ORIGINAL ARTICLE

Bali Medical Journal (*Bali MedJ)* 2023, Volume 12, Number 3: 2446-2450
P-ISSN.2089-1180, E-ISSN: 2302-2914

Intermittent pulse oximeter as a measurement of newborn oxygen: a cross-sectional study

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Received: 2023-05-15
Accepted: 2023-07-26
Published: 2023-08-22

ABSTRACT

Introduction: Intermittent monitoring using fingertip pulse oximeters is increasingly being used in guiding oxygen therapy and screening congenital heart defects in newborns. However, there are no evidence-based guidelines for using fingertip pulse oximeters for intermittent monitoring of newborns in low-resource settings. This research assesses the validity of the fingertip pulse oximeter to measure oxygen saturation in newborns against the continuous monitoring pulse oximeter as a standard method.

Method: A prospective study was conducted in the NICU and Neonatal Intermediate Unit of Dr. Soetomo Academic Hospital Surabaya. Newborns aged below 28 days using a respiratory device were included. Oxygen saturation measurements using a continuous monitoring pulse oximeter and intermittent pulse oximeter were done on the right hand and both feet. Paired t-test and Bland-Altman plot was performed to assess the validity.

Results: Eighty-five neonates were included. There is an agreement between Intermittent and continuous pulse oximeters in the normoxic group with a limit of agreement -1.29 (CI 95% -1.62 to -0.95) to 1.29 (CI 95% 0.95 to 1.62) and hypoxic group with a limit *of agreement* -3.36 (CI 95% -4.29 to -2.44) to 3.00 (CI 95% 2.08 to 3.92). Intermittent pulse oximeter measurement requires a longer time for maximum results compared to continuous pulse oximeter (p=0.001).

Conclusions: The intermittent pulse oximeter is available to be used alternately with a continuous pulse oximeter. However, it has limitations in hypoxemia settings, hence the application in real-time clinical practice needs further study.

Keywords: Intermittent pulse oximeter, Fingertip pulse oximeter, Newborn, Oxygen saturation.
Cite This Article: Nastiti, P.H., Handayani, K.D., Hidayat, T., Angelika, D., Utamayasa, I.K.A., Etika, R., Rachman, M.A., Utomo, M.T. 2023. Intermittent pulse oximeter as a measurement of newborn oxygen: a cross-sectional study. *Bali Medical Journal* 12(3): 2446-2450. DOI: 10.15562/bmj.v12i3.4688

INTRODUCTION

The pulse oximeter is a non-invasive method for measuring oxygen saturation, one of the main important parameters for newborns that are treated in the Neonatal Intensive Care Unit (NICU) or other care units.[1,2] International surveys show that pulse oximeters are routinely used during neonatal resuscitation. In Indonesia, SpO2 monitoring with a continuous pulse oximeter is often not possible and intermittent monitoring using a fingertip pulse oximeter is increasingly being used to guide oxygen therapy as well as screening congenital heart defects in newborns.[3,4] However, to date, there are no evidence-based guidelines for using fingertip pulse oximeters for intermittent monitoring of newborns in low-resource settings to measure SpO2 to guide intervention during the neonatal transition after birth.[5] The explanation above becomes a challenge to find alternative pulse oximeter options with more affordable maintenance costs. Therefore, the author is interested in conducting a study to evaluate the evidence of using the pulse oximeter in newborns to assess the validity of intermittent monitoring pulse oximeter.[6] This research assesses the validity of the fingertip pulse oximeter to measure oxygen saturation in newborns against the continuous monitoring pulse oximeter as a standard method.

METHOD

This observational cross-sectional study was conducted at the NICU and neonatal intermediate unit of Soetomo General Academic Hospital Surabaya from December 2021 to August 2022. All Newborns under 28 days of age with breathing assistance, regardless of gestational age, were included in this study. Parents who refused to participate and infants who were undergoing phototherapy were excluded. Newborns who meet the inclusion and exclusion criteria will undergo an initial clinical examination with Downe Score. Continuous and intermittent monitoring of pulse oximeters will setting-up to measure oxygen saturation. Oxygen saturation >95% was defined as normoxic in term newborns, meanwhile >90% in preterm. Fingertip intermittent pulse oximeter (by using Elitech Fox-2®) was performed on the right foot and continuous pulse oximeter (by using Masino SET®) on the left foot. The oxygen saturation level on the intermittent monitoring pulse oximeter will be compared to the continuous monitoring pulse oximeter as a standard. A continuous monitoring pulse oximeter has been widely used in studies around the world with accurate results suitable for

universal monitoring, therefore it is chosen as the gold standard of neonatal care. Meanwhile, arterial blood gas analysis as a diagnostic modality has low feasibility assessment because it requires invasive methods, trained medical personnel, and many blood samples.

Statistical analysis

The Bland-Altman plot was done to evaluate the agreement between oxygen saturation measurements using intermittent and continuous monitoring pulse oximeters. We also analyze the difference between intermittent and continuous pulse oximeters in the time required to achieve maximum oxygen saturation results using paired t-tests.

RESULTS

124 newborns were included and 39 of them were excluded. The study flow chart is shown in Figure 1. The characteristics of the 85 subjects who participated in this study can be seen in Table 1.

Subjects consisted of 47 infants (56%) in the normoxic group and 38 infants (44%) in the hypoxic group. There were significant differences in the characteristics of birth weight, gestational age, APGAR score, Downes score, and

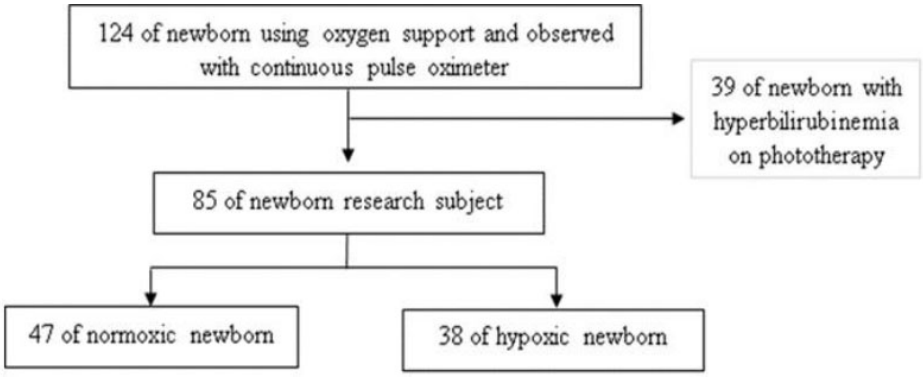

Figure 1. Study flow chart.

Table 1. Characteristics of research subjects

Variables	Oxygen Saturation				p-value
	Hypoxic		Normoxic		
	N	%	N	%	
Sex					
Boy	17	55	14	45	0.231
Girl	21	39	33	61	
Birth Weight (BW)					
Normal BW	14	46	16	54	0.032
Low BW	14	45	17	55	
Very low BW	5	33	10	67	
Extreme Low BW	5	55	4	45	
Gestational Age					
Term infant	14	46	16	54	0.034
Late Preterm Infant	9	45	11	55	
Very Preterm Infant	10	37	17	63	
Extreme Preterm Infant	5	62.5	3	37.5	
APGAR SCORE					
Mild Asphyxia	13	38	21	62	<0.001
Moderate Asphyxia	22	50	22	50	
Severe Asphyxia	3	42	4	58	
DOWNES SCORE					
No Respiratory Distress	19	37	32	63	0.004
Respiratory Distress	13	45	16	55	
Threatening Respiratory Distress	2	40	3	60	
O_2 Support					
Nasal O2/Masker	4	33	8	67	0.015
CPAP	2	12.5	14	87.5	
Ventilator	32	56	25	44	
Neonatal Sepsis					
Yes	21	39	33	61	0.231
No	17	55	14	45	
Congenital Anomaly					
Exist	25	41	36	59	0.391
Not Existed	13	56.5	11	43.5	

Table 2. Characteristics of research subjects based on oxygen saturation levels

Parameter	Hypoxic (n=38)				Normoxic (n=47)			
	mean	min	max	median	Mean	Min	max	median
O_2 Saturation Intermittent Pulse Oximeter	79	43	89	83	95	90	100	97
O_2 Saturation Continuous Pulse Oximeter	79	45	89	84	95	90	100	97

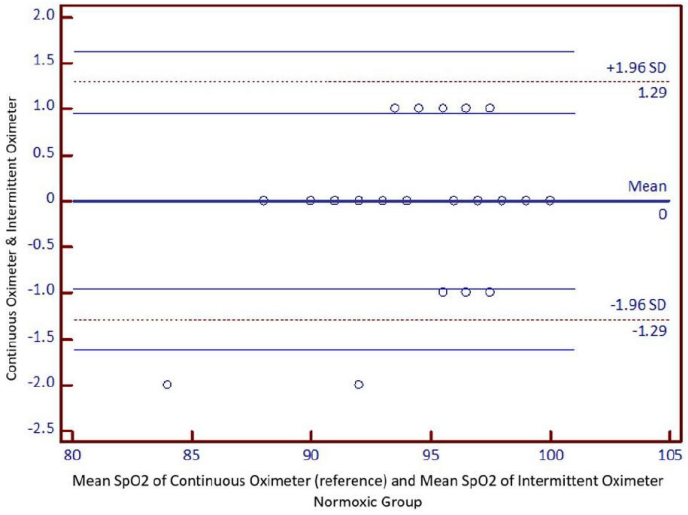

Figure 2. Bland Altman plot of oxygen saturation measured by continuous and by intermittent pulse oximeters in the normoxic group.

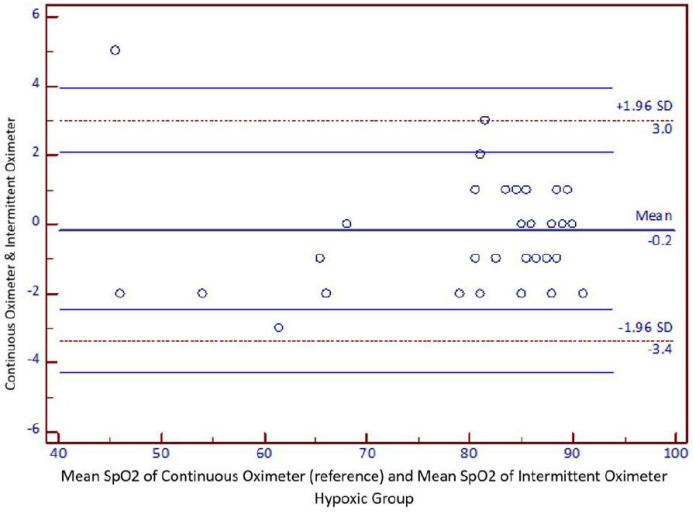

Figure 3. Bland Altman plot of oxygen saturation measured by continuous and intermittent pulse oximeters in the hypoxic group.

oxygen support among the normoxic and hypoxic groups (p<0.05). However, there were no differences in characteristics of sex, neonatal sepsis, congenital anomalies, and mortality <7 days between the two groups (p>0.05).

The average level of oxygen saturation measurement using intermittent pulse oximeter in the hypoxic group is 79% and 95% in the normoxic group while using continuous pulse oximetry in the hypoxic group is 79% and 97% in the normoxic group (Table 2).

Figure 2, depic t the agreement between oxygen saturation measured by continuous and intermittent pulse oximeter in the normoxic group with a *limit of agreement* -1.29 (95%CI -1.62 to -0.95) to +1.29 (95%CI 0.95 to 1.62). Every measurement in the Bland Altman plot showed various results, *p*=1 (<0.005), so there is no mean difference between these two measurements.

As well as the normoxic group, there is an agreement between oxygen saturation measured by intermittent and by a continuous pulse oximeter, since the Bland Altman plot is still inside the *limit of the agreement* range, lower limit of -3.36 (CI 95% -10.28 to 6.42) and upper limit +3.00 (CI 95% 3.55 to 6.91) (Figure 3). The mean difference was -0.184 (CI 95% -0.7184 to 0.34) with *p*=0.0048 (<0.005).

However, intermittent pulse oximeter measurement significantly requires a longer time for maximum results compared to the continuous pulse oximeter (p=0.001). The median of post-ductal in intermittent compared to continuous pulse oximeters was 8 to 5 seconds, while in pre-ductal was 6 to 5 seconds. Disruptions were found in 23.5% of research subjects during oxygen saturation measurement using an intermittent pulse oximeter. Therefore the measurement had to be repeated. The disruptions were generally related to newborns and tool factors that were found to be more common in fingertip oximeter measurements.

DISCUSSIONS

In our study oxygen saturation was measured at the same time in the post ductal (the left foot using intermittent pulse oximeter and the right foot using continuous pulse oximeter).[7,8] The study conducted at the Cipto Mangunkusumo tertiary hospital, Indonesia showed that oxygen saturation on the right and left foot in newborns aged 24-27 hours had a median of 98% and 98%-99% respectively.[9] Another study also showed median and mean of oxygen saturation in newborns admitted to "rooming-in" was 97% and 97.2% respectively.[10] Both studies imply no difference between oxygen saturation measurement on the right and the left foot of the newborn.[9-11]

Studied by Bland & Altman compared oxygen saturation measured by a monitor oximeter and by pulsed oximeter obtained a mean difference of 0.42 percentage points (95% CI 0.13 to 0.70) and the limits of agreement between - 2.0 to 2.8. Those limits of agreement are small enough to be confident to be used in place of a monitor oximeter for clinical purposes.[12] These results are in line with our study which showed a narrow *limit of agreement* (between -1.29 and 1.29). So, it implied that an intermittent pulse oximeter could be used as an alternative to a continuous pulse oximeter in the normoxic group. Meanwhile, in the hypoxic group, because

there was consistent bias showed by the value of the mean difference (d=0.18) and p-value 0.0048 (p<0.005), also the wide limit of agreement (-3.36 to + 3,009) indicated that intermittent pulse oximeter could not be applied in clinical practices.

Schmitt et al. reported that in low oxygen saturation levels (below 80%), pulse oximeter performance was not as accurate as in saturation above 90%, oxygen saturation value was higher in pulse oximeter measurement than in arterial blood gas (ABG) analysis.[13] The bias and precision between saturation were 5.8 and 4.8 in the group with saturation below 80%, 0.5 and 2.5 in saturation above 90%. It is advisable to do a blood gas analysis for confirmation in patients with oxygen saturation below 80%, measured by a pulse oximeter, because of the small margin safety value.[14] Another study by Ewer et al. compares oxygen saturation measured by ABG and pulse oximeter, indicating an accuracy reduction when the level of SaO2 <80% (bias from -15.0 to 13.1 while the precision was between 1.0 to 16.0).[15,16] At the level of SaO2 80%-85%, the inaccuracy of the pulse oximeter will be read 5% points greater. Furthermore, at SaO_2 levels of 50%, the error increased to nearly 40.[17] However, another study showed that intermittent pulse oximeters can be used in a wide variety of clinical conditions with an accuracy of ± 2% at the range of SpO2 70 to 100% and ± 3% 50 to 69%.[18]

There were conflicting studies in neonatal sepsis and septic shock about SpO2 bias. Secker and Spiers compared 80 pairs of SpO2 and SaO2 results in infants with septic shock. They found that those with low systemic vascular resistance as measured by pulmonary artery catheter had SpO2 lower than SaO2 with a mean difference of 1.4%, a statistically significant level without clinically relevant. It can be related to vasodilation in septic conditions resulting in arteriovenous shunts, so the oximeter misinterpreted the venous pulsations as arteriovenous.[19] Other factors that could explain this difference were: 1) the level of fluid resuscitation and tissue perfusion; 2) sepsis-induced cardiopulmonary disorders; 3) the location of the pulse oximeter probe; 4) the type of pulse oximeter and probe used; 5) use of vasoconstrictors; and 6) the presence of other comorbid conditions that may affect the SpO2 value unexpectedly. Thus, the multiple conditions that occur in patients with severe sepsis and septic shock make it difficult to predict the direction of the SpO2 bias.[18]

From all the advantages mentioned, intermittent pulse oximeters have limitations. Elitech Fox II® can be used properly on fingers whose thickness is 8-26 mm, so it is more appropriate for children up to adults.[20] Repeated oxygen measurements due to unreadable signals should be performed on a 23.5% intermittent pulse oximeter and a 4.7% in continuous pulse oximeter.[21-24] Based on the observation in our study, this can be caused by baby movements and device technical factors. However, there are no further studies that discuss both factors.

CONCLUSIONS

The intermittent pulse oximeter is available to be used alternately with a continuous pulse oximeter. However, it has limitations in the hypoxemia setting, hence the application in real-time clinical practice needs further study.

CONFLICT OF INTEREST

The author reports no conflicts of interest in this work.

FUNDING

The authors declared that no financial support or funding was obtained for this study.

ETHICAL CLEARANCE

Approval from the institutional ethics committee of Dr. Soetomo General Academic Hospital Surabaya was obtained with protocol number 0316/KEPK/XI/2021.

AUTHOR'S CONTRIBUTION

Prima Hari Nastiti, conceptualized the design of the study, acquired, and analyzed the data, interpreted the data, also drafting the manuscript, and revised it. Martono Tri Utomo conceptualized the design of this study, interpreted the data, and revised the manuscript. Kartika Darma Handayani acquired, analyzed the data, and revised the manuscript. Dina Angelika acquired, analyzed the data, and revised the manuscript. I Ketut Alit Utamayasa interpreted the data and revised the manuscript. Risa Etika interpreted the data and revised the manuscript. All authors read, and approved the final manuscript, and take full responsibility for the entire contents of the manuscript.

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