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ORIGINAL RESEARCH
Pediatric Cardiology

The prognostic value of cerebral oxygen saturation, lactate and mixed venous oxygen levels in predicting the major adverse events during pediatric cardiac surgery

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ABSTRACT

Objective: Major adverse events (MAE) that may occur after pediatric cardiac surgery increase the risk for mortality and morbidity. In this context, the objective of this study is to assess the prognostic value of perioperative cerebral oxygen saturation levels measured by near-infrared spectroscopy (NIRS-ScO2) and lactate and mixed venous blood oxygen saturation (MVO) levels in predicting the development of MAE after the surgery.

Material and Methods: The study population consisted of the patients who underwent pediatric cardiac surgery and were followed up in the pediatric cardiac intensive care unit between February 1, 2022, and June 1, 2022. MAEs include sudden cardiac arrest/death, unscheduled emergency re-operation, and low cardiac output syndrome. The roles of NIRS-ScO2, lactate, and MVO levels during the surgery in predicting MAE were investigated. The results were evaluated statistically.

Results: The study sample consisted of 130 patients, of whom 50% were male. The median age of the study sample was 4 (interquartile range: 1–7) months. MAE was detected in 16.9% of the cases. More than 30% change in theNIRS-ScO2 levels in the operative period (area under the curve [AUC]: 0.84, sensitivity 65%, specificity 85%, and positive predictive value [PPV]: 90%) and a MVO/lactate ratio<5 (AUC: 0.72, sensitivity 76%, specificity 82%, and PPV 88%) were determined to be strongly predictive of MAE.

Conclusion: More than 30% change in the perioperativeNIRS-ScO2 levels and an MVO/lactate ratio <5 can be used to predict the development of MAEs.

Keywords: Child; lactate; major adverse event; near-infrared spectroscopy; pediatric cardiac surgery.

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Pediyatrik kalp cerrahisi operasyonu sırasında serebral near-infrared spektroskopi, laktat ve mikst venöz oksijen değerlerinin majör advers olaylara etkisi

ÖZET

Amaç: Majör advers olaylar (MAO) pediyatrik kalp cerrahisi operasyonlarından sonra görülebilir ve mortalite ile morbiditeyi olumsuz olarak etkileyebilir. Bu çalışmada, operasyon sırasındaki serebral near-infrared spektroskopi (NIRS), laktat ve mikst venöz oksijen (MVO) değişikliklerinin MAO'yu öngörmedeki etkisinin değerlendirilmesi amaçlandı.

Gereç ve Yöntemler: Bu çalışma, 01 Şubat 2022-01 Haziran 2022 tarihleri arasında pediyatrik kardiyak yoğun bakım ünitesinde izlenen ve pediyatrik kalp cerrahisi operasyonu geçiren olgular üzerinde gerçekleştirildi. Ani kalp durması/ölüm, planlanmamış yeniden ameliyat ve düşük kalp debisi sendromu MAO olarak tanımlandı. Olgulardaki operasyon sırasındaki serebral NIRS, laktat ve MVO değerlerinin ve oranlarının MAO'yu tahmin etmedeki rolü araştırıldı. Sonuçlar istatistiksel olarak değerlendirildi.

Bulgular: Çalışma döneminde 130 olgu (%50'si erkek) mevcuttu. Median yaş 4 ay (IQR 1-7 ay) idi. Olguların %16,9'unda MAO saptandı. NIRS değerinin operatif dönemde %30'dan fazla değişmesi (AUC 0,84 duyarlılık %65, özgüllük %85, pozitif prediktif değer %90) ve MVO/laktat değerinin <5 olması (AUC 0,72 duyarlılık %76, özgüllük %82, pozitif prediktif değer %88) MAO olabileceğini güçlü bir şekilde tahmin etmekteydi.

Tartışma: Operasyon sırasındaki %30'dan fazla serebral NIRS değişikliği ve MVO/laktat oranının beşten küçük olması MAO gelişiminin tahmin edilmesi konusunda yardımcı olabilir.

Anahtar Kelimeler: Çocuk; laktat; majör advers olay; near-infrared spektroskopi; pediyatrik kalp cerrahisi.

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INTRODUCTION

Congenital heart diseases (CHD), which are observed in 0.6–1% of children, feature a broad spectrum of pathologies and subgroups. The timely and accurate diagnosis of CHD and adopting the appropriate treatment approach is very important to increase the chance of survival (1).

The survival rate in children that underwent congenital heart surgery has steadily increased in the past several decades due to technological developments and appropriate postoperative care to the point that the perioperative mortality rate has decreased below 5%. However, major adverse events (MAEs), which develop unexpectedly and adversely affect surgical outcomes, continue to be a major concern (2). MAEs include sudden cardiac arrest/death, unscheduled emergency re-operation, and low cardiac output syndrome (LCOS). It has been reported in different studies that MAEs were seen in 15–19% of the cases being followed up in intensive care units (ICUs) (3-5).

The complexity of CHDs and many different complications that may develop after congenital heart surgeries pose serious difficulties in managing the patients and making the right decision about the treatment approach to be adopted. To overcome these difficulties, different methods are employed, including physical examination, non-invasive/invasive hemodynamic measurements, scoring systems, measurement of cerebral oxygen saturation levels by near-infrared spectroscopy (NIRS-ScO2), and measurement of lactate and mixed venous blood oxygen saturation (MVO) levels (2-4). Serum lactate, MVO, and NIRS-ScO2 levels are used as indirect markers secondary to tissue hypoxia, which is used to assess the insufficiency of oxygen transport to the periphery. However, these markers have found limited use in predicting the MAEs, and there are not enough studies on the predictive value of these markers.

In view of the foregoing, perioperative serum lactate, MVO, and NIRS-ScO2 levels of children who underwent pediatric cardiac surgery at the cardiac surgery center, where this study was conducted, were measured, and the predictive value of these parameters in predicting MAEs was investigated.

MATERIALS AND METHODS

The population of this prospective study consisted of pediatric patients younger than 18 years of age who underwent congenital heart surgery between February 1, 2022, and June 1, 2022, in a cardiac surgery center in Turkey. Patients who had been diagnosed with a neurological disease, premature babies, patients who died during the surgery, and patients in whom cardiopulmonary bypass (CPB) was not used were excluded from the study. The study protocol was approved by the local ethics committee (Approval No: 95, Approval Date: March 30, 2022).

The study was carried out in accordance with the principles outlined in the Declaration of Helsinki.

A data collection form was created for each patient included in the study. The research data were collected using this form in three categories; preoperative data (demographic characteristics, cardiac diagnosis, echocardiography data), perioperative data (duration of CPB and surgery, surgical risk score measured by the Risk Adjustment for Congenital Heart Surgery scoring system, NIRS-ScO2, lactate, and MVO levels), and postoperative data (extubation time, length of stay in ICU and hospital, mortality, maximum vasoactive-inotropic score (VIS), blood gas analysis, MAEs].

Blood gas, NIRS-ScO2, lactate, and MVO values were measured and recorded before CPB (T0), before cross-clamp (T1), during cross-clamp (T2), and after CPB (T3).

A four-channel trend monitor (Somanetics 5100B, Troy, MI, U.S.) was used for cerebral monitoring. The NIRS sensor was placed on the right frontal region of the patients. Post-induction values were plotted as baseline NIRS-ScO2values, and then the changes in the cerebral oxygenation levels were evaluated.

All MVO measurements were made from catheters placed in the superior vena cava or venous blood in the right atrium (in the absence of a left-to-right shunt). Lactate levels were measured in the blood drawn from the arterial cannula inserted during the surgery. MVO/lactate ratios were calculated using the values obtained from the MVO and lactate measurements performed within the same hour.

The study's primary outcome was the development of an MAE within 48 h of surgery. MAE was defined by one or more of the following conditions: Cardiac arrest, unscheduled re-operation as an unexpected surgical procedure or as a result of a significant postoperative residual lesion, emergency chest opening to control bleeding from the sternum or to reduce pressure on the mediastinum, or the presence of LCOS. LCOS was defined by clinical changes such as altered consciousness, changes in skin appearance, cold extremities, weak pulse, and a capillary circulation time >2 s.

Statistical Analysis

Statistical analyses were performed using SPSS 21.0 (Statistical Package for the Social Sciences for Windows, version 21.0, IBM Corp., Armonk, NY, U.S., 2012). Continuous variables determined to conform to the normal distribution were expressed as median interquartile range (IQR) values, whereas the categorical variables were expressed as numbers and percentage values. Demographic characteristics and perioperative variables were compared with the Mann–Whitney U and Pearson's Chi-squared tests. The prognostic power of NIRS-ScO2 and MVO/lactate parameters in predicting MAEs were evaluated using the receiver operating characteristics (ROC) curve analysis. Probability $p<0.05$ was deemed to indicate statistical significance.

RESULTS

The study sample consisted of 130 patients, of whom 50% were male. The median age of the study sample was 4 (IQR: 1–7) months. MAE was detected in 16.9% of the cases. The demographic and clinical characteristics of all patients are summarized in Table 1.

Of the 22 patients who developed MAE, cardiac arrest occurred in 9 (6.9%) patients, LCOS developed in 9 (6.9%) patients, 7 (5.4%) patients were exitus, and the residual hemodynamic lesion was observed in 2 (1.5%) patients, and sternum was opened in 2 (1.5%) patients.

Changes in NIRS-ScO2, lactate, MVO, and MVO/lactate values at T0, T1, T2, and T3 are shown in Table 2. Accordingly, it was determined that the NIRS-ScO2 and MVO values were significantly lower and lactate and MVO/lactate values were significantly higher at T2 and T3 in cases with MAE ($p<0.05$).

The results of the ROC analysis for estimating MAE based on more than 30%, 20%, and 10% changes in NIRS-ScO2 values

Table 1. Demographic characteristics of patients

Parameters	Major Adverse event (–) (n=108)	Major Adverse event (+) (n=22)	p
Age, months	2 (1–5)	3 (2–6)	>0.05
Newborn	60 (55)	16 (72)	>0.05
Height (kg)	5 (3–7)	4 (3–6)	>0.05
Gender, Male	55 (51)	10 (46)	>0.05
Double Ventricle	86 (79)	14 (63)	>0.05
RACHS-1 ≥4	68 (62)	18 (82)	**0.003**
Duration of cardiopulmonary bypass (minutes)	95 (70–120)	115 (100–135)	**0.001**
Maximum VIS score in the first 48 h	5 (3–7)	10 (5–15)	**0.001**

Median (IQR) or n (%).

Table 2. NIRS, lactate, Mixed Venous Oxygen (MVO), and MVO/lactate changes according to the time during cardiopulmonary bypass

Cerebral NIRS	Major Advers event (–)	Major Advers event (+)	p
T0	62 (55–70)	60 (55–65)	>0.05
T1	62 (55–70)	60 (55–65)	>0.05
T2	55 (50–60)	44 (40–48)	**0.001**
T3	54 (50–58)	40 (35–45)	**0.001**
Mixed Venous oxygen (%)			
T0	59 (55–62)	51 (48–55)	>0.05
T1	58 (55–61)	50 (46–54)	>0.05
T2	59 (55–62)	47 (44–50)	**0.030**
T3	58 (56–60)	48 (46–50)	**0.042**
Lactate (mmol/Liter)			
T0	2.5 (2.1–2.9)	3 (2.5–3.5)	>0.05
T1	2.6 (2.2–3)	4.1 (3.7–4.5)	**0.035**
T2	2.8 (2.5–3.1)	5.4 (5–5.8)	**0.001**
T3	2.7 (2.5–3)	6 (5.5–7)	**0.001**
Mixed Venous oxygen/lactate Ratio			
T0	24 (21–27)	20 (17–23)	>0.05
T1	23 (20–26)	13 (10–16)	**0.015**
T2	22 (20–24)	12 (10–15)	**0.001**
T3	25 (23–27)	9 (7–11)	**0.001**

T0: Before cardiopulmonary bypass; T1: Before cross clamp; T2: During cross clamp; T3: After cardiopulmonary bypass Median (IQR).

during CPB are summarized in Figure 1. It was determined that more than 30% change in the NIRS-ScO2 value in the perioperative period predicted MAE with 65% sensitivity and 85% specificity (area under the curve [AUC]: 0.84, confidence interval [CI]: (0.80–0.88), and positive predictive value [PPV]: 90%, p<0.001]. A more than 30% change in the NIRS-ScO2value was determined to be an independent risk factor for MAE (odds ratio [OR]: 4.8, CI: 1.9–11). On the other hand, no statistically significant changes were observed in the MAE development rates with more than 20% or 10% changes in the NIRS-ScO2 values (p>0.05).

The results of the ROC analysis for estimating MAE based on the MVO/lactate ratio <5, <10, and <15 during CPB are summarized in Figure 2. It was determined that MVO/lactate values <5 strongly predicted MAE with 76% sensitivity and 82% specificity (AUC: 0.72, CI: 0.62-0.82, PPV 88%, p<0.001). An MVO/lactate

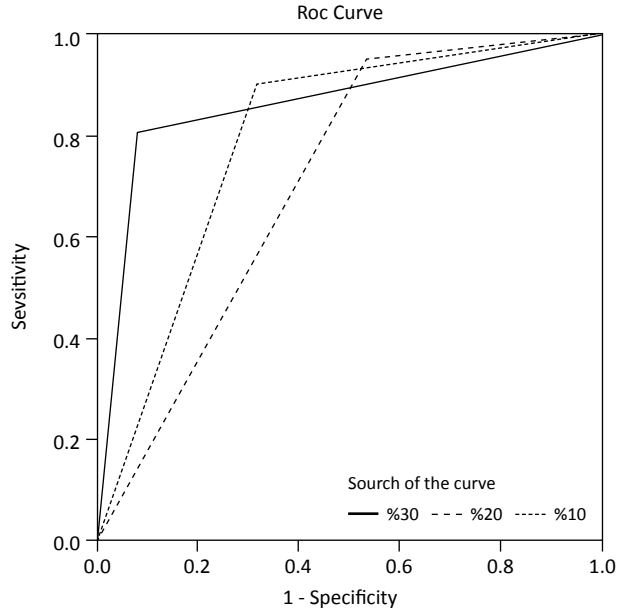

Figure 1. The role of % NIRS changes in predicting major adverse events during cardiopulmonary bypass.

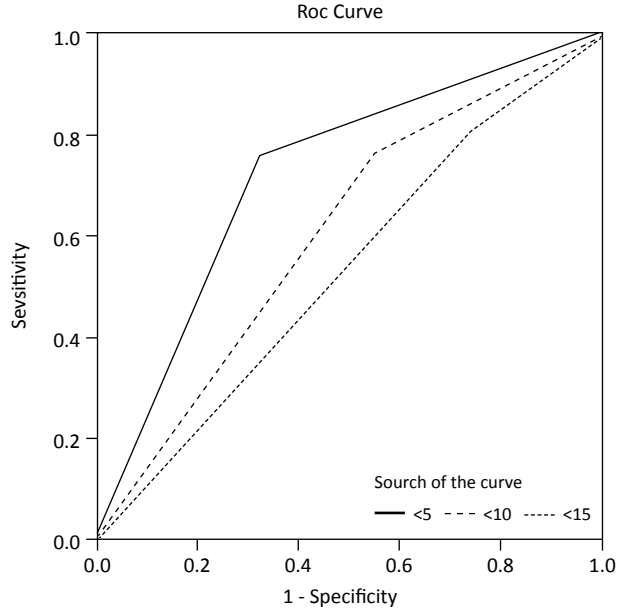

Figure 2. The role of different MVO/lactate ratios in predicting major adverse events during cardiopulmonary bypass.

value of <5 was determined to be an independent risk factor for MAE (OR: 2.7, CI: 1.3–6). On the other hand, no statistically significant changes were observed in the MAE development rates with MVO/lactate ratios <10 and <15 (p>0.05).

DISCUSSION

The prognostic values of NIRS-ScO2 level and lactate/MVO ratio for the development of MAE after pediatric cardiac surgery were investigated in this study. Consequentially, it was deter-

mined that a more than 30% change in the NIRS-ScO2 value and an MVO/lactate ratio <5 may be useful in predicting the development of MAEs in the first 48 h after pediatric cardiac surgery.

CPB is one of the essential methods used in congenital heart surgeries. However, CPB has certain drawbacks, leading to serious clinical and hemodynamic changes in the whole body. The body's inflammatory response to these serious clinical and hemodynamic changes may occur in the form of multiple organ failures, including myocardial failure, respiratory failure, neurological disorders, bleeding disorders, and kidney and liver function changes in the post-operative phase (6).

Different methods such as blood gas analysis and lactate, MVO, and cerebral perfusion pressure measurements have been used to continuously monitor hemodynamic changes that are a factor in mortality and morbidity (7-9). The cerebral NIRS monitoring is advantageous since it can be used during CPB. As a reason, unlike pulse oximeters, it is not dependent on the pulsatile flow. In this context, the cerebral NIRS monitor has been increasingly used as a standard monitoring method during CPB in pediatric and adult cardiac surgeries, given its low cost and the lack of adverse side effects.

In parallel, Tanidir et al. (10) suggested that the changes in the NIRS-ScO2 levels may guide clinicians in predicting instantaneous events. In addition, in the newborn series of 75 cases by Aly et al., (11) it was stated that the changes in the NIRS-ScO2 levels during CPB may predict long-term neurocognitive changes. Along these lines, in a study by Şen et al. (12) conducted with 91 adult patients who underwent coronary bypass and valve operation under CPB, a correlation was found between the perioperative changes in the NIRS-ScO2 levels and mortality and morbidity in ICU, and it was concluded that NIRS-ScO2 levels might be a good indicator for patient management in the pre- and post-operative period.

Similarly, more than 30% change observed in the NIRS-ScO2 levels in this study was determined to be an independent risk factor for MAE.

The studies on the methods that can predict the occurrence of MAEs are ongoing. Although lactate clearance, changes in lactate levels over time, MVO levels, CPB duration, and inflammatory markers have been used primarily for LCOS in different studies, an ideal method to predict MAE has yet to be found (2). In the infant series of 46 cases by Carmona et al., (13) CPB duration and high troponin I (inhibitory) and interleukin (IL) 8 levels were found to be independent risk factors for cardiac arrest. In another study, it was stated that low MVO might be a good marker for LCOS (14). In addition, in a series of 129 cases, it was suggested that serial lactate measurement could predict MAE (15). Furthermore, Schumacher et al. (16) determined that a 0.6 mmol/L/per hour decrease in lactate levels could predict a good prognosis with 90% sensitivity and 84% specificity.

Duke et al. (4) investigated the development of MAE in a series of cases operated for congenital heart disease and found the incidence of MAE as 13.3%. In addition, they found that high lactate levels, extended CPB durations, high CO2 difference, and base deficit values in patients followed up in ICU were associated with MAE. Rocha et al. (2) found the incidence of MAE to be 16% in their series of 194 cases, and they concluded that MVO/lactate >5 is a good marker for low MAE risk. In a series of 257 cases that underwent pediatric cardiac surgery by Murni et al., (17) the incidence of MAE and mortality were found as 19% and 13%, respectively. They determined that the presence of cyanotic congenital heart disease, a CPB duration of >120 min, use of at least two inotropes, and an increase in the lactate levels >0.75 mmol/L or more in the first 24 h could predict MAE.

In comparison, in this study, the incidence of MAE was found as 16.9%, and the CPB duration was found to be significantly higher in patients who developed MAE compared to the patients who did not develop MAE (114 min vs. 95 min, p<0.001). Moreover, in line with Rocha et al.'s study findings, it was determined that MVO/lactate ratios of <5 strongly predicted MAE.

Limitations of the Study

The study's primary limitation was that it was designed as a single-center study with a relatively small number of cases. Another limitation of the study was that the study sample was heterogeneous, and the cases had different physiologies. In addition, using NIRS and other measurement methods in the post-operative period could have allowed further comparisons.

It was determined that a more than 30% change in the NIRS-ScO2 level and MVO/lactate ratios of <5 may be useful in predicting the development of MAEs in the first 48 h after pediatric cardiac surgery.

Ethics Committee Approval: The study protocol was approved by the local ethics committee (Approval No: 95, Approval Date: March 30, 2022).

Informed Consent: Written informed consent was obtained from the families of the patients who participated in this study.

Conflict of Interest: No conflict of interest was declared by the authors.

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Authorship Contributions: Concept – HDÖ, EÖ; Design – HDÖ, EÖ, SS; Supervision – EÖ, FG; Fundings – HDÖ, EÖ, SS, FG; Materials – EÖ, SS; Data collection and/or processing – HDÖ, EÖ, SS; Analysis and/or interpretation – HDÖ, EÖ, SS, FG; Literature review – SS, FG; Writing – HDÖ, EÖ; Critical review – FG.

Etik Kurul Onayı: Çalışma protokolü yerel etik kurul tarafından onaylandı (Onay No: 95, Onay Tarihi: 30 Mart 2022).

Hasta Onamı: Yazılı hasta onamı bu çalışmaya katılan hastaların ailelerinden alınmıştır.

Çıkar Çatışması: Yazarlar çıkar çatışması bildirmemişlerdir.

Mali Destek: Yazarlar bu çalışma için mali destek almadıklarını beyan etmişlerdir.

Yazarlık Katkıları: Fikir – HDÖ, EÖ; Tasarım – HDÖ, EÖ, SS; Denetmele – EÖ, FG; Kaynaklar – HDÖ, EÖ, SS, FG; Malzemeler – EÖ, SS; Veri Toplanması ve/veya İşlemesi – HDÖ, EÖ, SS; Analiz ve/veya Yorum – HDÖ, EÖ, SS, FG; Literatür Taraması – SS, FG; Yazıyı Yazan – HDÖ, EÖ; Eleştirel İnceleme – FG.

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