

Original Research Article

Level of agreement on SpO₂ and response time between fingertip pulse oximeter and conventional bedside pulse oximeter among preterm neonates: a tertiary care study

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ABSTRACT

Background: Fingertip pulse oximeters are used to measure peripheral oxygen saturation (SpO₂) levels in newborns and have been recommended to improve access to monitoring devices in resource-limited settings. However, evidence regarding their use in preterm neonates is limited. Therefore, this study aimed to assess the level of agreement in peripheral oxygen saturation and response time between fingertip pulse oximeters and conventional bedside pulse oximeters in preterm neonates.

Methods: A cross-sectional analytical study was conducted among 201 preterm neonates admitted to the neonatal intensive care unit (NICU) of a tertiary care hospital in Puducherry, India. Preterm neonates who met the inclusion criteria were enrolled using consecutive sampling. Medical records were reviewed to obtain information on clinical and sociodemographic characteristics. Both a conventional bedside pulse oximeter and a fingertip pulse oximeter were used to assess SpO₂ and response times. Data were analyzed using paired t-tests (t-test), Wilcoxon signed-rank tests (Wilcoxon SR test), Intraclass correlation coefficients (ICC) and Bland-Altman analyses.

Results: A significant difference in SpO₂ values ($p < 0.001$) was observed between the devices, while response times showed no significant difference ($p = 0.107$). The ICC indicated fair to good agreement for both parameters ($p < 0.001$). Bland-Altman analysis revealed no significant bias, supporting the consistency between the devices.

Conclusions: The fingertip pulse oximeter demonstrated clinically acceptable agreement with the conventional bedside device for measuring SpO₂ in preterm neonates.

Keywords: Agreement, Oxygen saturation, Oximetry, Premature

INTRODUCTION

According to the World Health Organization (WHO) estimates, 13.4 million preterm births occur annually.¹ They may play a significant role in the morbidity, mortality and other long-term health issues that affect newborns. They are at risk for a variety of complications, such as respiratory distress syndrome, a chronic lung disease, intestinal injury, weakened immune systems, cardiovascular disorders, issues with hearing and vision

and neurological insult. Technological advancements over the last few decades have improved the survival rate of extremely preterm infants. Reliable technologies that enable non-invasive monitoring of critical parameters would be beneficial in conducting meticulous subject surveillance and providing long-term indications.² Monitoring peripheral oxygen saturation (SpO₂) levels is necessary in clinical practice to titrate oxygen therapy and prevent the risks of hypoxemia and hyperoxemia.³ Hypoxemia or low blood oxygen saturation, is a frequent

complication of pneumonia.⁴ Studies have shown that around one-fifth of hospitalized newborns in low-resource settings have SpO₂ levels below 90%. Physical examination may not always detect it, even with severe illness or congenital heart problems.⁵ An internationally recognized, non-invasive reliable way for detecting hypoxemia is pulse oximetry.⁶ Compared with arterial blood gas analysis, pulse oximetry is more affordable, less uncomfortable, simpler to use and more widely accessible.⁷ In a recent study, the correlation between pocket pulse oximeter and arterial blood gas analysis was evaluated in patients with COVID-19 and the results showed that the pocket pulse oximeter and arterial oxygen saturation measurement were correlated and levels were within acceptable bounds.⁸ In compliance with the guidelines provided by the European Resuscitation Council, a pulse oximeter was administered to 97% of neonates during resuscitation in the delivery room.⁹ The commonly used sites to obtain a uniform and sustained waveform from the pulse oximeter in sick neonates are the wrist, ankle, palm and sole.¹⁰

In NICU, it is recommended to use a conventional bedside pulse oximeter with a probe connected to the standard monitor for monitoring oxygen saturation levels in neonates.⁷ It is the recommended technique for measuring oxygen levels in newborns and enables continuous monitoring.¹¹ When assessing a sick newborn's oxygen requirements, pulse oximetry can aid in the identification of newborns with respiratory problems and managing babies in low-income country settings and also offers vital information regarding oxygen saturation during the first twenty-four hours of life.¹²

Only a few studies have been conducted on the use of fingertip pulse oximeters for the routine screening of all healthy newborns in the early postnatal period.⁵ Portable fingertip pulse oximeters are recommended in the literature to improve access to vital medical instruments in resource-limited areas.¹¹ Given, the purpose of this study was to evaluate the level of agreement on SpO₂ and response time between the fingertip pulse oximeter and conventional bedside pulse oximeter among preterm neonates admitted to the NICU in a tertiary care hospital.

METHODS

Study design

This study was a cross-sectional analytical study.

Sample

This study was conducted in a neonatal intensive care unit of a tertiary care hospital in Puducherry, India, between September 2024 and January 2025. Preterm neonates born between 28 and 36 weeks of gestation and admitted to the NICU were included. Preterm neonates with hypothermia, edema, cyanosis, limb anomalies,

congenital heart disease and persistent pulmonary hypertension were excluded. The sample size was estimated at 201 based on an expected ICC of 0.8, a 5% significance level and a precision of 0.05; therefore, 201 preterm neonates were enrolled. Eligible preterm neonates whose parents provided informed consent were recruited using a consecutive sampling technique until the required sample size was achieved.

Data collection tools

The data collection proforma was prepared to include demographic and clinical characteristics and oxygen saturation details of the neonates.

Demographic characteristics comprised data regarding gender and length of stay in the hospital. Clinical characteristics included gestational age of the neonates, birth weight, oxygen administration details (whether the child was connected to the oxygen support or not), what was the mode of oxygen delivery the child was connected to (Endotracheal ventilation, continuous positive airway pressure, high-flow nasal cannula, Oxygen hood, nasal cannula, non-invasive ventilation) and the diagnosis of the child was noted (low birth weight, respiratory distress syndrome, pneumonia, asphyxia, apnea of prematurity, transient tachypnea of newborn and sepsis). These variables were recorded as dichotomous alternatives (yes or no). The continuous variables included oxygen saturation details, namely the SpO₂ value and response time of both the fingertip pulse oximeter (MD300C52) and conventional bedside pulse oximeter (Nellcor or Masimo signal extraction technology)

Data collection procedure

Data regarding demographic and clinical characteristics of the neonates were collected from the medical records. The researcher connected the conventional bedside pulse oximeter to the wrist of the preterm neonates and the digital timer was turned on for calculating the response time (Response time is defined as the time taken for the first good sustained signal pulse waveform to appear) and then displayed SpO₂ value was noted. Then the fingertip pulse oximeter (Conventional spectrophotometry technology- using light emitting diode) was applied on the same hand (over the fingertips) and the response time and SpO₂ value were noted. In between the preterm neonates, the fingertip pulse oximeter was disinfected with 70% isopropyl alcohol and allowed to dry for 1 minute. All the measurements were performed by the same investigator.

Statistical analysis

The SpO₂ value and response time obtained between fingertip pulse oximeter and conventional bedside pulse oximeter were compared using a paired t-test (t-test) or the Wilcoxon signed-rank tests (Wilcoxon SR test). The level of agreement between fingertip pulse oximeter and

conventional bedside pulse oximeter on SpO₂ value and response time was assessed using ICC. In addition, Bland-Altman analysis was also used to assess the level of agreement on the SpO₂ value. Data were analyzed using SPSS version 20.0.

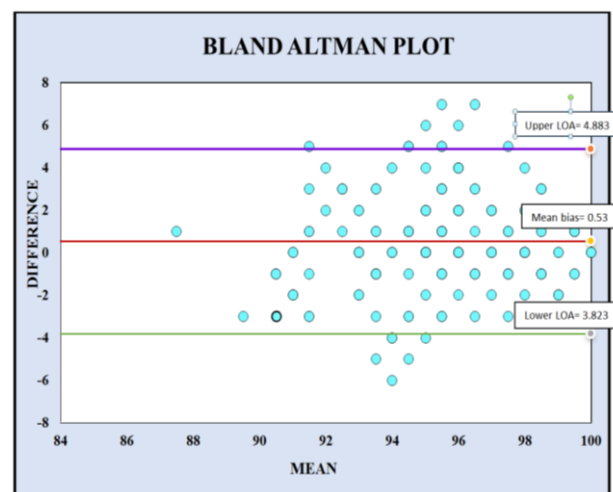
RESULTS

Out of the two hundred and one preterm neonates, 108 (53.7%) were males. Regarding the clinical characteristics, 116 (57.7%) were on room air. For those needing oxygen support, only 17.9% were on noninvasive ventilation. Regarding the diagnosis, the majority (91.5%) were actually low birth weight and the mean birth weight was 1614.81 ($\pm$ 524.71) grams. The mean gestational age and mean length of hospital stay were approximately 32.57 ($\pm$ 2.14) weeks and 20.97 ($\pm$ 16.10) days, respectively (Table 1).

t-test revealed a significant difference in the SPO₂ values between the finger-tip pulse oximeter and the conventional bedside pulse oximeter among preterm neonates ($t=3.37$; $p=0.000$). Wilcoxon SR test revealed no significant difference in response time between the Finger Tip Pulse Oximeter and the Conventional Bedside Pulse Oximeter ($W=7937.5$; $p=0.1074$), as shown in Table 2.

However, the intraclass correlation for SpO₂ (ICC=0.65; $p<0.001$) and for response time (ICC=0.738; $p<0.001$), indicated a significant fair good agreement between the fingertip pulse oximeter and the conventional bedside pulse oximeter (Table 3).

Bland-Altman analysis for SpO₂ values measured between fingertip pulse oximeter and conventional bedside pulse oximeter indicates the mean difference or bias was 0.53, while the upper and bottom line indicate the agreement limits (4.883, -3.823) at the 95% confidence interval. Therefore, there is no statistically significant difference between the fingertip pulse oximeter and the conventional bedside pulse oximeter Figure 1.



Violet line refers to the upper line of agreement and green line refers to the lower line of agreement corresponding to 1.96 SD's from the mean difference. Red line refers to the mean bias.

Figure 1: Bland-Altman plot of SpO₂ value between fingertip pulse oximeter and conventional bedside pulse oximeter (n=201).

Table 1: Distribution of the demographic and clinical variables among preterm neonates admitted in the neonatal intensive care unit (n=201).

Variables		Frequency, N (%)
Gender of the preterm	Male	108 (53.7)
	Female	93 (46.3)
Presence of oxygen support	Yes	85 (42.3)
	No	116 (57.7)
Mode of oxygen delivery	Endotracheal ventilation	3 (1.6)
	Continuous positive airway pressure	21 (10.4)
	High flow nasal cannula	21 (10.4)
	Oxygen hood	3 (1.5)
	Nasal cannula	1 (0.5)
	Non-invasive ventilation	36 (17.9)
	Room air	116 (57.7)
Low birth weight	Yes	184 (91.5)
	No	17 (8.5)
Respiratory distress syndrome	Yes	100 (49.8)
	No	101 (50.2)
Pneumonia	Yes	1 (0.5)
	No	200 (99.5)
Asphyxia	Yes	6 (3.0)
	No	195 (97.0)
Apnea of prematurity	Yes	23 (11.4)

Continued.

Variables	Frequency, N (%)
	No
	178 (88.6)
Transient tachypnea of newborn	Yes
	24 (11.9)
	No
	177 (88.1)
Sepsis	Yes
	16 (8.0)
	No
	185 (92.0)
Gestational age (GA in weeks)	32.57±2.14*
Birth weight (in grams)	1614.81±524.71*
Length of hospital stay (in days)	20.97±16.10*

*Mean (SD) was reported

Table 2: Comparison of SpO₂ values and response time between fingertip pulse oximeter and conventional bedside pulse oximeter (n=201).

Variables	Statistical test	P value
SpO ₂ values	t=3.37	0.000*
Response time	W=7937.5	0.1074

*Significant, t=paired t-test, W=Wilcoxon signed rank test.

Table 3: The agreement level between the SpO₂ values and response time of fingertip pulse oximeter and conventional bedside pulse oximeter in preterm neonates (n=201).

Variables	ICC*	95% confidence interval (lower, upper)	P value
SpO ₂ values	0.65	0.558, 0.720	<0.001
Response time	0.738	0.654, 0.802	<0.001

*ICC=Intraclass correlation.

DISCUSSION

A noninvasive tool for continuously determining the peripheral oxygen saturation rate is the pulse oximeter.¹³ The absorption spectra of oxygenated blood (oxyhemoglobin) and deoxygenated blood (deoxyhemoglobin) are different. A sensor with a light-emitting diode and a light-detecting photodiode is applied to a cutaneous vascular bed, like a transilluminatable fingertip. Plethysmography may detect arterial pulsations and adjust for light absorption by non-pulsating venous blood and tissue. A microprocessor analyzes the ratio of absorption at the red and infrared wavelengths and a preset calibration curve is used to estimate SpO₂.¹¹

Continuous neonatal monitoring in the NICU and neonatal wards facilitates early detection of changes in physiological parameters and enables timely intervention. For neonatal monitoring, the use of Masimo signal extraction technology (SET)-based probes in the NICU are widely recommended worldwide. Technological advancements have significantly improved the accuracy of these monitors, particularly the ability of pulse oximeters to provide reliable measurements in conditions of low perfusion. As a result, specialized probes and cardiac monitors are commonly used in pediatric settings. However, conventional monitors are not suitable for wearable physiological monitoring applications because they are expensive and cause discomfort to the wearer. All of the aforementioned annoyances can be avoided with wearable technology. Fingertip pulse oximeters are now available for children ages two to three and older,

but in most setups, the most vulnerable population, including newborns does not have access to this crucial monitoring. Furthermore, concerns remain regarding the accuracy, quality and feasibility of using fingertip pulse oximeters in this population.^{14,15} Evidence from previous studies highlights the clinical value of pulse oximetry in assessing and identifying hypoxemia. A study conducted among term and preterm neonates found SpO₂ values of 89% and 97%, respectively, may be reasonable oxygen saturation limits for healthy infants within the first 24 hours at an altitude of 1800 meters.¹⁶ Furthermore, pulse oximetry significantly improved referral decisions for hypoxemic children with pneumonia from 0% to 27.2%.¹⁷ Similarly, another study showed that SpO₂ ≤94% strongly predicted severe illness, severe pneumonia and hospitalization. The study concluded that pulse oximetry is a valuable tool for identifying severe illness in outpatient children.¹⁸

In this study, intraclass correlation indicated significant fair-good agreement between SpO₂ value of fingertip pulse oximeter and conventional bedside pulse oximeter (ICC=0.65; 95% confidence interval). Consistent with this, a study conducted in India showed a strong correlation. The correlation coefficients (r) of the SpO₂ readings between the finger pocket and SET-based neonatal pulse oximeter were r=0.9, p<0.001 and r=0.9, p<0.001, respectively.⁷ Similarly, a study conducted in Brazil found that there was no significant difference between the fixed monitor and portable oximeters with a p<0.05. A strong positive correlation between the devices was indicated by the Pearson Coefficient, which ranged

from 0.8265 to 0.8785, indicating a good agreement.¹³ Likewise, another study reported no significant difference between the oxygen saturation from portable pulse oximeters and traditional ICU monitors ($p>0.05$).¹⁹ In this study, intraclass correlation indicated a significant fair good agreement between response time of fingertip pulse oximeter and conventional bedside pulse oximeter (ICC=0.738), with of upper limit of 0.802 and a lower limit of 0.654 at the 95% confidence interval.

In this study, according to the Bland-Altman analysis, there was no significant difference between the fingertip pulse oximeter and the conventional bedside pulse oximeter at a mean difference of 0.53. This finding is consistent with previous studies. A study conducted in India demonstrated statistically significant agreement in the neonates' right foot, according to the Bland-Altman technique. The limits of agreement ranged from -0.7% to 0.7% with a confidence interval of 95%.⁷ Similarly, another study reported agreement between the two devices based on Bland-Altman analysis, as the mean difference was close to zero.¹³ Likewise, a study conducted in Pakistan found comparable oxygen saturation readings on the right middle finger using the two devices. The highest and lowest limits were 3.2758 and 2.5258, respectively, with a mean difference of 0.375.¹⁹

According to the researcher, the fingertip pulse oximeter provides clinically acceptable SpO₂ measurements in preterm neonates; however, further validation is needed to ensure accuracy during motion artifacts.

The limitations of the study include relatively small sample size and the single time-point assessment of SpO₂ levels and response time. Another limitation is related to the time to detect SpO₂ levels during motion artifacts in preterm neonates.

CONCLUSION

In this study, the findings demonstrated fair to good agreement in both SpO₂ values and response times. The overall agreement and comparable response times suggest that the fingertip pulse oximeter provides clinically acceptable SpO₂ measurements in preterm neonates. The findings suggest that fingertip oximeters could be considered a feasible alternative in low-resource settings, particularly when portability and ease of use are needed, without compromising clinical accuracy.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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