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Original article

OXYGEN SATURATION INDEX FOR ASSESSMENT OF RESPIRATORY FAILURE IN NEONATES

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Abstract: **Introduction:** Acute respiratory failure (ARF) is the most common problem seen in the preterm and term infants admitted to neonatal intensive care units. Etiology is not uniform, and mostly depend on gestational age. For adequate treatment is certainly important to recognize and treat underlying disease, but at the same time, we have to supply adequate respiratory support, tissue perfusion and oxygen deliveries. For a good outcome we need reliable estimation method for functional state of respiratory system, as well as monitoring the effects of treatment. Current assessment ARF is with blood gas, chest X-ray and Oxygenation index (OI). OI is quite aggressive assessment method for neonates, because it involves arterial blood sampling. Promoted in recent studies, Oxygen saturation index (OSI) measured by pulse oximetry, attempts to objectively score respiratory disease with parameters available non-invasively. **The aim** of our research is to evaluate correlation between OSI and OI in neonates with ARF requiring mechanical ventilation. **Material and methods:** In a retrospective cohort study 101 neonates were selected, treated at the Department of intensive therapy and care, Pediatric clinic of Tuzla, due to ARF requiring mechanical ventilation.

We reviewed data such as gestational age, birth weight, gender, Apgar scores, values of Score for Neonatal Acute Physiology-Perinatal Extension, all the parameters from the arterial blood gas analysis, pulse oximetry values, Oxygenation Index and Oxygenation Saturation Index, that were calculated by the formulas. OSI and OI were calculated and correlated. Mean values of OSI and OI correlated with *Pearson's* coefficient of 0.76; $p < 0.0001$ (95% CI = 0.66-0.83). OSI correlated with SNAP-PE with *Pearson's* coefficient of 0.52; $p < 0.0001$ (95% CI = 0.36-0.65). Comparing the values of OSI between patients who died and those who survived, we found that OSI correlated with the outcome with Spearman's coefficient of -0.47; $p < 0.0001$ (95% CI = -0.16 - -0.31). Bland-Altman plot confirmed correlation between OSI and OI in mean values, identifying discrepancy between two indices for extreme values. **In conclusion**, OSI correlates significantly with OI in infants with respiratory failure. This noninvasive method of oxygenation assessment, utilizing pulse oximetry, can be used to assess the severity of ARF and mortality risk in neonates.

Key words: neonates; respiratory failure; Oxygenation Index; Oxygenation Saturation Index.

INTRODUCTION

Due to the high predisposition to problems with breathing, acute respiratory failure (ARF) is the most common reason for admission to Neonatal intensive care units (NICU). The causes of neonatal respiratory failure mostly depend on gestational age. In premature neonates, the most common cause is respiratory distress syndrome due to surfactant deficiency. Acute respiratory failure in term and near term infants is usually a result of aspiration syndromes, infections and congenital anomalies, including primary pulmonary hypertension. The pathophysiological sequence is represented as combination of primary surfactant deficiency and surfactant inactivation process with various factors, such as pneumonia, sepsis and asphyxia (1).

In the treatment of respiratory insufficiency it is very important to recognize and treat the underlying disease. But before that and at the same time, we have to realize, as soon as possible, adequate respiratory support and adequate tissue perfusion and oxygen deliveries. Mechanical ventilation in children is still a more complex area, whose safe and successful application requires good knowledge of pulmonary physiology and pathophysiology that is changing with age, and ventilation should be designed according to the age, lung disease characteristics and pathophysiological process causing respiratory insufficiency. Currently, there are many options, strategies and modalities, suggesting that we have not created the ideal mode yet, that would maximally respond to the needs of the child, expedite recovery with minimal complications (1).

The requirement for a good outcome is a reliable estimation method for functional state of respiratory system, as well as monitoring the effects of treatment. Neonates with respiratory insufficiency need continuous expansion pressure to menage appropriate functional residual volume and capacity. Deterioration and improvement in the severity of disease and pulmonary functional status is reflected as a change in need for pressure / volume and oxygen expressed through the distending pressure or fraction of inspired oxygen (FiO2) or both. Estimation method that incorporates these parameters would potentially help in objective assessment of the severity of the pulmonary disease. Current assessment of pulmonary disease is with blood gas, chest X-ray and Oxygenation index (OI). OI has its limitations and resource implications (2). A noninvasive alternative assessment tool would allow clinicians to use it more frequently. Promoted in recent studies, Oxygen saturation index (OSI) attempts to objectively score respiratory disease with parameters available with less invasive procedures (3).

Optimizing oxygenation is crucial for neonates on the intensive treatment. Transcutaneous pulse oximetry is usually used to assess oxygenation, whereas the Oxygenation Index, one of the respiratory indices, is used to categorize the severity of oxygenation failure and pulmonary status of neonates requiring mechanical ventilation (2, 3). Respiratory indices are preferred over pulse oximetry in categorizing the severity of illness and have been used in many neonatal trials (4, 5, 6, 7). Traditional respiratory indices, including OI, require indwelling arterial lines, which in turn is associated with multiple complications (4). In order to avoid complications related to invasively obtained respiratory indices, some of noninvasively obtained indices of oxygenation failure and pulmonary status have been proposed in recent studies (3-7), such as the Oxygenation Saturation Index that has been used as a substitute to OI (3, 4). In our study we sought to determine the relation between OSI and OI in intubated, critically ill neontes. **Our primary objective** was to evaluate if the Oxygen saturation index correlates with Oxygenation index in neonates with respiratory failure requiring mechanical ventilation support.

PATIENTS AND METHODS

Our study was retrospective and was conducted at the Department of intensive therapy and care, Pediatric clinic of University Clinical Center of Tuzla and included patients treated during the one-year period (from January 2017 through December 2017). Our including criteria were: neonatal age, involve term and preterm neonates, admited to the NICU, because of respiratory failure requiring mechanical ventilation and had an ABG available for review. We analyzed medical records of all consecutive neonates who were admitted to the NICU during the one-year period, and from total of 332 patients we selected those who were appropriate for the study, and thus extracted the final sample out of 101 neonates. We reviewed data such as gestational age (GA), birth weight (BW), gender, Apgar scores at the first and fifth minutes. We also reviewed values of Score for Neonatal Acute Physiology-Perinatal Extension (SNAP-PE), as already been measured for each individual neonate, received in the NICU, next all the parameters from the arterial blood gas (ABG) analysis, next Oxygenation Index (OI) calculated by the formula, and next Oxygenation Saturation Index (OSI), also calculated according to its own formula. Characteristics of the patients are shown in Table 1. For each selected participant only one blood gas was evaluated. Oxygen saturation (SaO_2) was noted on the ABG analysis and by transcutaneous pulse oximetry recorded in the List of respiratory parameters,which is an integral part of medical records for each patient treated in our Department, and also includes recorded data about the set respiratory parameters continuously for a period of mechanical ventilation (Flow, Fraction of inspired oxygen (FiO_2), Peak inspiratory pressure (PIP), Positive end-expiratory pressure (PEEP), Mean Airway Pressure (MAP), inspiratory time (IE), expiratory time (ET), respiratory rate (spontaneous and given), pulse rate, pulse oximetry, ABG parameter). In our institution for ABG monitoring for neonates who require respiratory support, we attempt to get an ABG on admission and blood test sample in these cases is taken from umbilical arterial catheter or a peripheral arterial line or by arterial puncture. The OI was calculated according to the following formula: value of Fraction of inspired oxygen multiplied by value of Mean airway pressure divided by value of arterial partial pressure of oxygen ($FiO_2 \times MAP/ PaO_2$ (3). OSI were calculated according to formula: value of Fraction of inspired oxygen multiplied by value of Mean airway pressure divided by value of peripheral capillary oxygen saturation ($FiO_2 \times MAP/SpO_2$ (3). OSI and OI, according to the above formulas, were calculated, and subsequently, were correlated mutually. We did not stratify the patients according to gestational age. The study was approved by the institutional review board (Ethics Committee of the Institution). Statistical analysis used by the standard methods of descriptive statistics. The significance of differences between samples was tested using parametric and nonparametric tests of significance and methods of linear correlation, using a statistical program Arcus QuicStat and Systat software.

RESULTS

During 2017, 462 children were treated at the Intensive Care Unit, including 332 neonates, 150 term and 182 preterm infants. 148 children were treated with mechanical ventilation, including 101 neonates, who are involved in the study.

A total of 101 patients were analyzed, 51 (50.5%) male and 50 (49.5%) female, 25 term and 76 preterm. Most infants, 64 (63.3%), were admitted to the NICU in the first day of life. The average age of the patients at the time of admission was 1 day,with the interquartile range of 1-3 days, and with a minimum of 1 hour and a maximum of 14 days. Gestational age ranged around the average of 36 weeks, with the interquartile range 32-36 weeks, and with a minimum of 26 and maximum of 41 weeks. Descriptive characteristics of the patients are shown in Table 1.

Regarding the outcome, 87 neonates (86.1%) survived, and 14 neonates (13.8%) died, i.e. 11 premature and 3 term infants. The median for the full length of intensive treatment was 8 days, with interquartile range 5-13 days, and with a minimum of 2 and maximum of 50 days. There were no significant differences in the length of treatment between survivors and nonsurvivors (Mann-Whitney, $Z = -1.74$, $p = 0.083$).

In all of neonates with respiratory failure pulmonary gas exchange was variously impaired with estimation parameters as presented in Table 2.

Table 2. *Respiratory indices of analyzed neonates with respiratory failure*

Parameter	Meian	Minimum	Maximum
Oxygenation index (OI)	15.3	3.6	58.3
Mean alveolar pressure (MAP)	8.0	6.0	12.0
Fraction of inspired oxygen (FiO_2)	50.0	21.0	100.0
Arterial oxygen partial pressure (PaO_2)	48.6	22.3	58.4
Arterial oxygen saturation (SaO_2)	84.8	48.2	94.0
Pulse oxymetri saturation (SaO_2)	94.0	78.0	100.0
PaO_2/FiO_2	80.3	21.5	187.5
Oxygenation saturation index (OSI)	7.3	2.9	11.9

The aim of this study was to investigate if the Oxygen saturation index (OSI) correlates with Oxygenation index (OI) in neonates with respiratory failure requiring mechanical ventilation support. We compared these two indices and we found linear correlation between Mean values of OSI and OI in our sample with Pearson's correlation coefficient of 0.76; and $p < 0.0001$ (95%CI = 0.66-0.83) as shown in the Figure 1.

In order to evaluate OSI as assessment tools in neonates, we compared results of OSI with the values of SNAP-PE scores for each patient and we found that OSI correlated with SNAP-PE score with Pearson's correlation coefficient of 0.52; and $p < 0.0001$ (95%CI = 0.36-0.65).

We also compared the values of OSI between patients who died and those who survived and we found that OSI correlated with the outcome with Spearman's

Table 1. *Clinical characteristics of analyzed neonates and deliveries*

	X ± SD		Minimum	Maximum
Birth weight (grams)	2407.7 ± 923.9		590.0	4450.0
Birth length(centimeters)	47.3 ± 6.6		28.0	59.0
SNAP-PE score	34.8 ± 8.6		5	86
	Median	Interquartile range	Minimum	Maximum
Apgar score 1th minute	7	5-8	0	9
Apgar score 5th minute	8	7-9	1	9
Gestational age (weeks)	36	32-36	26	41
Postnatal age (days)	1	1-3	1	14
Gender (Number)	Male / female		51/50	
Delivery characteristics	n		%	
Caesarean section	42		41.6	
Multiple births	23		22.7	
Inborn	61		60.4	
Outborn	40		39.6	

X ± SD – Mean ± standard deviation

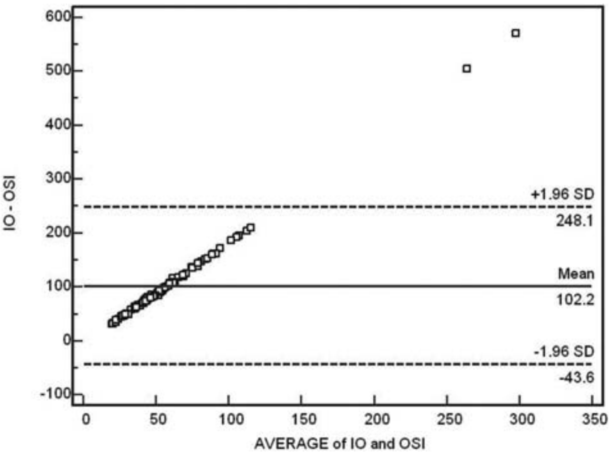

Figure 1. *Linear correlation between Oxygenation Saturation Index (OSI) and Oxygenation Index (OI)*

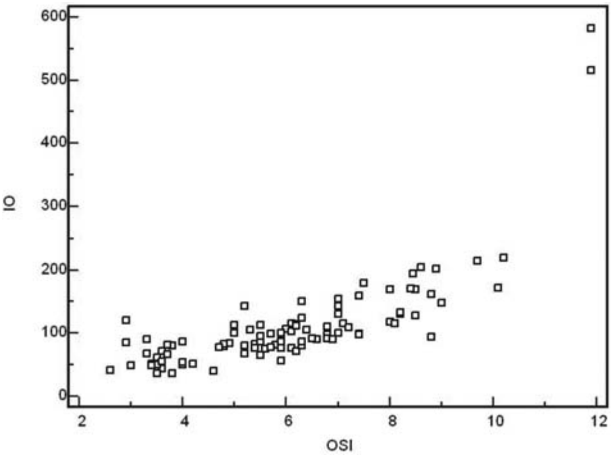

Figure 2. *Bland-Altman plot for Oxygenation Saturation Index (OSI) and Oxygenation Index (OI)*

correlation coefficient of -0.47; and $p < 0.0001$ (95%CI = -0.16- -0.31).

In addition we tested correlation between OSI and OI with the Bland–Altman plot as shown in the Figure 2. Bland-Altman plot shows the compatibility of two indices. According to the chart, the two indices are agreed in mean values, but there was disagreement in the extreme values and tendency to drop OSI in relation to IO at lower values, or to excess the value of OSI in relation to IO in the upper values. It means that OSI can be considered reliable in the average values for the parameters of assessment, but it is not highly reliable for limit values.

DISCUSSION

Hypoxic respiratory failure (HRF) can be defined as a relative deficiency of oxygen, often associated with insufficient ventilation. This deficiency can be reflected by progressive respiratory and metabolic acidosis and remains a persistent challenge in the management of some neonates. HRF accompany common respiratory diseases in neonates such as aspiration syndrome, pneumonia, respiratory distress syndrome (RDS), and congenital diaphragmatic hernia (2). Overall incidence of HRF in neonates, as measured by the overall rate of mechanical ventilation, is 18 per 1000 live births. This rate is 100-fold greater in very low birthweight infants and is also greater in males. Overall mortality rates ranged from approximately 10% to 15%. (8). In Bosnia and Herzegovina, HRF is a leading cause of neonatal mortality and is responsible for nearly 90 neonatal deaths each year, including preterm neonates (9).

HRF is a clinical problem that occurs in many different settings, including wide spectrum of diseases. Our sample of 101 neonates constitutes heterogeneous groups of gestational age, lung maturity, as well as of the underlying disease processes and postnatal interventions. The problem sometimes involves only one area of dysfunction, but most commonly several types of dysfunction are mixed in pathophysiology, including the effect of our treatment. Therefore, clinicians should continually reassess the underlying pathophysiology and adjust treatment accordingly (10).

In fact, the main task in HRF treatment is the best possible oxygenation for all tissues, in order to prevent and avoid hypoxemia. This is achieved through mechanical ventilation, often with the use of high concentrations of oxygen, which is almost inevitable. However, we must not cross the border when the damage outweighs the benefit in light of the fact that exposure to hyperoxia may result in opposite effect and cause complications. So, with equal care, we must avoid both hypoxia and hyperoxia in the treatment of critically ill neonates with respiratory insufficiency (2). Hypoxia causes pulmonary vasoconstriction, normoxia results in pulmonary vasodilation, but hyperoxia does not lead to additional vasodilation.

The evaluation of the hypoxic infant is one of the most common problems for the pediatric clinician. The optimal PaO_2 in the management of HRF is not clear. Some recent findings suggest that gentle ventilation with avoidance of hyperoxia and hyperventilation results in good outcomes in neonates with respiratory failure (1).

Respiratory indices including oxygenation index (OI), mean airway pressure (MAP), FiO_2, PaO_2, arterial oxygen saturation (SaO_2) and PaO_2/FiO_2 values, have been used mostly in recent studies investigating neonates with HRF (2, 3, 4). These values were carried out using arterial blood gas values. For instance, Serdar et al (2) evaluate early outcomes of surfactant treatment in term neonates with HRF using exactly such indices.

The use of the PaO_2/FiO_2 ratio and OI to assess HRF is limited exclusively to the arterial sampling

ABG. In neonates, in whom we perform a maximum saving approach to diagnostic procedures, ABG and complementary noninvasive monitoring techniques, provide information essential for clinician assessment, therapeutic decisions, even predicting the outcomes (6). Rapid changes in physiology, difficult access to the sampling site, and small total blood volume, represent special challenges (7). With the advancements in pulse oximetry in recent years, this noninvasive measure of systemic oxygenation has become the fifth vital sign (7), and has likely led to the decrease in arterial blood gas measurements. The results of this study demonstrate that noninvasive methods of oxygenation assessment, utilizing pulse oximetry as a substitute for PaO_2, can be calculated and used as a substitute for assessment of respiratory failure in neonates.

Oxygen saturation as measured by pulse oximetry (SpO_2)/fraction of inspired oxygen (FiO_2) has demonstrated to be an adequate marker for lung disease severity in children under mechanical ventilation (3, 4). Lobete et al. (3) sought to validate the utility of SpO_2/FiO_2 ratio in a population of critically ill children under mechanical ventilation, noninvasive ventilation support, and breathing spontaneously. They conclude that SpO_2/FiO_2 ratio is an adequate noninvasive surrogate marker for PaO_2/FiO_2 ratio. They suggest SpO_2/FiO_2 ratio may be an ideal noninvasive marker for patients with acute hypoxemic respiratory failure. Khemani et al. (7) sought to validate the comparability of SpO_2/FiO_2 to PaO_2/FiO_2 and OSI to OI in children. They have found that noninvasive indices are a good substitute severity markers in children with respiratory failure specifically for SpO_2 between 80% and 97%.

The aim of our study was to investigate if OSI correlates with OI in neonates with respiratory failure requiring mechanical ventilation support.We compared these two indices and we found linear correlation between mean values of OSI and OI in our sample with Pearson's correlation coefficient of 0.76; and $p < 0.0001$ (95%CI = 0.66-0.83). Mean values of both indices in our study showed a significant correlation,which is consistent with reports of Khemani et al. (7) that also highlight conformity of two indices for SpO_2 between 80% and 97%.

We tested the correlation between OSI and OI with the Bland–Altman plot, showing the two indices were agreed in mean values, but there was disagreement in the extreme values and tendency to drop OSI in relation to OI at lower values, or to excess the value of OSI in relation to OI in the upper values. It means that OSI can be considered reliable in average values for the parameters of assessment, but it is not highly reliable for limit values. Other similar noninvasive indices, also show better compliance and strongest association with the OI for neonates ranking SpO_2 between 88% and 94% as Iyerand Mhanna report (5).

In order to evaluate OSI as assessment tools in neonates, we compared results of OSI with the values of SNAP-PE scores for each patient and we foundthat OSI correlated with SNAP-PE score with Pearson's correlation coefficient of 0.52; and $p < 0.0001$ (95%CI = 0.36-0.65). We also compared the values of OSI between patients who died and those who survived and we found that OSI correlated with the outcome with Spearman's correlation coefficient of -0.47; and $p < 0.0001$ (95%CI = -0.16- -0.31). Ghuman et al. (6) investigated the relationship between markers of oxygenation, PaO_2/FIO_2 ratio, SpO_2/FIO_2 ratio, OI, and OSI, and mortality in children with acute hypoxemic respiratory failure. They conclude that in pediatric acute hypoxemic respiratory failure, easily obtainable pulmonary specific markers for severityof disease (SpO_2/FIO_2 ratio and OSI) may be useful for the early identification of children at high risk of death.

There are some limitations to our study. Firstly, this was a retrospective study. A prospective study of data collected, with close attention to the variance of the pulse oximeter and the exact timing of the arterial blood gas measurement with the recording of the SpO_2, is required in future validation studies of these measures. Another limitation is that, again due to the use of SpO_2 data due to reliability report in the conduct of large-scale clinical trials. Thirdly, the oxygen-hemoglobin dissociation curve and thus the relationship between PaO_2 and SpO_2, are known to be affected by a variety of variables, including pH, temperature, $PaCO_2$, and concentration of 2,3 diphosphoglycerate (1). Compared to the other models, OSI would be the preferable method, as it has the advantage of including the Paw and also utilizing the noninvasive measure of oxygenation (SpO_2). Although these values require validation in a prospective trial, utilizing this new criterion clinically has the potential to allow more accurate diagnosis of respiratory failure in neonates.

CONCLUSION

OSI correlates significantly with OI in critically ill neonates with respiratory failure. This noninvasive method may be used to assess the severity of hypoxic respiratory failure and mortality risk in neonates without arterial access. These results additionally confirm that noninvasive oxygenation assessment method, utilizing pulse oximetry as a substitute for invasively obtained value of partial pressure of oxygen through the arterial puncture, can be calculated and used as a substitute for assessment of respiratory failure in neonates.

Abbreviations:

ABG — Arterial blood gas
ARF — Acute respiratory failure

BW — Birth weight
ET — Expiratory time
FiO_2 — Fraction of inspired oxygen
GA — Gestational age
HRF — Hypoxic respiratory failure
IT — Inspiratory time
MAP — Mean Airway Pressure
NICU — Neonatal intensice care unit
OI — Oxygenation index
OSI — Oxygenation saturation index
Paw — airway pressure
PaO_2 — arterial partial pressure of oxygen
PEEP — Positive end-expiratory pressure
PIP — Peak inspiratory pressure
RDS — Respiratory distress syndrome
SaO_2 — Oxygen saturation
SNAP-PE — Score for Neonatal Acute Physiology-Perinatal Extension
SpO_2 — peripheral capillary oxygen saturation

DECLARATION OF INTEREST

The autors declare that there are no conflicts of interests.

Licensing

Sažetak

OKSIGENACIJSKI SATURACIJSKI INDEKS U PROCENI RESPIRATORNE INSUFICIJENCIJE NOVOROĐENČADI

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Uvod: Akutna respiratorna insuficijencija (ARI) je najčešći problem koji se sreće u neonatalnoj jedinici intenzivne nege. Etiologija nije uniformna i uglavnom zavisi od gestacijske starosti. Za adekvatan tretman je svakako važno prepoznati i lečiti osnovnu bolest, ali istovremeno moramo snabdeti odgovarajuću respiratornu podršku, perfuziju tkiva i isporuku kiseonika. Za dobar ishod potreban je pouzdan metod procene funkcionalnog stanja respiratornog sistema, kao i praćenje efekata tretmana. Prema važećim načelima težina ARI procenjuje se na osnovu nalaza gasnih analiza, radiografije pluća i Oksigenacijskog ndeksa (OI). OI je prilično agresivan metod procene novorođenčadi, jer uključuje uzimanje uzoraka arterijske krvi. Respiratorni indeks promovisan u najnovijim studijama pod nazivom Oksigenacijski saturacijski indeks (OSI) daje mogućnost objektivne procene respiratorne bolesti pomoću neinvazivne pulsne oksimetrije. **Cilj** našeg istraživanja bila je procena korelacije između OSI i OI kod novorođenčadi sa ARI na mehaničkoj ventilaciji. **Materijal i metode:** U retrospektivnoj kohortnoj studiji odabrano je 101 novorođenče, lečeno u Odseku za intenzivnu terapiju i negu Klinike za dečije bolesti u Tuzli koji su zbog ARI zahtevali mehaničku ventilaciju. Analizirani su klinički podaci kao što su: gestacijska dob, porođajna težina, Apgar skor, bodovna vrednost procene težine bolesti novorođenčadi (SNAP-PE), acidobazni status, Oksigenacijski indeks i Oksigenacijski saturacijski indeks, koji su izračunati i potom međusobno korelirani. Srednje vrednosti OSI i OI korelirale su sa Pearsonovim koeficijentom od 0,76; $p < 0,0001$ (95% CI = 0,66-0,83), a OSI je korelirao sa SNAP-PE sa Pearsonovim koeficijentom od 0,52; $p < 0,0001$ (95% CI = 0,36-0,65). Poredeći vrednosti OSI među pacijentima koji su umrli i koji su preživeli, utvrdili smo da je OSI korelirao sa ishodom sa Spearmanovim koeficijenta -0,47; $p < 0,0001$ (95% CI = -0,16 - -0,31). Bland-Altman metoda potvrdila je korelaciju između OSI i OI u srednjim vrednostima, identifikujući neusaglašenost između dva respiratorna indeksa za ekstremne vrednosti. **U zaključku**, OSI značajno korelira sa OI kod novorođenčadi sa respiratornom insuficijencijom. Ovaj neinvazivni metod procene oksigenacije, baziran na pulsnoj oksimetriji, može se koristiti za procenu težine ARI i rizika smrtnosti kod novorođenčadi.

Ključne reči: novorođenče; respiratorna insuficijencija; Oksigenacijski indeks, Oksigenacijski saturacijski indeks.

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