining core body temperature moderately hypothermic during surgery [9-10]. On the other hand, the normothermic CPB strategy was widely practiced in adult cardiac surgeries, and this perfusion approach was neglected in pediatrics since there was less strong evidence about clinical outcomes in this group [11].

The main finding of this study revealed that the NIRS evaluations had no statistical differences between hypothermic and normothermic CPB strategies. Since this index measures cerebral venous oxyhemoglobin saturation and reflects the adequacy of tissue oxygen delivery, both study groups revealed good tissue perfusion. However, using isolated NIRS for perfusion adequacy is not a sensitive index. It cannot predict other clinical deterioration outcomes, such as neurological disturbance and even low cardiac output states, after pediatric cardiac surgeries [2, 8, 12].

Nevertheless, there is some evidence that this strategy can prevent some post-cardiac surgery neurological complications, especially delirium [13]; the etiology of neurocognitive dysfunction after cardiac surgery with CPB remained a challenging phenomenon [14]. Furthermore, the mechanism of delayed cognitive impairments and recovery in pediatric patients after cardiac surgery is unknown [15].

So, it seems that more clinical investigation with close follow-up of the pediatrics after cardiac surgery in hypothermic and normothermic strategies is crucial.

Conclusion

Although monitoring any physiological parameter can provide vast information to nurses, perfusionists, and some medical groups during and after pediatric cardiac surgery, ensuring cerebral perfusion in pediatrics undergoing hypothermic as in normothermic CPB strategy may be necessary. Also, providing and applying an optimal strategy for cerebral perfusion monitoring in this group in the perioperative period can potentially impact patient outcomes and enhance their care.

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