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Accuracy of Fingerprint Pulse Oximeter Compared to Neonatal Pulse Oximetry in Early Detection of Critical Congenital Heart Disease in Newborn Infants

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Abstract: Critical congenital heart disease (CHD) requires immediate diagnosis and intervention, but its asymptomatic nature in early life presents a significant challenge for detection. This study aimed to determine the suitability of a common fingertip pulse oximeter as a low-cost screening tool compared to the standard neonatal pulse oximeter for the early detection of critical CHD. A cross-sectional study was conducted with 150 newborn subjects at a health center in Kediri. The results indicated that while the neonatal pulse oximeter measured pulse frequency and saturation more quickly, there was no statistically significant difference in the preductal (p=0.053) and postductal (p=0.099) oxygen saturation values recorded by the two devices. However, despite a weak positive correlation, a Bland-Altman analysis revealed poor agreement and reliability between the two instruments, with an average bias of 0.93% (95% CI: -7.38 to 9.24) for preductal and 0.74% (95% CI: -8.49 to 9.24) for postductal measurements. In conclusion, although no subjects were diagnosed with critical CHD, the findings suggest that the fingertip pulse oximeter is not a sufficiently reliable substitute for neonatal pulse oximetry in screening for this condition due to the poor agreement between the two methods.

Keywords: Critical CHD; Fingertip saturation pulse; Neonatal saturation pulse

Introduction

The diagnosis and management of congenital heart disease (CHD) have progressed significantly, establishing early intervention as mandatory to reduce patient morbidity and mortality. A critical diagnostic challenge, however, persists in the immediate postnatal period (Alexander et al., 2017; Duarte et al., 2024). Physical examination alone is an insuf ficient screening tool, as cardiac murmurs are often not immediately audible due to neonatal physiological changes, including the natural decrease in pulmonary vascular resistance (Gonzalez et al., 2021). While prenatal diagnosis through fetal echocardiography is possible, its inconsistent availability results in many infants with critical CHD (CCHD) remaining undiagnosed before birth (Cody et al., 2024; Shackleford et al., 2021).

Consequently, newborns with CCHD frequently appear healthy and are discharged home (Shackleford et al., 2021; Steward et al., 2020). Days later, the physiological closure of the ductus arteriosus can precipitate acute circulatory collapse in infants with ductus-dependent lesions, leading to severe outcomes such as metabolic acidosis, hypoxic-ischemic encephalopathy (HIE), necrotizing enterocolitis (NEC), cardiac arrest, or death (Boos et al., 2022; Cagliari, 2022;

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Ziemer & Haverich, 2017). Pulse oximetry screening offers a non-invasive method to address this diagnostic gap (Al-Beltagi et al., 2024; Cabanas et al., 2024). The technology can detect mild hypoxemia, an early indicator of CCHD, often before clinical manifestations such as cyanosis become apparent (Griesman et al., 2020; van Vliet et al., 2024).

The current gold standard for this screening is new-generation neonatal pulse oximetry, but this equipment is expensive and not always practical for universal use (Al-Beltagi et al., 2024). In contrast, fingertip pulse oximeters are affordable, portable, and easy to use. This study, therefore, aims to determine the suitability and agreement of saturation values obtained from fingertip pulse oximetry compared to the established neonatal pulse oximetry standard in the early detection of critical congenital heart disease in newborns. This research is expected to provide additional information regarding the accuracy of finger pulse oximeters for early detection of critical congenital heart disease in newborns.

Method

Time and Place of Research

This research was conducted as a suitability test utilizing a cross-sectional study design to assess the level of agreement between two different measurement devices. The study occurred in the combined treatment room at the Kediri Community Health Center in West Nusa Tenggara, Indonesia, from April to September 2023.

Population and Sample

The study population consisted of all vigorous newborns at the location, with a calculated minimum sample size of 144 subjects. 150 newborns who met the eligibility criteria were enrolled via consecutive sampling. Inclusion criteria stipulated that subjects must be vigorous newborns between 24 and 72 hours of age with a gestational age of at least 37 weeks. The only basis for exclusion was the refusal of parents to provide consent for participation.

Data Collection

Data collection involved several instruments: a One Med brand weight scale and thermometer, an Oximetry brand fingertip pulse oximeter, and an Oxy9® brand neonatal pulse oximeter. For each enrolled infant, paired measurements of oxygen saturation (SpO_2) and pulse frequency were taken from both a preductal site (the right hand) and a postductal site (a foot) using both the neonatal and fingertip devices. The time required to obtain a stable reading was recorded for each measurement.

Data Analysis

All collected data were compiled and analyzed using SPSS version 25.0. Due to the non-normal distribution of the data, the Wilcoxon signed-rank test was chosen for the analysis of paired groups. The level of agreement between the two oximeters was evaluated using a Bland-Altman analysis. Before commencing the study, the research proposal was reviewed and granted full ethical approval by the Research Ethics Committee of the Faculty of Medicine at the University of Mataram (UNRAM).

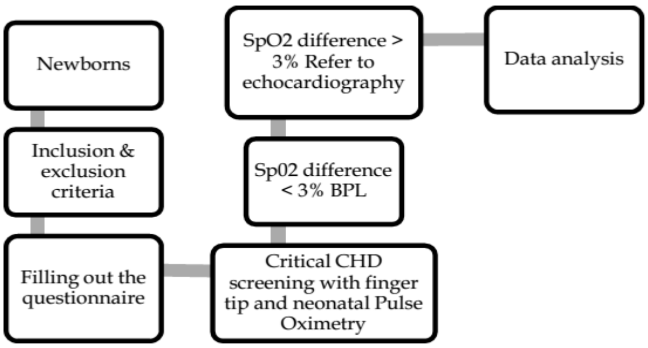

Figure 1. Flow of study

Result and Discussion

Characteristics of Research Subjects

The study's results are based on a sample of 150 newborns, comprising a nearly balanced gender distribution (49.3% male, 50.7% female) and a majority with normal birth weights (91.3%) and high Apgar scores (90.7%). Specifically, 74 men and 76 women, respectively. Most newborn babies' weight is in the normal range, namely 2500 grams to 3999 grams. Most temperatures at birth were normal (36.5–37.5 °C), namely 53.3%. A total of 136 babies (90.7%) were born with an APGAR score of 7-10, 11 babies (7.3%) were born with an APGAR score of 4-6, and 3 babies were born with an APGAR score of 0-3 (2.0%). (Table 1).

Table 1. Characteristics of Research Subjects

Characteristics		Total (n=150)	Percentage (%)
Gender	Male	74	49.3%
	Female	76	50.7%
Age	<24 hour	94	62.6%
	24- 48 hour	56	37.4%
Birth weight	1500 – 2499 gram	12	8.0%
	2500 – 3999 gram	137	91.3%
	>4000 gram	1	0.7%
Birth length	< 44 cm	1	0.7%
	≥ 44 cm	149	99.3%
Temperature	35.5 – 36.4°C	70	46.7%
	36.5 – 37.5°C	80	53.3%
First minute	7 – 10	136	90.7%
APGAR	4 – 6	11	7.3%
score	0 – 3	3	2.0%

Differences of Pulse Frequency in Neonatal and Fingertip Pulse Oximetry

The median preductal pulse frequency measured on neonatal pulse oximetry showed 131.5 times per minute (102-164 times per minute) and 120 times per minute (75-155 times per minute) on fingertip pulse oximetry. On the other hand, the median postductal pulse frequency showed results of 132 times per minute (101-170 times per minute) in neonatal pulse oximetry and 120 times per minute (75-159 times per minute) in pulse oximetry. Based on the analysis, a significant difference was found in the pulse frequency measured using neonatal and fingertip pulse oximetry in the preductal and postductal areas, with the same P value of 0.00 ($P < 0.05$). The pulse frequency in neonatal pulse oximetry has a pulse frequency that tends to be lower, but when seen clinically, this difference is not clinically significant (Table 2).

Table 2. Differences of Pulse Frequency in Neonatal and Fingertip Pulse Oximetry

Pulse Frequency Neonatal	Pulse Oximetry (x/minute) (median, min-max)	Pulse Frequency Fingertip (x/minute) (median, min-max)	p-value
Preductal (n=150)	(131.5, 102-164)	(132, 101-170)	0.000
Postductal (n=150)	(120.5, 75-155)	(120, 75-159)	0.000

Differences of Oxygen Saturation in Neonatal and Fingertip Pulse Oximetry

Preductal SpO2 measurements utilizing two different forms of pulse oximetry were found to assess oxygen saturation with a median result of 96% (87-100%) in neonatal pulse oximetry and a median of 96% (80-99%) in fingertip pulse oximetry. Postductal SpO2 measurements showed a median of 96% (75-100%) in neonatal pulse oximetry and 96% (71-99%) in fingertip pulse oximetry. Based on the analysis, it was found that there was no significant difference in the saturation values measured using neonatal and fingertip pulse oximetry in both the preductal and postductal areas, with P values of 0.053 and 0.099, respectively ($P > 0.05$). (Table 3).

Table 3. Differences of Oxygen Saturation in Neonatal and Fingertip Pulse Oximetry

	Oxygen Saturation Neonatal Pulse Oximetry (%) (median, min-max)	Oxygen Saturation Fingertip Pulse Oximetry l (%) (median, min-max)	p-value
Preductal (n=150)	(96, 87-100)	(96, 80-99)	0.053
Postductal (n=150)	(96, 75-100)	(96, 71-99)	0.099

Differences in Time for Saturation Measurements in Neonatal and Fingertip Pulse Oximetry

The median preductal oxygen saturation measurement time measured on neonatal pulse oximetry shows 15 seconds (5-85 seconds) and 50 seconds (6-101 seconds) on fingertip pulse oximetry. On the other hand, the median postductal pulse frequency shows results of 15 seconds (5-87 seconds) in neonatal pulse oximetry and 50 seconds (6-118 seconds) in fingertip pulse oximetry. Based on the analysis, a significant difference was found in the time of saturation measurement measured using neonatal pulse oximetry and fingertip in the preductal and postductal areas, with the same P value of 0.00 ($p < 0.05$) (Table 4).

Table 4. Differences in Time for Saturation Measurements in Neonatal and Fingertip Pulse Oximetry

	Saturation measurement time Neonatal Pulse Oximetry (seconds) (median, min-max)	Saturation measurement time Fingertip Pulse Oximetry (seconds)(median, min-max)	P-value
Preductal (n=150)	(15, 5-85)	(50, 6-101)	0.000
Postductal (n=150)	(15, 5-87)	(50, 6-118)	0.000

Correlation Test for Oxygen Saturation in Neonatal and Fingertip Pulse Oximetry (Oxywave)

Oxygen saturation measurement using two pulse oximetry device types showed abnormal data distribution with positive and significant correlation test results based on the Spearman Rank test. The results of the correlation coefficient showed a figure of 0.310 in the preductal ($p<0.00$) and 0.337 in the postductal ($p<0.00$). This indicates a weak positive correlation between the two measurements (Figures 2 and 3).

A test was carried out using the Bland-Altman curve to evaluate the agreement between two quantitative methods, namely SpO2 measurement with neonatal pulse oximetry and fingertip pulse oximetry (Figure 4). The findings of preductal SpO2 measurements varied ($p=0.08$, $p>0.05$), with an average bias limit (0.93%) above +9.24% and a lower limit of appropriateness of -7.38%. This plot quantifies the average bias and limits of agreement between two measurements within a 95% accuracy period, so that it can be concluded that the two pulse oximeter devices are in agreement. The red line shows the mean bias, and the two green lines show the upper and lower goodness-of-fit limits with the 95% confidence interval. There were also outliers of 7 measurements, which were above the upper suitability limit, and 1 measurement, below the lower. On the other hand, the tabulation results of the Bland Altman curve based on postductal SpO2 measurements showed a mean bias of 0.74%, an upper limit of suitability of +9.24% and a lower limit of -8.49%. A total of 6 measurements passed the upper suitability limit, and 2 measurements passed the lower suitability limit (Figure 5).

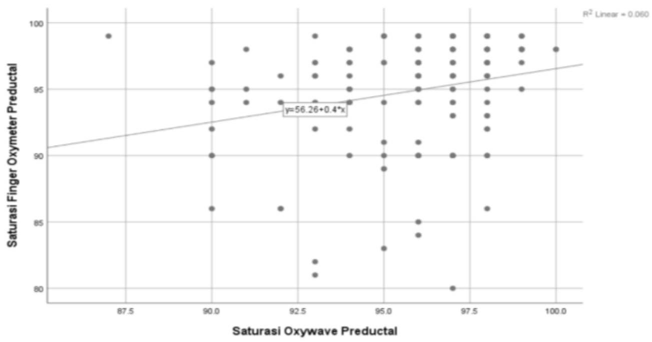

Figure 2. Spearman rank plot test curve of preductal O2 saturation on neonatal and fingertip pulse oximetry (Oxywave)

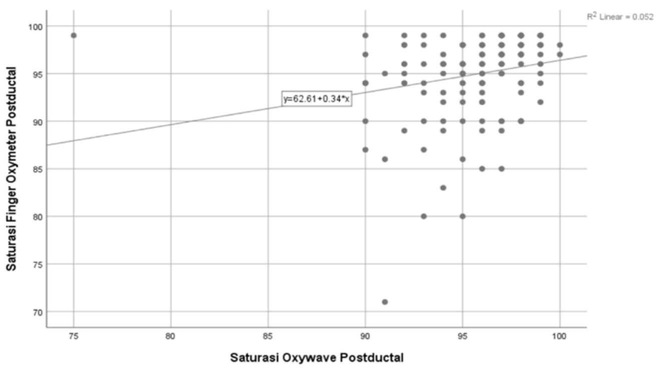

Figure 3. Spearman rank plot test curve postductal O2 saturation on neonatal and fingertip pulse oximetry (Oxywave)

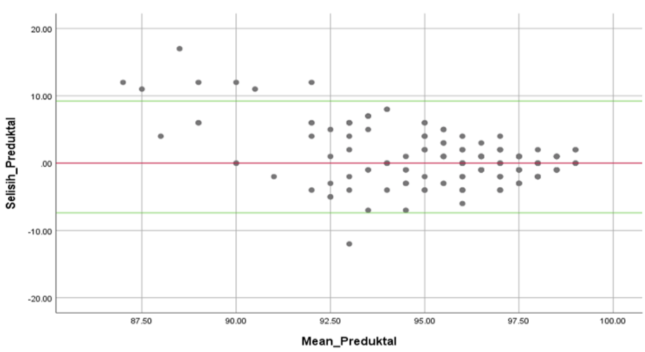

Figure 4. Bland altman curve plot of preductal oxygen saturation on neonatal and fingertip pulse oximetry (Oxywave) suitability limit

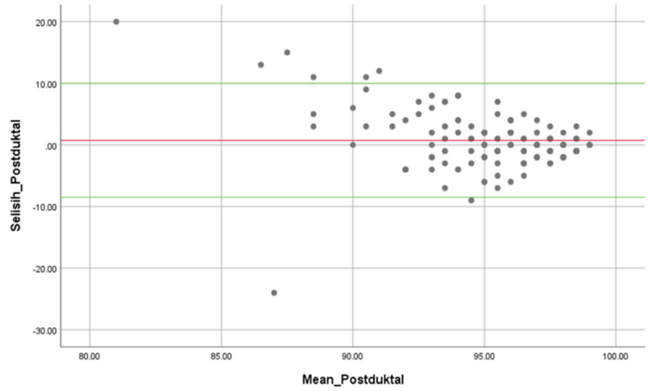

Figure 5. Bland altman curve plot of postductal oxygen saturation on neonatal and fingertip pulse oximetry (Oxywave)

Characteristics of Research Subjects

The study sample of 150 newborn infants was characterized by a nearly equal gender distribution and a majority exhibiting normal physiological parameters at birth, including normal birth weight (91.3%) and high Apgar scores (90.7%). A notable characteristic of the sample was that most subjects (62.6%) had their oxygen saturation measured at less than 24 hours of age. While some previous studies have stated that SpO2 levels in infants younger than 24 hours tend to be lower than those measured after this period (Morgan et al., 2017), this study found that the mean oxygen saturation was similar between the two age groups. The average preductal and postductal saturation was 95% for both subjects measured before and after 24 hours of age.

Differences in Device Performance and Clinical Agreement

A comparative analysis of the two devices revealed significant differences in performance. The neonatal pulse oximeter was significantly faster, and a statistically significant difference was found in the measured pulse frequency (P=0.00), although this was not determined to be clinically significant. This finding is consistent with previous research, which also obtained higher readings in neonatal pulse oximetry without a meaningful clinical difference (Bachman et al., 2020). Importantly, there were no clinically significant differences in the primary outcome of saturation readings between the two devices (P=0.053 and 0.099, respectively), with both recording a median value of 96%. This similarity in median values was also noted in the research by Govender et al. (2018) and Neophytou et al. (2017), suggesting that fingertip pulse oximeters could be a promising tool for CCHD screening, particularly in resource-limited settings (Chen et al., 2022). The longer reading times for the fingertip device may be attributed to several factors, including infant movement and differences in sensor technology; neonatal sensors are specifically designed to be adjusted to the infant's digits, whereas the fingertip oximeter's fixed shape may not adhere as effectively (Jubran, 2015).

However, while a weak positive correlation was found between the devices, a more rigorous Bland-Altman analysis demonstrated poor clinical agreement. The analysis showed a small mean bias close to the ideal value of zero (Giavarina, 2009; Weir et al., 2018). Critically, the 95% limits of agreement were unacceptably wide for both preductal (-7.38% to +9.24%) and postductal (-8.49% to +9.24%) measurements. This range of potential error is much greater than the clinically acceptable absolute difference of 5% or less, which is considered equivalent for such devices (Harris et al., 2019). This wide variance means one device could measure a normal saturation value for a given patient while the other indicates hypoxemia according to standard clinical definitions (Al Rajeh et al., 2021; Levy et al., 2021; Wong et al., 2021). The presence of these large concordance limits reflects a level of clinically meaningful variation and indicates that the two methods are not reliably interchangeable. Further analysis also revealed a proportional bias ($p<0.05$), where the difference between the devices increased as oxygen saturation decreased, a phenomenon that has been observed in other studies (Chan et al., 2022; Harris et al., 2019).

Study Limitations and Findings on Critical CHD

This study, no infants had a preductal and postductal oxygen saturation difference greater than 3%; consequently, no critical CHD cases were detected. This finding is similar to a comparable study by Menahem et al. (2021), Siefkes et al. (2020), Willim et al. (2021). The absence of CCHD cases meant that not all diagnostic values, such as sensitivity, could be assessed, although the specificity of the screening was 74.2%. This lack of positive cases is likely due to the relatively small sample size in relation to the low prevalence of CCHD in the general population (Sola et al., 2020). Data on potential obstacles further limited the study during measurement—such as infant movement, signal failures, or unstable readings—which were not systematically collected, which could have strengthened the analysis of device performance.

Conclusion

Accuracy of fingerprint pulse oximeter compared to neonatal pulse oximetry in early detection of critical congenital heart disease in newborn infants in this study, researchers did not find newborns with critical CHD. There were significant differences in pulse rate and saturation reading time between fingertip pulse oximetry and neonatal pulse oximetry. However, there was no significant difference in saturation results obtained from the two devices. There was a weak positive correlation between preductal and postductal oxygen saturation measured using fingertip pulse oximetry and pulse oximetry. Further research is expected to find cases related to critical congenital heart disease in newborns using finger pulse oximeters for early detection.

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Author Contributions
For this manuscript, T.P.K. and L.S.S. were responsible for the conceptualization. The methodology was defined by T.P.K. Formal analysis was conducted by L.S.S. The investigation, resources, and data curation were handled by W.S.S.P. The original draft was prepared by L.S.S., while the writing, review, and editing process involved L.S.S., P.A.W., T.P.K., and W.S.S.P. Supervision and project administration were managed by T.P.K. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest
The authors declare no conflict of interest.

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