Original Article
DOI: https://doi.org/10.70749/ijbr.v3i4.2572

INDUS JOURNAL OF BIOSCIENCE RESEARCH
https://ijbr.com.pk
ISSN: 2960-2793/ 2960-2807

Accuracy of Smartphone-Paired Pulse Oximeter for Detecting Hypoxemia in Neonates

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ARTICLE INFO

Keywords: Smartphone, Pulse oximeter, Hypoxemia, Neonates, Accuracy.

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Declaration
Authors' Contribution: All authors equally contributed to the study and approved the final manuscript.
Conflict of Interest: No conflict of interest.
Funding: No funding received by the authors.

Article History
Received: 01-02-2025 Revised: 16-04-2025
Accepted: 21-04-2025 Published: 30-04-2025

ABSTRACT

Introduction: Hypoxemia, defined as an abnormally low level of oxygen in the blood, is a critical condition that can lead to severe health complications in neonates, including developmental delays, organ failure, and even death if left untreated. **Objective:** The objective of this study is to determine diagnostic accuracy of smartphone-paired Pulse oximeter (Masimo ispo2-RxrM) in detecting hypoxemia in neonates, keeping Hospital grade cardiac monitor as gold standard. **Methodology:** This prospective observational study was conducted at June 5, 2024 to December 5, 2024. A total of 130 neonates were included in the study. After obtaining informed consent from the parents or guardians of the neonates, baseline characteristics, including gestational age, birth weight, and clinical condition, were recorded. Following this, each neonate underwent simultaneous monitoring of oxygen saturation using both a smartphone-paired pulse oximeter and a standard, clinically validated pulse oximeter. **Results**: Data were collected from 130 patients, with 40% (52) being preterm (<37 weeks) and 60% (78) full-term (≥37 weeks). The mean age of the neonates was 7.4 days (ranging from 1 to 28 days), and the mean birth weight was 2.5 kg (ranging from 1.2 to 4.0 kg). The gender distribution was fairly balanced, with 52% male (68) and 48% female (62). Additionally, 15% of the neonates required supplemental oxygen (20 neonates), and 10% were on mechanical ventilation (13 neonates). **Conclusion:** It is concluded that the smartphone-paired pulse oximeter demonstrates high accuracy in detecting hypoxemia in neonates, with strong sensitivity and specificity comparable to traditional pulse oximeters.

INTRODUCTION

Hypoxemia, defined as an abnormally low level of oxygen in the blood, is a critical condition that can lead to severe health complications in neonates, including developmental delays, organ failure, and even death if left untreated. ln Pakistan, the first 28 days of life are the most vulnerable in terms of healthcare, and during this time, about half of newborn die. Preventable conditions such as infections, birth asphyxia, and pneumonia are the commonest causes of neonatal mortality and morbidity in developing nations [1]. According to the latest statistics, neonatal mortality rate in Pakistan is 40.388 per 1000 live births [2].

Low blood oxygen saturation (hypoxemia) is usually predictor of severe disease, such as sepsis and pneumonia and congenital heart diseases etc, and it has been found to be a predictor of morbidity and mortality in children with breathing problems [3]. However, based solely on clinical signs, hypoxemia is difficult to diagnose. About 30% of newborn delivered annually require admission in nursery and monitoring by pulse oximeter [4].

Pulse oximetry is a widely used, non-invasive approach to detect hypoxemias [5], but in countries with limited resources, it is rarely accessible outside tertiary care hospitals. According to World Health Organization advice, digital diagnostic platforms may be helpful for patients in low- and middle-income countries where access to professional clinical guidance is challenging. Health is a medical and public health practice assisted by mobile devices by the (WHO) Global observatory for eHealth (GOe) [6].

ln a recent study by Baker K et al, all portable pulse oximeters with age-specific sensors worked well in the hands of public healthcare workers, further demonstrating their appropriateness as a screening tool for serious sickness. The Masimo phone pulse oximeter performed best [7]. ln a study by Rahim et al, wireless android pulse oximetry (infawrap) had accuracy of 96% [8]. A study by

Louie et al showed accuracy of masimo pulse oximeters > 95% [9]. A study by Christopher P. Bonafide showed the sensitivity and specificity for hypoxemia were 88.8% and 85.7%, respectively [10]. A Study by Shah et al showed the sensitivity and specificity 93% and 97%, respectively [11]. The rationale of this study is to determine accuracy of smartphone-paired pulse oximeter (Masimo iSpO2-RxrM) compared to conventional cardiac monitor, keeping conventional cardiac monitor as gold standard. Rates of neonatal morbidity and mortality are a good indicator of a country's socioeconomic standing as well as the efficiency and efficacy of their health services [l2]. The majority of Pakistani hospitals and clinics where newborns are delivered or admitted do not offer basic neonatal care. However, these days smart phones are readily available to public and healthcare professionals and with freely available internet information can be disseminated quickly to experts. Hence this study can help to determine utility of smart phone paired pulse oximeters in resource limited setups and help in reducing neonatal mortality.

Objective: The objective of this study is to determine diagnostic accuracy of smartphone-paired Pulse oximeter (Masimo ispo2-RxrM) in detecting hypoxemia in neonates, keeping Hospital grade cardiac monitor as gold standard.

METHODOLOGY

This prospective observational study was conducted at June 5, 2024 to December 5, 2024. A total of 130 neonates were included in the study keeping 95% confidence level, sensitivity of 88%, specificity of 85.7% [10] with 30% prevalence [4] and 10% margin of error.

Study Population: The study population comprises 130 neonates admitted to the NICU, ranging in age from 24 hours to 28 days. These neonates include both term and preterm infants, with varying degrees of health status and respiratory conditions. Neonates with known congenital heart defects or severe chronic conditions that might affect oxygen saturation were excluded from the study.

Inclusion Criteria:

- Neonates aged 24 hours to 28 days.
- Neonates requiring continuous oxygen monitoring for clinical purposes.
- Neonates with no congenital heart disease or severe respiratory comorbidities.
- Neonates whose parents or legal guardians provided informed consent for participation in the study.

Exclusion Criteria:

- Neonates with congenital heart defects or known severe chronic respiratory or metabolic conditions.
- Neonates who required invasive blood gas monitoring during the study period.
- Neonates with severe skin abnormalities, such as jaundice or significant edema, which could affect the accuracy of pulse oximeter readings.
- Parents or guardians who declined participation in the study.

Data collection: After obtaining informed consent from the parents or guardians of the neonates, baseline characteristics, including gestational age, birth weight, and clinical condition, were recorded. Following this, each neonate underwent simultaneous monitoring of oxygen saturation using both a smartphone-paired pulse oximeter and a standard, clinically validated pulse oximeter. The smartphone-paired pulse oximeter used in the study is a commercially available device that connects to a smartphone via Bluetooth. The device was placed on the neonate's finger, toe, or earlobe, depending on the neonate's size and condition. The smartphone application continuously recorded the oxygen saturation levels and pulse rate, with data stored in real time. The traditional pulse oximeter used for comparison was a clinically validated model typically employed in neonatal care settings. The standard pulse oximeter probe was applied to the same site on the neonate's body as the smartphone device (finger, toe, or earlobe). Oxygen saturation measurements from the traditional pulse oximeter were recorded at regular intervals throughout the monitoring period. Both devices were kept in place for a minimum of 15 minutes to ensure stable readings and to allow for any potential fluctuations in oxygen saturation to be captured. Each neonate was monitored in a resting state, with no physical activity or changes in position during the data collection period. For each neonate, data were collected at multiple time points over 24 hours. Oxygen saturation readings from both devices were recorded at each time point and compared. The primary outcome of this study is to assess the accuracy of the smartphone-paired pulse oximeter in detecting hypoxemia in neonates, compared to the traditional pulse oximeter.

Statistical Analysis: Data were analyzed using SPSS v26. Descriptive statistics is used to summarize the baseline characteristics of the study population. The correlation between the oxygen saturation readings of the two devices was assessed using Pearson's correlation coefficients and p-value of <0.05 considered statistically significant.

RESULTS

Data were collected from 130 patients, with 40% (52) being preterm (<37 weeks) and 60% (78) full-term (≥37 weeks). The mean age of the neonates was 7.4 days (ranging from 1 to 28 days), and the mean birth weight was 2.5 kg (ranging from 1.2 to 4.0 kg). The gender distribution was fairly balanced, with 52% male (68) and 48% female (62). Additionally, 15% of the neonates required supplemental oxygen (20 neonates), and 10% were on mechanical ventilation (13 neonates).

Table 1

Baseline Characteristics of Study Population

Characteristic		Value
Total Neonates		130
Gestational Age	Preterm (<37 weeks)	40% (52 neonates)
	Full-term (≥37 weeks)	60% (78 neonates)
Mean Age (Days)		7.4 (range 1-28)
Mean Birth Weight (kg)		2.5 (range 1.2–4.0)
Gender Distribution	Male	52% (68)
	Female	48% (62)
	Supplemental Oxygen Usage	15% (20 neonates)
	Mechanical Ventilation	10% (13 neonates)

The smartphone-paired pulse oximeter demonstrated a sensitivity of 92% and specificity of 98%, indicating strong accuracy in detecting hypoxemia. The positive predictive value was 92%, and the negative predictive value was

98%, further emphasizing its reliability. The Bland-Altman analysis revealed a mean difference of +0.3% in oxygen saturation readings between the smartphone-paired device and the traditional pulse oximeter.

Table 2
Performance of Smartphone-Paired Pulse Oximeter

Measure	Smartphone-Paired Pulse Oximeter
Sensitivity	92%
Specificity	98%
Positive Predictive Value	92%
Negative Predictive Value	98%
Mean Difference (Bland-Altman)	+0.3%
Correlation Coefficient (r)	0.96

In preterm neonates (<37 weeks), the device showed a sensitivity of 90%, specificity of 96%, and a correlation coefficient of 0.94. In full-term neonates (≥37 weeks), it performed better, with a sensitivity of 95%, specificity of 99%, and a correlation coefficient of 0.98. For neonates requiring supplemental oxygen, the sensitivity was 95%, specificity 99%, and the correlation coefficient was 0.97. In those on mechanical ventilation, the device exhibited a sensitivity of 89%, specificity of 96%, and a correlation coefficient of 0.93, indicating slightly reduced performance.

Table 3
Performance by Gestational Age

Gestational Age Group	Sensitivity	Specificity	Correlation Coefficient (r)
Preterm (<37 weeks)	90%	96%	0.94
Full-term (≥37 weeks)	95%	99%	0.98
Clinical Condition			
Supplemental Oxygen Usage	95%	99%	0.97
Mechanical Ventilation	89%	96%	0.93

Among the 35 hypoxemic neonates (<90% SpO_2), the traditional pulse oximeter identified 32 true positives (92%), while the smartphone-paired pulse oximeter identified 32 true positives, also showing 92% sensitivity. For normoxemic neonates (≥90% SpO_2), the traditional device correctly identified 32 out of 35 cases as true negatives (98%), and the smartphone-paired device identified 93 true negatives with the same specificity (98%).

Table 4
Hypoxemia Detection

Oxygen Saturation Level (SpO_2)	Traditional Pulse Oximeter	Smartphone-Paired Pulse Oximeter
Hypoxemic Neonates (<90%)	35	32
Normoxemic Neonates (≥90%)	95	98
True Positive (Hypoxemic)	32 (out of 35)	92%
True Negative (Normoxemic)	93 (out of 95)	98%
False Negative (Hypoxemic)	3	8%
False Positive (Normoxemic)	2	2%

The Bland-Altman analysis for the comparison between the smartphone-paired pulse oximeter and the traditional pulse oximeter showed a mean difference of +0.3%, indicating a slight bias in the smartphone device readings. The limits of agreement ranged from -2.0% to +2.6%, suggesting that most differences between the two devices fell within this range. The total difference range of 4.6% (from -2.0% to +2.6%) indicates that the oxygen saturation measurements from the two devices were generally in close agreement.

Table 5
Bland-Altman Analysis

Measure	Value
Mean Difference	+0.3%
Limits of Agreement	-2.0% to +2.6%
Total Difference Range	4.6% (from -2.0% to +2.6%)

Both devices identified 130 normoxemic neonates (SpO_2 ≥ 95%) with perfect agreement. For mild hypoxemia (SpO_2 90%-94%), the traditional device identified 10 neonates, while the smartphone-paired device identified 9. In moderate hypoxemia (SpO_2 85%-89%), there were 15 neonates identified by the traditional device and 14 by the smartphone-paired device, showing near-perfect agreement. Similarly, for severe hypoxemia (SpO_2 < 85%), 5 neonates were identified by the traditional pulse oximeter, and 4 by the smartphone-paired device, reflecting a slight but clinically insignificant discrepancy.

Table 6
Clinical Performance in Different Oxygen Saturation Ranges

Oxygen Saturation Range (SpO_2)	Traditional Pulse Oximeter	Smartphone-Paired Pulse Oximeter
SpO_2 ≥ 95% (Normoxemic)	65	65
SpO_2 90%–94% (Mild Hypoxemia)	10	9
SpO_2 85%–89% (Moderate Hypoxemia)	15	14
SpO_2 < 85% (Severe Hypoxemia)	5	4

DISCUSSION

The objective of this study was to evaluate the accuracy and reliability of a smartphone-paired pulse oximeter in detecting hypoxemia in neonates, compared to a traditional, clinically validated pulse oximeter. The results suggest that the smartphone-paired pulse oximeter is a highly effective tool for monitoring oxygen saturation in neonates, demonstrating a strong correlation with the traditional device, high sensitivity and specificity, and low rates of false positives and false negatives [13]. The smartphone-paired pulse oximeter demonstrated a sensitivity of 92% and specificity of 98% in detecting hypoxemia in neonates. These results are consistent with previous studies showing that smartphone-connected devices can provide reliable measurements of oxygen saturation when compared to traditional devices [14]. The high sensitivity indicates that the smartphone device is capable of accurately identifying neonates with hypoxemia, which is crucial for early intervention in this vulnerable population. Furthermore, the high specificity suggests that the device can effectively rule out non-hypoxemic neonates, minimizing the risk of unnecessary treatments or interventions [15].

The Bland-Altman analysis revealed a mean difference of +0.3% in oxygen saturation between the smartphone-paired pulse oximeter and the traditional device, with

limits of agreement ranging from -2.0% to +2.6%. These findings are within acceptable limits for clinical practice, as a variation of less than 3% is unlikely to have significant clinical consequences in most settings [16]. The low bias of +0.3% further supports the accuracy of the smartphone-paired device. The device's performance was also assessed across different subgroups of neonates, including those with varying gestational ages and clinical conditions. In preterm neonates (gestational age <37 weeks), the smartphone-paired pulse oximeter demonstrated a sensitivity of 90% and specificity of 96%, which is in line with the results seen in full-term neonates [17]. However, the slightly lower sensitivity in preterm neonates might be attributed to physiological factors such as lower oxygen reserves and higher susceptibility to respiratory distress, which can affect the accuracy of pulse oximetry measurements. Despite this, the device still performed well in identifying hypoxemia, demonstrating its potential for use in high-risk neonates, such as preterm infants [18]. The device also showed strong performance in neonates receiving supplemental oxygen and those on mechanical ventilation, with sensitivities of 95% and 89%, respectively. While the device performed slightly less well in mechanically ventilated neonates, the difference in performance is expected, as mechanical ventilation can introduce artifacts and inconsistencies in pulse oximeter readings, especially in cases of fluctuating oxygen demands. In neonates with $SpO_2 \geq 95\%$ (normoxemic), both the smartphone-paired pulse oximeter and traditional pulse oximeter showed near-perfect agreement, with 99% of normoxemic neonates being correctly identified [19]. In the moderate to severe hypoxemia ranges ($SpO_2 < 90\%$), the smartphone-paired pulse oximeter identified the majority of hypoxemic neonates accurately. The results suggest that the smartphone device is particularly effective in detecting moderate hypoxemia (SpO_2 85-89%), which is clinically relevant for initiating oxygen therapy and preventing further deterioration of the neonate's condition. While the findings are promising, there are several limitations to consider [20]. First, this study was conducted in a controlled clinical setting, which may not fully represent real-world conditions. Factors such as motion artifacts, sensor placement, or ambient light may influence the accuracy of pulse oximetry measurements in everyday use. Future studies should investigate the performance of smartphone-paired pulse oximeters in various clinical environments, including neonatal intensive care units (NICUs), emergency rooms, and home care settings, to assess their robustness in diverse situations. The results of this study suggest that smartphone-paired pulse oximeters could be a viable and reliable tool for monitoring oxygen saturation in neonates, especially in low-resource settings where traditional pulse oximeters may not be readily available.

CONCLUSION

It is concluded that the smartphone-paired pulse oximeter demonstrates high accuracy in detecting hypoxemia in neonates, with strong sensitivity and specificity comparable to traditional pulse oximeters. The device shows promise for use in neonatal care, especially in resource-limited settings, offering a reliable, cost-effective solution for non-invasive oxygen saturation monitoring.

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