Original Article

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Paediatrics Section

Clinical Utility of Oxygen Saturation Index Compared with Oxygenation Index in Neonatal Respiratory Diseases: A Prospective Observational Study

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ABSTRACT

Introduction: The neonatal period is one of the most critical phases in an individual's life. During this time, newborns undergo significant physiological changes as they adapt from the intrauterine to the extrauterine environment. Respiratory diseases in neonates are associated with an increased risk of mortality, morbidity, and adverse neurological outcomes. Hence, monitoring neonates using oxygenation indices is essential.

Aim: To determine the correlation between the Oxygen Saturation Index (OSI) and the Oxygenation Index (OI) among term and preterm neonates mechanically ventilated for respiratory diseases.

Materials and Methods: A prospective observational study was conducted among 80 neonates with primary respiratory diseases requiring mechanical ventilation, admitted to a tertiary care hospital in North Karnataka, India. Newborns with cardiac diseases were excluded. All neonates were monitored using a pulse oximeter for OSI and Arterial Blood Gas (ABG) analysis for OI. Pearson's correlation analysis and Receiver Operating Characteristic (ROC) curve analysis (p-value <0.05) were used to assess the relationship between OI and OSI.

Results: Out of 80 neonates, 59 (73.75%) were inborn and 21 (26.25%) were outborn, 52 (65%) neonates were preterm and 28 (35%) were term, with a male-to-female ratio of 7:3. Of 80 neonates, 48 (60%) newborns were diagnosed with Respiratory Distress Syndrome (RDS), 21 (26.25%) with Meconium Aspiration Syndrome (MAS), and 11 (13.75%) with pneumonia. About 35 (43.8%) neonates had a gestational age between 28 and 33 weeks, with RDS being the most prevalent disease in this group. The most common cause of respiratory disease among term neonates was MAS. Out of 80 neonates, 44 (55%) survived and 36 (45%) expired. OI showed a moderate positive correlation with OSI (r-value=0.444, p-value=0.01). The Area Under the Curve (AUC) value for OSI in predicting mortality was higher compared to that for OI, and both were found to be statistically significant (p-value=0.001).

Conclusion: OSI, being non invasive, can be used as an alternative to OI for monitoring oxygenation in ventilated neonates with respiratory diseases. It is also cost-effective and reduces the risk of sepsis and phlebotomy-induced anaemia.

Keywords: Blood gas analysis, Infant, Newborn, Pulse oximetry, Respiratory insufficiency

INTRODUCTION

Respiratory distress is the most common indication for Neonatal Intensive Care Unit (NICU) admission and mechanical ventilation [1,2]. The estimated incidence of neonates with respiratory failure requiring mechanical ventilation is approximately 18 per 1,000 live births [3,4]. Respiratory diseases in neonates are associated with an increased risk of mortality, morbidity, and adverse neurological outcomes [5-7]. The severity of pulmonary disease and the adequacy of ventilatory support are assessed using various invasive and non invasive indices. The OI is one such metric used to determine the degree of respiratory illness and to guide appropriate therapeutic interventions for improved neonatal outcomes. However, OI is limited by its reliance on indwelling arterial catheters for frequent ABG sampling and by its intermittent assessment of oxygenation [8,9].

The OSI is a non invasive method of monitoring oxygenation, in which arterial oxygen tension (PaO_2) is replaced with oxygen saturation (SpO_2) in the OI equation [8]. OSI is particularly useful in mechanically ventilated neonates when ABG monitoring is not readily available. It also allows continuous monitoring of oxygenation status, unlike the intermittent measurements obtained with OI [8,9].

OSI has been established in paediatric intensive care units as a reliable tool for assessing the severity of respiratory failure and lung injury in paediatric patients [10,11]. However, literature evaluating the efficacy of OSI compared to OI in monitoring term and preterm neonates with respiratory diseases is limited. Therefore, this study was conducted to assess the correlation between OSI and OI among term and preterm neonates mechanically ventilated for respiratory diseases.

MATERIALS AND METHODS

A prospective observational study was conducted among 80 neonates admitted to a Level III NICU of a tertiary care hospital in North Karnataka, India between August 2022 and February 2024. The study was approved by the Institutional Ethics Committee (Ref: SDMIEC/2022/253, dated 27/07/2022).

Inclusion criteria: Term and preterm neonates receiving mechanical ventilation for primary respiratory diseases were included in the study.

Exclusion criteria: Neonates with congenital heart disease diagnosed by echocardiography were excluded from the study.

Sample size: Using a probability sampling technique and the formula $N = Z\ \alpha^2 \times \text{sensitivity}\ (1 - \text{sensitivity})/d^2 \times P$, with a sensitivity

of 85%, specificity of 91%, and positive predictive value of 88%, as reported by Muniraman HK et al., the calculated sample size was 78 [12]. Hence, 80 neonates were included in the study.

Study Procedure

All neonates were monitored using a pulse oximeter for OSI and ABG analysis for OI. SpO_2 was measured using a Masimo Radical Pulse Oximeter (Masimo Inc., Irvine, CA). SpO_2 values were recorded after ensuring a stable waveform for 60 seconds, while avoiding movement artefacts and haemodynamic instability. ABG analysis was performed using an ABG analyser. Under strict aseptic precautions, 0.5 cc of arterial blood was collected in a preheparinised syringe and immediately sent for blood gas analysis. Ventilator parameters including Peak Inspiratory Pressure (PIP), Positive End-Expiratory Pressure (PEEP), Inspiratory Time (Ti), Total time (Tt), and Fraction of inspired Oxygen (FiO_2) were recorded at the time of ABG sampling.

The OI was calculated using the formula [13]

$OI = \{(FiO_2 \times MAP)/PaO_2\} \times 100.$

The OSI was calculated using the formula [13]:

$OSI = \{(FiO_2 \times MAP)/SpO_2\} \times 100.$

Mean Airway Pressure (MAP) was calculated using the formula [14]:

$MAP = k \times \{(PIP-PEEP) \times Ti /T(total)\} + PEEP$

where k is a constant with a value of 1 for pressure control ventilation and 0.5 for volume control ventilation. The collected data were entered into a prestructured proforma.

STATISTICAL ANALYSIS

Data were entered into a Microsoft Excel spreadsheet, and statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS version 20.0). Pearson's correlation analysis and ROC curve analysis (p-value <0.05) were used to evaluate the relationship between OI and OSI.

RESULTS

Eighty neonates were included in the study of which 24 (30%) neonates were female and 56 (70%) were male, 59 (73.8%) neonates were inborn, while 21 (26.2%) were outborn, 52 (65%) neonates were preterm, and 28 (35%) were term neonates. Among the study population, 35 (43.8%) of neonates were between a gestational age of 28 and 33 weeks, 13 (16.3%) were between 34 and 36 weeks, 28 (35%) were between 37 and 42 weeks, and the remaining 4 (5%) were born at a gestational age of less than 28 weeks.

[Table/Fig-1] depicts the various indications for mechanical ventilation among the study subjects. Respiratory Distress Syndrome (RDS) was the most common diagnosis in preterm neonates, while Meconium Aspiration Syndrome (MAS) was the most common cause in term neonates.

Indication	n (%)
Respiratory Distress Syndrome (RDS)	48 (60)
Meconium Aspiration Syndrome (MAS)	21 (26.25)
Pneumonia	11 (13.75)

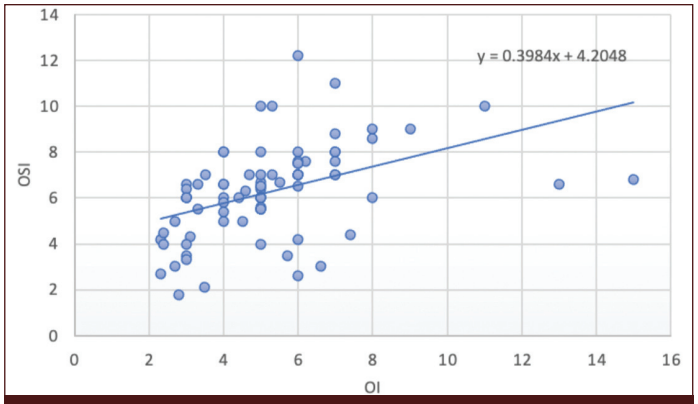
[Table/Fig-1]: Indication for mechanical ventilation.

[Table/Fig-2] depicts the mean values of OI and OSI in term, preterm, and total neonates. The study demonstrated a positive correlation between OI and OSI, with a correlation coefficient (r) of 0.444, which was statistically significant (p-value=0.01). A stronger correlation was observed within the oxygen saturation range of 85-95%.

Gestational age	OI Mean±SD	OSI Mean±SD
Preterm	5.06±1.55	6.19±2.08
Term	5.55±3.11	6.47±1.83
Total	5.23±2.22	6.29±1.99

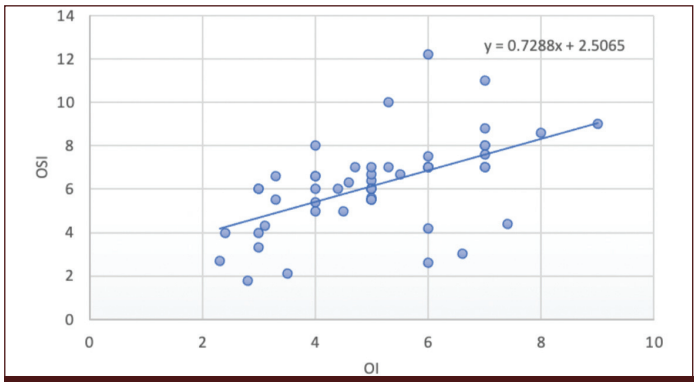
[Table/Fig-2]: Mean and standard deviation values of OSI and OI.

The linear regression equation derived from the study was: OSI= 0.3984 × OI + 4.2048 [Table/Fig-3].

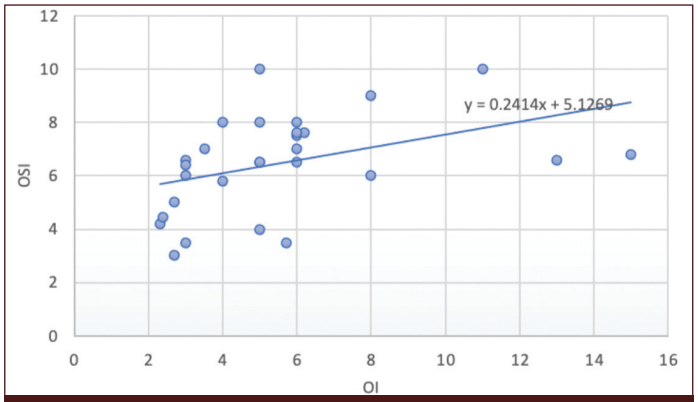


[Table/Fig-3]: Correlation between OI and OSI.
OI: Oxygenation index; OSI: Oxygen saturation index

The study revealed a moderate correlation between OSI and OI in both preterm neonates (r-value=0.54, p-value=0.001) and term neonates (r-value=0.41, p-value=0.03), as depicted in [Table/Fig-4,5]. The correlation coefficient was higher in preterm neonates compared to term neonates.



[Table/Fig-4]: Correlation between OI and OSI in preterm neonates.
OI: Oxygenation index; OSI: Oxygen saturation index



[Table/Fig-5]: Correlation between OI and OSI in term neonates.
OI: Oxygenation index; OSI: Oxygen saturation index

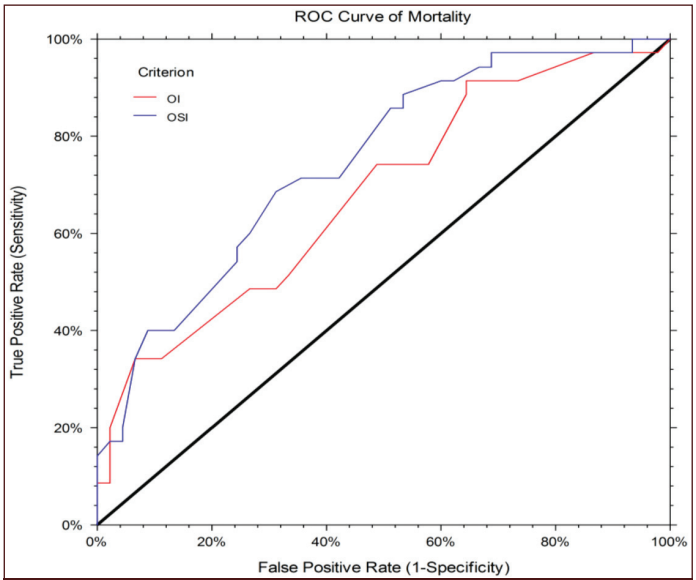
In the present study, 44 neonates (55%) survived, while 36 (45%) expired. As depicted in [Table/Fig-6], OI and OSI values among

survivors were lower than those of non survivors. On performing an unpaired t-test, this difference was found to be statistically significant (p-value=0.001).

	Survivors	Non survivors	
	Mean±SD	Mean±SD	p-value
OI	4.53±1.52	6.08±2.62	0.001
OSI	5.59±1.72	7.14±1.98	0.001

[Table/Fig-6]: Comparison of OI and OSI in non survivors and survivors.
OI: Oxygenation index; OSI: Oxygen saturation index; SD: Standard deviation

ROC curve analysis for OI and OSI in predicting mortality revealed an area under the curve (AUC) of 0.696 for OI and 0.724 for OSI. The AUC value for OSI was higher than that for OI. Both values were statistically significant (p-value=0.001) [Table/Fig-7].



[Table/Fig-7]: Receiver operating characteristic (ROC) curve of accuracy in prediction of mortality by OI and OSI.

Based on ROC curve analysis, the cut-off value for OI in predicting mortality was 7, with a sensitivity of 34.3% and specificity of 93.3%. The cut-off value for OSI in predicting mortality was 6.6, with a sensitivity of 68.6% and specificity of 68.9%.

Kappa statistics indicated a 66.25% agreement between OI and OSI in predicting mortality (p-value=0.0004). As depicted in [Table/Fig-8], the sensitivity and specificity of OSI compared to OI in predicting mortality were 86.67% and 61.54%, respectively.

Statistic	Value	95% CI
Sensitivity	86.67%	59.54% to 98.34%
Specificity	61.54%	48.64% to 73.35%
Positive predictive value	34.21%	26.50% to 42.85%
Negative predictive value	95.24%	84.44% to 98.66%
Accuracy	66.25%	54.81% to 76.45%

[Table/Fig-8]: Sensitivity, specificity, PPV and NPV of OSI over OI.

DISCUSSION

The results of the study suggest that OSI, calculated by replacing PaO_2 with SpO_2, can be as precise as OI in determining the severity of hypoxic respiratory failure in neonates. The linear regression equation obtained from the study, OSI= 0.3984 × OI + 4.2048, facilitates the derivation of one index from the other. This model provides clinicians with a rapid, non invasive method for continuously evaluating neonatal respiratory status, thereby reducing the need for frequent arterial blood sampling.

In the present study, RDS was observed in 48 neonates, MAS in 21 neonates, and congenital pneumonia in 11 neonates. Preterm neonates demonstrated a higher incidence of RDS, whereas MAS and congenital pneumonia were more common among term neonates. In a study by Todkar M and Ashtekar S, RDS was the most common cause of respiratory distress (27.36%) in neonates, followed by transient tachypnoea of the newborn (19.47%), with congenital pneumonia being the third most common cause [15].

Similarly, a study by Jain P et al., reported an aetiological spectrum comparable to the present study, including RDS (32.8%), transient tachypnoea of the newborn (27.2%), MAS (14.8%), and pneumonia (18%). Preterm neonates exhibited a higher incidence of RDS, while transient tachypnoea of the newborn and MAS were predominant among term neonates [7]. However, it is important to note that the present study included only neonates with respiratory distress who required mechanical ventilation.

A comparable study conducted by Doreswamy SM et al., demonstrated a Pearson product-moment correlation coefficient (r) of 0.91 for OSI [16]. In the present study, the observed value was 0.444; both indicate a favourable correlation. Similar results were reported by Bui-Binh-Bao S et al., with a correlation coefficient of 0.791 in a cohort of 123 term and preterm neonates [17]. Additionally, in a study by Sunil B and Nithya E, involving 50 neonates, a positive correlation between OSI and OI was observed, with an r value of 0.727 [18].

Maneenil G et al., also reported similar findings, with a correlation coefficient of 0.90. However, their study cohort included neonates with persistent pulmonary hypertension of the newborn, cyanotic congenital heart disease, and other causes of respiratory failure [19]. Comparable results were observed in studies by Muniraman HK et al., with a correlation coefficient of 0.89, and Rawat M et al., in a study involving 74 neonates (r=0.952) [12,20]. In contrast to these retrospective studies, the present study was prospective, ensuring accurate timing of SpO_2 measurements with corresponding ABG samples.

The moderate correlation between OSI and OI observed in the present study, compared to the stronger correlations reported in previous studies, may be attributed to the fact that the study cohort predominantly consisted of neonates with mild to moderate hypoxemic respiratory failure (HRF), with lower OI values. The correlation coefficient tends to be lower in mild to moderate HRF compared to cohorts with more severe hypoxemia. This could also partly be explained by the non linear relationship between SpO_2 and PaO_2 in neonates with HRF.

In this study, the correlation between OI and OSI was stronger in the saturation range of 85-95%, which was consistent with the findings of Muniraman HK et al., and Maneenil G et al., [12,19]. As oxygen saturation varies non linearly with PaO_2, SpO_2 can be used instead of PaO_2 for certain saturation ranges only, since at extreme values, oxygen saturation does not correlate well with PaO_2 [21].

The correlation between OI and OSI was stronger in preterm neonates than in term neonates, similar to the findings of Muniraman HK et al., which showed a stronger correlation among preterm neonates with gestational ages less than 34 weeks (<28 weeks, r=0.93; 28-33 weeks, r=0.93) compared with late preterm (r=0.86) and term (r=0.70) neonates [12].

The mean OI and OSI values among survivors were lower than those of non survivors. Similar results were reported by Alanazi I et al., where median values of OSI and OI were higher in non survivors compared to survivors during the first two days of ventilation; however, these differences were not statistically significant from Day 3 onward [22].

In the present study, the overall mortality was 45%. The tertiary-care study setting caters to both inborn and outborn babies, including more premature (26 to 34 weeks of gestation) and low birth weight infants. Preterm and low birth weight infants have immature lungs and immune systems, making them more susceptible to sepsis, which may have contributed to the observed mortality.

ROC curve analysis for OSI and OI in predicting mortality demonstrated an AUC of 0.724 for OSI, which was comparable to the findings of Sunil B and Nithya E, who reported an AUC of 0.91 in a cohort of 40 neonates [18]. In that study, ROC analysis for OSI showed high sensitivity (97.37%) and specificity (75.00%). In the present study, the sensitivity and specificity of OSI compared to OI in predicting mortality were 86.67% and 61.54%, respectively. This indicates that OSI has high sensitivity but moderate specificity compared to OI, making it useful for identifying neonates at risk of mortality, though with a tendency to overestimate mortality risk.

Limitation(s)

The study was conducted at a single tertiary-care centre, limiting the generalisability of the findings to other healthcare settings. Additionally, the non linear relationship between SpO_2 and PaO_2, particularly at higher saturation levels (>95%), may have affected the strength of correlation between OSI and OI.

Further multicentre studies with larger and more diverse neonatal populations are needed to improve generalisability, refine OSI thresholds, and validate its role in guiding clinical management in neonatal HRF.

CONCLUSION(S)

The study found a positive correlation between OSI and OI using the Pearson correlation test. OSI, being non invasive, can be used in lieu of OI for real-time monitoring of oxygenation in ventilated neonates with respiratory diseases. It is cost-effective, with a less risk of sepsis and phlebotomy-induced anaemia.

Author contribution: KPP contributed to the article concept and critically revised it for intellectual content. KHA contributed to data collection and analysis. KS contributed to study design, data analysis, and drafting of the manuscript. All authors have read and approved the manuscript.

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