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THE VALUE OF CENTRAL VENOUS OXYGEN SATURATION IN PREDICTING MAJOR ADVERSE EVENTS AFTER OPEN HEART SURGERY AMONG CHILDREN WITH CONGENITAL HEART DISEASE

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ABSTRACT

Background: The imbalance between the body's oxygen supply and demand is one of the causes leading to some complications in resuscitation after congenital heart surgery. A low $ScvO_2$ is one of the valuable indicators predicting some major events after congenital open heart surgery. **Objectives:** Evaluate the value of $ScvO_2$ in predicting MAE in children with congenital heart disease at the Vietnam National Children's Hospital in 2022 - 2023. **Methods:** A cross-sectional and descriptive study was conducted on 117 children with congenital heart disease undergoing open heart surgery to describe the distribution of the value of $ScvO_2$ according to time, weight, RACHS-1 score, time of aortic clamp and time of cardiopulmonary bypass at 4 times: immediately after leaving the Surgical Cardiac Intensive Care Unit (T1), after 6h (T2), after 12h (T3), after 24h (T4); Predictive ability of $ScvO_2$ for some major adverse events (MAE) after open heart surgery in children with congenital heart disease. **Results:** The value of $ScvO_2$ dropped to its minimum level after 6 hours of admission to the Surgical Cardiac Intensive

Care Unit (54.42 ± 12.76%) and gradually increased at T3 and T4. The difference between times was statistically significant with $p < 0.01$. The proportion of study patients with MAE was 24.8%. The value of $ScvO_2$ after 6 hours of admission to the post-operative Surgical Cardiac Intensive Care Unit, with a cut-off point of 54.5%, had the best ability to predict MAE during the study times. Sensitivity is 93.1%, while specificity is 69.3%, and the area under the curve AUC was 0.879. **Conclusions:** $ScvO_2 \leq 54.5\%$ at time T2 can predict MAE after open heart surgery in children with congenital heart disease, with very good AUC, specificity, and sensitivity.
Keywords: $ScvO_2$; MAE; Congenital open heart surgery

GIÁ TRỊ CỦA ĐỘ BÃO HÒA OXY TĨNH MẠCH TRUNG TÂM ($SCVO_2$) TRONG DỰ ĐOÁN CÁC BIẾN CỐ BẤT LỢI CHÍNH SAU PHẪU THUẬT TIM MỞ Ở TRẺ EM MẮC BỆNH TIM BẨM SINH

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TÓM TẮT

Đặt vấn đề: Sự mất cân bằng giữa cung cấp và nhu cầu oxy của cơ thể là một trong những nguyên nhân dẫn đến một số biến chứng trong hồi sức sau phẫu thuật tim bẩm sinh. $ScvO_2$ thấp là một trong những chỉ số có giá trị trong dự đoán một số biến cố bất lợi chính (MAE) sau phẫu thuật tim mở do tim bẩm sinh.

Mục tiêu: Đánh giá giá trị của $ScvO_2$ trong dự đoán các biến cố bất lợi chính (MAE) ở trẻ em mắc bệnh tim bẩm sinh tại Bệnh viện Nhi Trung ương trong giai đoạn 2022 - 2023. **Phương pháp:** Nghiên cứu mô tả cắt ngang được thực hiện trên 117 trẻ mắc bệnh tim bẩm sinh được phẫu thuật tim mở nhằm mô tả sự phân bố giá trị $ScvO_2$ theo thời gian, cân nặng, điểm RACHS-1, thời gian kẹp động mạch chủ và thời gian chạy tuần hoàn ngoài cơ thể tại 4 thời điểm: Ngay sau khi vào khoa Hồi sức Tim mạch Ngoại (T1), sau 6 giờ (T2), sau 12 giờ (T3), sau 24 giờ (T4); đồng thời đánh giá khả năng dự đoán của $ScvO_2$ đối với một số biến cố bất lợi chính (MAE) sau phẫu thuật tim mở ở trẻ mắc bệnh tim bẩm sinh. **Kết quả:** Giá trị $ScvO_2$ giảm xuống mức thấp nhất sau 6 giờ nhập khoa Hồi sức Tim mạch Ngoại (54,42 ± 12,76%) và tăng dần ở T3 và T4. Sự khác biệt giữa các thời điểm có ý nghĩa thống kê với $p < 0,01$. Tỷ lệ bệnh nhân trong nghiên cứu có MAE là 24,8%. Giá trị $ScvO_2$ sau 6 giờ nhập khoa hồi sức sau mổ với điểm cắt 54,5% có khả năng dự đoán MAE tốt nhất trong các thời điểm nghiên cứu. Độ nhạy là 93,1%, độ đặc hiệu là 69,3% và diện tích dưới đường cong (AUC) là 0,879. **Kết luận:** $ScvO_2 \leq 54,5\%$ tại thời điểm T2 có thể dự đoán MAE sau phẫu thuật tim hở ở trẻ em mắc bệnh tim bẩm sinh, với AUC, độ đặc hiệu và độ nhạy rất tốt.
Từ khóa: $ScvO_2$; MAE; Phẫu thuật tim mở

INTRODUCTION

Congenital heart disease is one of the most common congenital diseases in children, becoming more and more common in pediatric practice. Worldwide, the incidence of congenital heart disease is about 0.8%

in live births. The incidence is higher in stillborn infants (3 - 4%), spontaneous abortion (10 - 20%) and premature birth (about 2% except for ductus arteriosus) [1].

Open heart surgery under extracorporeal circulation (EC) has been proven to be a useful method to save the lives of patients diagnosed with congenital heart disease. However, this method has a significant potential risk of death if it is not well controlled during surgery, running an extracorporeal circulator, and post-operative resuscitation due to major adverse events (MAE) such as cardiac output syndrome, cardiac arrest, chest re-opening, death... [2]. Identifying patients at risk for MAE is challenging, but it can help doctors and nurses monitor and allocate appropriate resources to patients, there are specific treatment strategies to prevent or quickly address and treat MAE if available.

Central venous oxygen saturation ($ScvO_2$) is one of the indicators that reflects the balance between tissue oxygen supply and demand. Recent studies around the world show that the predictability of $ScvO_2$ measured intermittently to detect major events after congenital open heart surgery is significant in clinical practice [3].

In Vietnam, there have not been many systematic studies on the role of $ScvO_2$ in children after open heart surgery to orient the times when to do $ScvO_2$ testing and evaluate the prognostic role of $ScvO_2$ value on complications and treatment results. Vietnam National Children's Hospital is the leading hospital in the country in the field of pediatric care. Every year, nearly 1000 patients undergo open heart surgery, most

of whom are patients with complex congenital heart disease and low weight. To improve the effectiveness of treatment, especially in the postoperative recovery period, it is necessary to determine the prognostic role of $ScvO_2$, and this study was conducted to: *Evaluate the value of $ScvO_2$ in predicting MAE in children with congenital heart disease at the Vietnam National Children's Hospital in 2022 - 2023*.

METHODS

Participants, time and location of research

The study included congenital heart patients undergoing open heart surgery at the Hospital during the period from April 18, 2023 to September 30, 2023. The main inclusion criteria were: (i) Patients aged 0 to 5 years; (ii) Patients diagnosed with congenital heart disease by echocardiography and/or cardiac catheterization at Vietnam National Children's Hospital; (iii) Patients with a risk score for congenital heart surgery (RACHS-1 $\geq$ 2); (iv) Patients undergoing open-heart surgery under the extracorporeal circulation; (v) Patient's family agreed to participate in the study. The exclusion criteria were: (i) Patients died during surgery or immediately after surgery but not be resuscitated at the Surgical Cardiac Intensive Care Unit; (ii) Patients could not place the central venous catheter.

Study design

A cross-sectional and descriptive study was conducted from April 18, 2023 to September 30, 2023 at Vietnam National Children's Hospital. The progression of $ScvO_2$ was monitored over time in postoperative resuscitation and the predictability of

$ScvO_2$ with some of MAE following congenital open heart surgery was evaluated.

Sample size and sampling method

Sample size was calculated according to the sample size estimation formula to determine sensitivity and specificity for a test index.

$$n = \frac{FP + TN}{1 - P_b}$$

$$FP + TN = \frac{Z^2_{(1-\alpha/2)} \times P_{dh} \times (1 - P_{dh})}{1 - P_b}$$

With P_b (proportion of children with AME after surgery [1]) = 0.16, P_{dh} = 0.90, w = 0.05, the estimated minimum sample size is n = 84.

Sampling method: Convenient sampling of patients who met the sampling criteria was included in the study. 117 research patients were involved in this study.

Variables

The following independent variables were collected: (1) demographic information including sex, age (days), weight (kg), time of cardiopulmonary bypass (minutes), time of aortic clamp (minutes), RACHS-1 score; (2) $ScvO_2$ (%) were recorded corresponding to central venous blood gas analysis and were performed as blood gas on the GEM 3500 blood gas machine. The values of $ScvO_2$ at T1, T2, T3, and T4 corresponded to the time the children transferred to the Surgical Cardiac Intensive Care Unit, after 6 hours, after 12 hours, and after 24 hours; (3) Lactate (mmol/L) and Glucose (mmol/L) were obtained from standard arterial blood gas analysis at time points T1, T2, T3 and T4;

Dependent variables included: Major adverse events after surgery were those that occurred within 48 hours

of surgery, including one of four adverse events: Death, cardiac arrest, cardiac surgical reopen, low cardiac output syndrome (LCOS) [1,2,4]. In there, LCOS was diagnosed according to Fabio Carmona's criteria when at least 2 of the following criteria are present: (1) Clinical findings and/or tests suggest signs of low cardiac output: Weak rapid pulse, cold extremities, Refill ≥ 3 seconds, hypotension (systolic blood pressure below the 5th percentile by age), low urine output (< 1 ml/kg/hour for at least 6 hours, no response to diuretics), continuous increase in blood lactate levels > 2 mmol/l for 2 consecutive blood gases, metabolic acid; Vasopressor drug scale > 20; Death within 48 hours of surgery; LVEF < 50% by echocardiography [5].

Statistical analysis

Univariate and multivariate logistic regressions were employed to identify factors predicting MAE. Independent variables were sex, age, weight, time of cardiopulmonary bypass, time of aortic clamp, RACHS-1 score, $ScvO_2$, Lactat, and Glucose. Significant factors from univariate analysis were included in multivariate analysis. The Youden Index was used to select the best forecast threshold $ScvO_2$ (cut-off point). The best forecast threshold at the time when the Youden index had the greatest value (Youden = sensitivity + specificity value - 1). The curve (ROC) was used and the area under the ROC curve (AUC) was calculated to find the value of $ScvO_2$ in anticipation of some major adverse events. The accuracy of the test was determined based on AUC on the following scales: AUC from 0.5 - 0.59: the test had no prognostic value; AUC from 0.6 - 0.69: the

test had little prognostic value; AUC from 0.7 - 0.79: the test had a good prognostic value; AUC from 0.8 - 0.89: the test had a good prognostic value; AUC from 0.9 - 1.0: the test had a very good prognostic value.

Ethical considerations: The study was approved by the Ethics Council in Biomedical Research at Vietnam National Children's Hospital according to Decision No. 695/BVNTW-HDDD dated April 18, 2023.

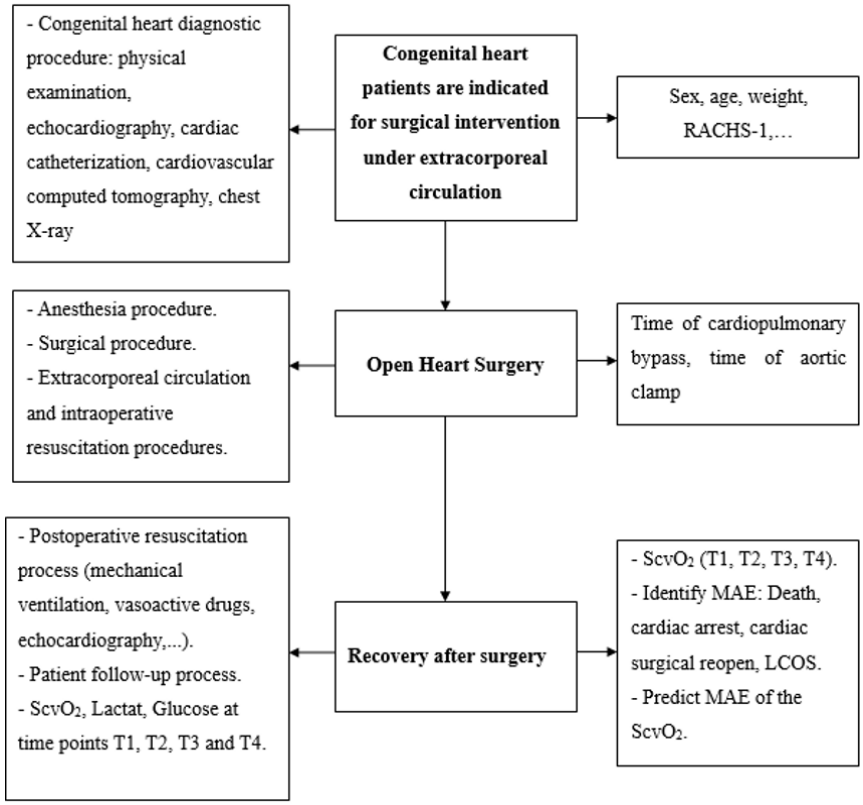

Figure 1. Research flowchart

RESULTS

A total of 117 congenital heart patients with open heart surgery were eligible to participate in the study, of which 73 patients were male (62.4%), and 44 patients were female (37.6%). The median age of the studied patients was 2.7 (0.6 - 7.6) months, with 35.9% of

them being neonates under 1 month old. The median weight of the studied patients was 4 kg, and 61.5% of them had a weight below 5 kg.

Table 1. Classification of Congenital Heart Disease in the Study Subjects

Type of Congenital Heart Disease	n	%
Ventricular septal defect /Atrial septal defect	11	9.4
Atrioventricular septal defect	7	6.0
Tetralogy of Fallot	26	22.2
Double outlet right ventricle	4	3.4
Transposition of the great arteries	21	17.9
Ventricular septal defect with coarctation of the aorta	13	11.1
Interrupted aortic arch	7	6.0
Pulmonary atresia	9	7.7
Total anomalous pulmonary venous return	7	6.0
Others	12	10.3
Total	117	100

The majority of cases involved complex congenital heart disease. Tetralogy of Fallot was the most common, with 26 patients, accounting for the highest proportion (22.2%). Transposition of the great arteries followed, with 21 patients (17.9%). Only 9.4% of patients had an isolated ventricular septal defect or atrial septal defect without accompanying anomalies.

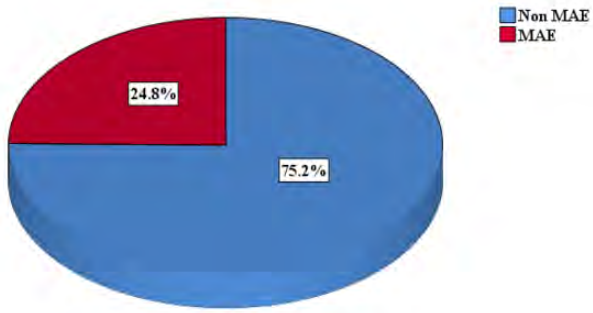

Chart 1. The incidence of MAE after surgery

29 out of 117 patients were found with MAE after their surgery (accounting for 24.8%). MAE was mainly LCOS with an incidence of 23.9% of the study patients.

Table 2. Ability to predict MAE of $ScvO_2$ at different times after surgery

Time	Sensitivity	Specificity	AUC	Cut-off point (%)	p
T1	86.2%	56.8%	0.748	60.5	0.000
T2	93.1%	69.3%	0.879	54.5	0.000
T3	65.5%	75.0%	0.711	55.5	0.001
T4	34.5%	85.2%	0.562	55.5	0.32

$ScvO_2$ at T1, T2 and T3 after leaving the post-operative Surgical Cardiac Intensive Care Unit had the ability to predict MAE after surgery, with statistical significance $p < 0.01$, but $ScvO_2$ at T2 with a cut-off of 54.5% had the best ability to predict MAE with AUC = 0.879 with $p < 0.01$.

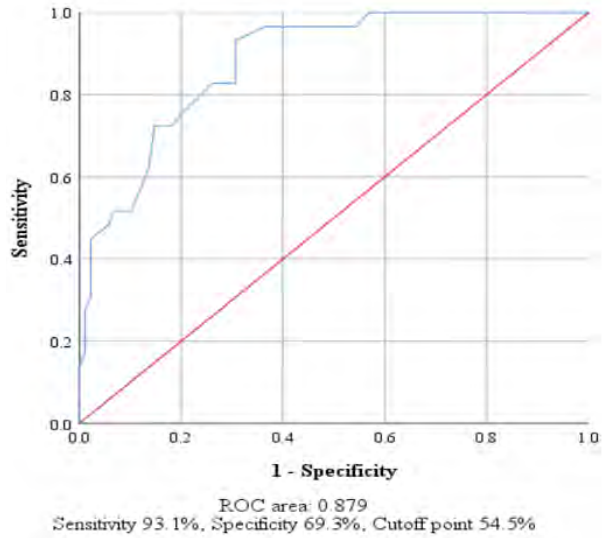

Figure 2. Prediction value of major adverse events of $ScvO_2$ at time T2

The ability to predict MAE of $ScvO_2$ at T2 with a cut-off point of 54.5% has a sensitivity of 93.1%, a specificity of 69.3%, and the area under the ROC curve is 0.879.

Table 3. Ability to predict major adverse events of several factors

Element	Sensitivity	Specificity	AUC	Cut-off point	p
RACHS-1	96.6%	42.0%	0.704	3.0	0.001
Glucose at T2 (mmol/L)	58.6%	67.1%	0.634	10.75	0.031
Lactate at T2 (mmol/L)	75.9%	70.5%	0.795	2.45	0.000

The ability to predict MAE of the RACHS-1 score with a 3-point cut-off had a sensitivity of 96.6%, specificity of 42.0%, and the area under the curve of 0.704, statistically significant with $p < 0.01$. The ability to predict MAE of Glucose at T2 with a cut-off point of 10.75 mmol/L had a sensitivity of 58.6%, specificity of 67.1%, and the area under the curve of 0.634, statistically significant with $p < 0.01$. The ability to predict MAE of Lactate at T2 with a cut-off point of 2.45 mmol/L had a sensitivity of 75.9%, specificity of 70.5%, and the area under the curve of 0.795, statistically significant with $p < 0.05$.

Table 4. Univariate analysis of preoperative factors predicting post-operative MAE

Element		Major adverse event (MAE)			
		MAE | n (%)	Non MAE | n (%)	OR (95%CI)	p
Age	< 30 days	15 (51.7)	27 (30.7)	2,4 (1.0 - 5.7)	0.043
	≥ 30 days	14 (48.3)	61 (69.3)		
Weight	< 5kg	24 (82.8)	48 (54.5)	4.0 (1.4 - 11.4)	0.01
	≥ 5kg	5 (17.2)	40 (45.5)		
RACHS-1	≥ 3 *	28 (96.6)	51 (58.0)	20.3 (2.6 - 156.1)	0.004
	< 3 *	1 (3,4)	37 (42.0)		

** The cut-off value for the prediction of major adverse events of RACHS-1.*

Some clinical factors: age under 30 days, weight under 5kg, and RACHS-1 score ≥ 3 were prognostic factors for MAE after surgery, statistically significant with $p < 0.05$.

Table 5. Univariate analysis of postoperative factors in predicting MAE after surgery

Element		Major adverse event (MAE)			
		MAE | n (%)	Non MAE | n (%)	OR (95%CI)	p
Lactate at T2 (mmol/L)	≥ 2.45*	22 (75.9)	26 (29.5)	7.5 (2.9 - 19.7)	0.000
	< 2.45*	7 (24.1)	62 (70.5)		
Glucose at T2 (mmol/L)	≥ 10.75*	17 (58.6)	29 (33.0)	2.9 (1.2 - 6.8)	0.016
	< 10.75*	12 (41.4)	59 (67.0)		
$ScvO_2$ at T2 (%)	≤ 54.5*	27 (93.1)	27 (30.7)	30.5 (6.8 - 137.5)	0.000
	> 54.5*	2 (6.9)	61 (69.3)		

** The cut-off values predicting MAE of Lactate at T2, Glucose at T2, $ScvO_2$ at T2.*

Some values of $ScvO_2$ at T2 ≤ 54.5%, lactate at T2 ≥ 2.45 mmol/L, Glucose at T2 ≥ 10.75mmol/L were prognostic factors for MAE after surgery, statistically significant with $p < 0.05$.

Table 6. Multivariate analysis of prognostic factors for MAE

Element	OR (95%CI)	p
$ScvO_2$ at T2 ≤ 54.5%	29.7 (5.5 - 160.7)	0.000
Lactate at T2 ≥ 2.45 mmol/L	3.3 (1.5 - 15.9)	0.009
RACHS-1 ≥ 3	17.3 (1.4 - 216.7)	0.027

Multivariate Logistic regression analysis of prognostic factors for MAE after surgery showed that $ScvO_2$ at T2 ≤ 54.5%, Lactate at T2 ≥ 2.45 mmol/L, RACHS-1 score ≥ 3 were independent prognostic factors with statistical significance at $p < 0.05$.

DISCUSSION

This is one of the few studies on $ScvO_2$ after congenital open heart surgery in children. The study was conducted on 117 congenital heart patients undergoing open heart surgery under extracorporeal circulation at Vietnam National Children's Hospital. The results showed that 73/117 patients were male

(62.4%), mainly in the low weight patients (less than 5 kg) which accounted for 72/117 (61.5%). The group of complex congenital heart patients with RACHS-1 cardiovascular surgery risk score at III and IV was 78/117 (66.7%). The incidence of some major adverse events was 24.8%.

The trend of developing strategies in the treatment of congenital heart disease is to have complete repair surgery as soon as possible to bring the malformed heart back to physiological function, so the age for surgery in studies is often very early. The age range in our study is similar to the research results of some other authors in the world. Matteo Taiana's study on 98 children undergoing congenital heart repair surgery from June 2018 to October 2020 at Integrated Trust University Hospital with an average age of 32.0 ± 48.0 months, including 55 male children accounting for 56.1%, average weight 12.7 ± 13.8kg [6]. A research by Naoki Hirai, and Junichi Saito in Japan in 2023 on 33 children (weighing less than 10kg) who underwent heart surgery showed that the median age was 11.0 (2.0 - 16.0) months, weight was 7.2 (4.5 - 9.2)kg [7]. In recent years, Vietnam National Children's Hospital has received many patients with complicated congenital heart defects in the newborn stage or complex malformations that need early intervention, so many complex surgical techniques have been successfully implemented to treat these patients at the hospital.

Similarly, some other studies in the world also revealed a trend of surgery in patients with low weight. Ilias Iliopoulos's study in 83 children under 17 years old after open heart surgery in 2020 in the

United States showed that the average weight of children with congenital heart surgery was 5.1kg (interquartile range was 3.5 - 7,2 kg) [8].

The prevalence of some major adverse events after congenital open heart surgery

MAE after congenital heart surgery increases mortality and respiratory complications such as prolonged mechanical ventilation time, kidney failure, prolonged recovery time and length of stay, and increased treatment costs.

Identified MAE include low cardiac output syndrome (LCOS), cardiac arrest, re-open the chest, and death occurring within 48 hours of congenital open heart surgery. Among them, diagnosing LCOS by invasive cardiac measurement gives accurate values. However, there are still many risks of high treatment costs, especially in children. Therefore, many centers around the world diagnose LCOS after pediatric heart surgery based on clinical characteristics, acidosis, blood lactate, and echocardiography. This is a limitation in our center's research as well as in some other centers globally. In our study, 29/117 patients had at least one major adverse event, accounting for 24.8%. This rate is similar to some other centers in the world with a common range from 10 - 50% [2,4,1,9].

Predictive value of MAE of central venous oxygen saturation ($ScvO_2$) after open heart surgery

$ScvO_2$ is a clinical marker for the use of oxygen by the upper half of the body, and its value indicates the interaction between cardiac output, arterial blood oxygen levels, and tissue oxygen separation. When hemoglobin levels and SaO_2 values are within normal limits, changes in $ScvO_2$ values will directly reflect

the patient's cardiac output and hemodynamic status. Therefore, $ScvO_2$ has prognostic value in the frequency of adverse events and mortality in the postoperative recovery period.

Diagnosis of MAE, including LCOS, requires invasive measurement and monitoring of cardiac indicators with many adverse events, especially in young children, low weight, high treatment costs; Therefore, it is currently rarely applied in some cardiovascular centers in the world as well as in Vietnam. At the cardiovascular center, Vietnam National Children's Hospital, diagnosis is generally based on clinical signs, often late when reduced tissue perfusion affecting organ function appears. Aiming at studying the role of $ScvO_2$ in the prognosis of high-risk cardiac surgery patients, we investigated the change in the value of $ScvO_2$ in the postoperative period, thereby evaluating the role of $ScvO_2$ in predicting MAE after congenital open heart surgery through the ROC curve model and Youden index to determine the most appropriate sensitivity, specificity, area under the AUC curve, and cut-off point of $ScvO_2$ at each time point.

$ScvO_2$ levels at T1, T2, and T3 can predict MAE, however, $ScvO_2$ measured 6 hours after exiting the post-operative Surgical Cardiac Intensive Care Unit is the most effective predictor of outcomes, showing a sensitivity of 93.1%, a specificity of 69.3%, and an area under the curve (AUC) of 0.879, with an optimal cut-off point of 54.5%. At the time immediately after the patient was moved to the postoperative recovery department, it was able to predict MAE with sensitivity of 86.2%, specificity of 56.8%,

area under the curve (AUC) of 0.748. At T3, AUC is at 0.711, but this is a late time point with limited clinical practical significance. In 2008 in Canada, Michael D. Seear did a research on predicting MAE after cardiovascular surgery in children. The study used ROC curve analysis, $ScvO_2$ < 40% was the best level to predict MAE with a sensitivity of 73.7%, specificity of 95.4%, positive predictive value of 58.3%. $ScvO_2$ at all time points after surgery can predict MAE [2]. A study by Victória Helena Stelzer Rocha et al in Brazil in 2021 on the ratio between central venous oxygen saturation and arterial lactate ($ScvO_2$/Lactate) and predicted MAE after cardiovascular surgery found that $ScvO_2$ in the group of patients with MAE was significantly lower than in the group of patients without MAE. $ScvO_2$ at all times after surgery was able to predict MAE. The lowest $ScvO_2$ level recorded from 0 to 48 hours post-surgery could predict MAE with an area under the ROC curve of 0.763, though this study did not establish a specific cut-off value for $ScvO_2$ [1].

CONCLUSION

The value of $ScvO_2$ decreases to the lowest threshold at T2 (after being admitted to the postoperative Surgical Cardiac Intensive Care Unit for 6 hours); The incidence of MAE was 24.8%; $ScvO_2$ at T2 with a cut-off point of 54.5% is the best level to predict MAE at the time of study with sensitivity at 93.1%, specificity at 69.3%, AUC at 0.879. In multivariate analysis, the value of $ScvO_2$ at T2 $\leq$ 54.5% is an independent factor in predicting MAE in childen after congenital open heart surgery.

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