To Validate Use of Transmittance Sensor of Peripheral Pulse Oximeter for Forehead Pulse Oximetry in Newborns

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Abstract

Introduction: Peripheral pulse oximeters with continuous monitoring of heart rate and saturation have revolutionized neonatal care. Motion artifacts, hypothermia, and poor perfusion are some of the barriers for reliable reading in the transmittance type of peripheral pulse oximeters. This study was planned to assess the effectiveness of transmittance sensors applied over the forehead for monitoring the heart rate and saturation.

Material and Methods: An observation study was conducted over a period of 1 month. Two pulse oximeters (Masimo RAD97) were applied simultaneously, one over the periphery (right hand/wrist) and the other over the forehead using an innovative headband. A total of 540 readings of heart rate and saturation (SpO2) from each site were recorded. A difference of more than 5 beats/minute in heart rate and 2% saturation were considered clinically significant.

Results: Forty-five neonates with mean gestational age of 35.3 ± 3.2 weeks and birth weight of 2109 ± 683 grams were enrolled. Forehead pulse oximeter could pick up the heart rate and SpO2 readings in all the babies. A statistically significant difference of 3.8 beats/minute in heart rate and 2.5% in SpO2 was noted (p-value < 0.0001). The difference in heart rate was not clinically significant.

Conclusion: We propose that the transmittance type peripheral pulse oximeter sensors can be used over the forehead. It has the potential to avoid erroneous readings due to motion artifacts, hypothermia, or shock. Saturation nomograms for the forehead pulse oximetry need to be established before it can be used to monitor and manage the neonates for the same.

Keywords

Transmittance pulse oximeter, forehead pulse oximeter, newborns, neonates

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Introduction

Human beings depend on oxygen for life. All organs require oxygen for their metabolism, but the brain and heart are particularly sensitive.[1] Severe hypoxia for a few minutes can be fatal. Early detection and treatment of hypoxemia may prevent serious complications.[2] Pulse oximetry is the monitoring of peripheral oxygen saturation (SpO_2). It has gained widespread popularity over the last decade in a wide range of clinical applications, especially in neonatal or pediatric intensive care. It has revolutionized modern medicine with its ability to noninvasively monitor the oxygen saturation of hemoglobin in arterial blood (SaO_2) continuously. The advantages over arterial blood gas are its noninvasive, low cost, ease of use, low associated morbidity, and continuous monitoring including trend analysis. Despite these benefits, it has several limitations. It might not give accurate readings or might not pick up the saturation in conditions like shock, hypothermia, elevated or dependent limb position, and arteriovenous compression due to bandages especially in newborns, and regional anesthesia or due to motion artifact.[3]

There are two common types of pulse oximeter sensors – transmittance and reflectance4. The transmittance pulse oximeter (TPO) sensor is configured with an optical emitter and detector. They are positioned on opposing surfaces of the tissue with sensors applied to the finger, ear lobe, or toe. In

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the reflectance pulse oximeter (RPO) sensor, the emitter and the detector are located side by side and the sensor can be applied to a single surface, such as on the forehead. With both sensors, red and infrared light are emitted into the tissue and the detector measures the scattered light that is transmitted through blood-perfused tissues. In TPO, measurements may not be accurate in conditions like poorly perfused tissues, and motion artifacts may emerge in case of arm or leg movements. The RPO is a potential alternative to the traditional TPO in such cases.[5] RPO can measure SpO_2 on the forehead. Arteries that supply the forehead do not vasoconstrict in response to stimuli such as cold temperatures and shock that would affect the periphery and can continue to provide adequate pulsations and saturation monitoring.[6-8] Also, detection of hypoxia at the forehead can occur one to two minutes sooner than the limbs under conditions of peripheral vasoconstriction.[9,10] The vascular density of the region immediately above the eyebrow is sufficient to create the needed pulse sizes for reliable pulse oximetry using modern-day monitors. The other advantages of the forehead include less susceptibility to motion artifacts as compared with the hands and easy accessibility to the sensor site in the operating room.[11]

But RPOs for the forehead are expensive and not easily available in resource-limiting settings like ours. Not many studies have been done to validate the use of transmittance sensors as reflectance pulse oximetry in neonates. To answer this research question, a new innovative method of applying transmittance pulse oximeter on forehead was planned to assess and compare the effectiveness of transmittance pulse oximeter on forehead with peripheral pulse oximetry.

Materials and Methods

An observation study was conducted in a neonatal intensive care unit, in a tertiary care hospital in North India over a span of one month. The study was approved by the institutional ethics committee. Newborns admitted were enrolled after obtaining informed, written consent from the parents. Any neonate with congenital malformation of the head, subgaleal hematoma, or any forehead injury was excluded.

Neonates were monitored by the two pulse oximeters simultaneously (Figure 1). One was put over the forehead and the other on the periphery (right wrist/hand). The transmittance pulse oximeter of Masimo RAD97 was used for monitoring as the probe ends are free and have individual wires, which can be easily applied over the forehead using an innovatively designed headband (Figure 2). Different size headbands were designed for term and preterm babies by using Velcro on the outer side for fixation and stretchable velvet on the inner side. For term babies, headband was designed with length of 45 cm and breadth of 1.5 cm, that can be used in babies with head circumference between 30 and 40 cm and for preterm babies, headband was designed with length of 35 cm and breadth of 1.5 cm that can be used in babies for head circumference between 25 and 30 cm. Multiple holes were made of diameter of the clip end (nearly 0.5 cm) and distance between two holes was kept 1 cm keeping in mind the proximity of clip ends. Both probe ends were placed over the forehead in close proximity touching each other. Another similar pulse oximeter was applied over the right hand/wrist for peripheral pulse oximetry. As the unit had ten-Masimo RAD97-pulse oximeters, the principal investigator chose five babies by chit system daily. For each observation, three readings were recorded every 20 seconds and their mean was taken for final recording. For each patient, data from the two pulse oximeters were recorded every half hour for next six hours in predesigned proforma. Hence, a total of 12 readings were recorded for each baby. So, a total of 540 (45x12) readings were recorded. After recording the data, heart rate (HR) and SpO2 values obtained from the forehead monitor were compared with the peripheral recordings. A difference of more than or equal to 2% in SpO2 readings and a difference of more than or equal to 5 beats per minute in HR readings from both the monitors were considered clinically significant.

Statistical Analysis

On the basis of a pilot study on 10 patients, prior to the study, mean HR was 150.83 ± 7.48 per minute and 147.44 ± 8.55, respectively and mean SpO_2 was 96.44 ± 1.87% and 93.41 ± 1.71% measured by forehead and peripheral pulse oximeter, respectively. Taking these values as reference, the minimum required sample size with 80% power of study and 5% level of significance was 44 patients. To reduce margin of error, total sample size taken was 45.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0. Categorical variables were presented as number and percentage (%) and quantitative data were presented as the means ± standard deviation (SD) or as median with 25th and 75th percentiles (interquartile range). The Bland–Altman plot was used to compare the parameters measured by forehead pulse oximeter and peripheral pulse oximeter. For statistical significance, *p*-value of less than 0.05 was considered statistically significant.

Observations and Results

A total of 45 subjects were included in the study with the mean gestational age of 35.3 ± 3.2 weeks and mean birth weight of 2109 ± 683 grams. Demographic profile and the vitals of the enrolled population are given in Table 1.

The mean value of HR (per minute) and SpO_2 (%) of study subjects as measured by forehead pulse oximeter and peripheral pulse oximeter was 148 ± 4.5 and 95.9 ± 0.9 & 144.1 ± 4.8 and 93.4 ± 0.7, respectively (Table 2).

Figure 1. Simultaneous Pulse Oximetry from Peripheral and Forehead Area.

The average of the differences of HR was 3.8 per minute. The limits of agreement estimated an interval of -7.8 to 15.5. Significant difference was seen in the measurement of HR between forehead pulse oximeter and peripheral pulse oximeter (p-value < 0.0001; Figure 3).

The average of the differences of SpO_2 was 2.5 %. The limits of agreement estimated an interval of –1.6 to 6.6. Significant difference was seen in the measurement of SpO_2 between forehead pulse oximeter and peripheral pulse oximeter (p value < 0.0001; Figure 4).

In further subgroup analysis, for HR between 120 and 160 per minute (n = 531), there was a statistically significant difference of 3.9 per minute between peripheral and forehead pulse oximeter (p < 0.0001), compared to a nonsignificant difference of 0.4 beats per minute between the two, when the HR was > 160/min (n = 9; p = 0.768; Supplementary Table 1). Similarly, when the SpO2 was ≤ 90%, the difference between the two was 5.1% (n = 7; p = 0.004), compared to a difference of 2.6% when the peripheral saturation was 91–95% (n = 491; p <0.0001) and difference of 0.6% when the peripheral saturation was >95% (n = 42; p = 0.034; Supplementary Table 2).

Perfusion index (PI) was compared to estimate the signal difference between the two sites. Forehead PI was on average 0.428 more than the peripheral pulse oximeter. The limits of agreement estimated an interval of -0.776 to 1.632 (p-value < 0.0001) (Supplementary Figure 1).

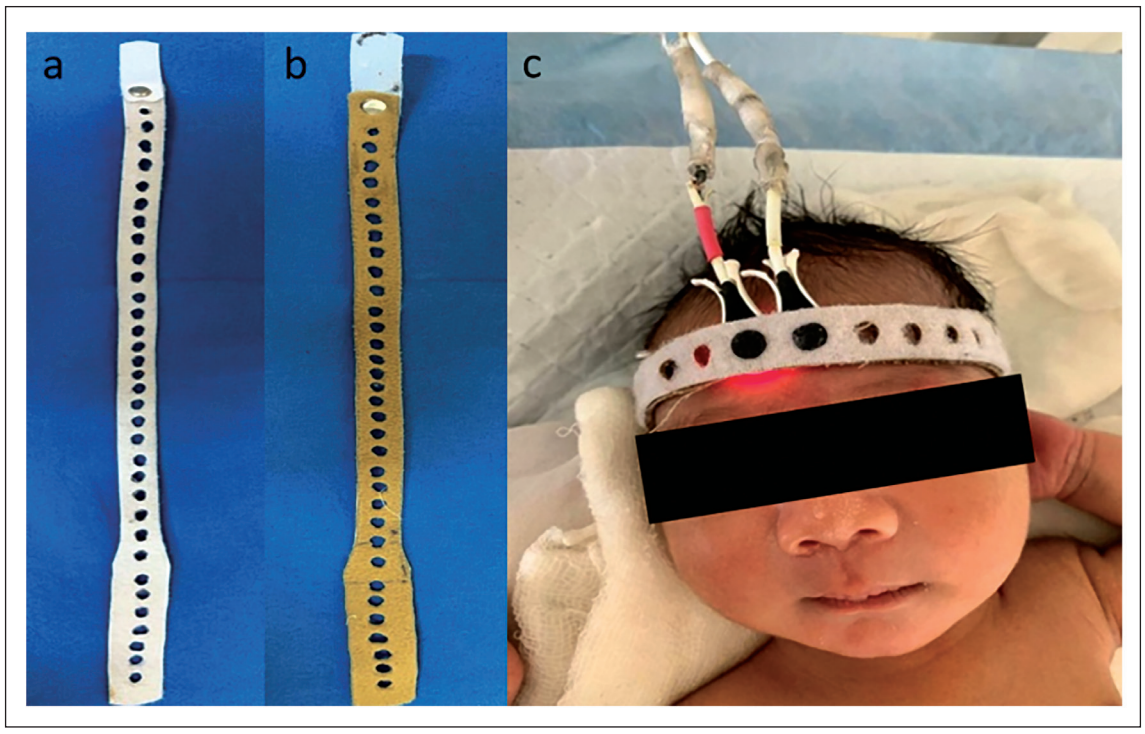

Figure 2. Innovative Headband (a—Front, b—Back), Applied Over Forehead (c) for Pulse Oximetry.

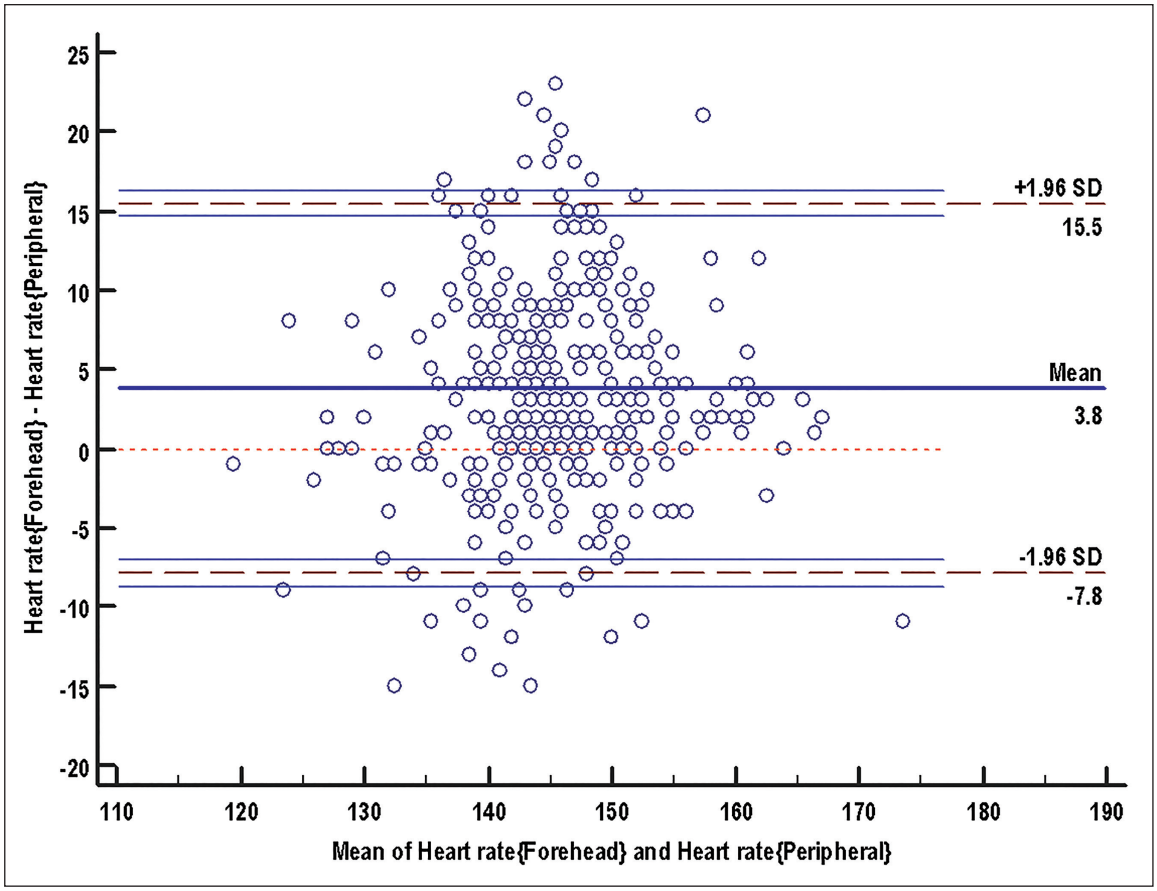

Figure 3. Bland–Altman Plot for Comparison of Heart Rate (Per Minute) Measured by Forehead Pulse Oximeter and Peripheral Pulse Oximeter.

Table 1. Distribution of Baseline Characteristics of Study Subjects.

Baseline characteristics	Frequency (%)	Mean ± SD / Range
Gestational age (weeks)		
Preterm	30 (66.7%)	
Term	15 (33.3%)	
Mean ± SD		35.3 ± 3.2
Range		29–40.4
Gender		
Female	18 (40%)	
Male	27 (60%)	
Birth weight (grams)		
1000–1500	11 (24.4%)	
1501–2500	23 (51.1%)	
>2500	11 (24.4%)	
Mean ± SD		2109 ± 683
Range		1075–3925
Respiratory rate (per minute) Mean ± SD		51 ± 4
Systolic blood pressure (mm Hg) Mean ± SD		71 ± 4
Diastolic blood pressure (mm Hg) Mean ± SD		39 ± 3
Mean arterial pressure (mm Hg) Mean ± SD		48 ± 4
Temperature (°C) Mean ± SD		36.6 ± 0.1
Sepsis (clinical/lab*)	15 (33.3%)	
Hypoglycemia	2 (4.4%)	
Hypocalcemia	13 (28.9%)	
Requirement of respiratory support	20 (44.4%)	
Invasive ventilation	2 (4.4%)	
NIV	2 (4.4%)	
CPAP	5 (11.1%)	
HHHFNC	9 (20%)	
Nasal cannula	2 (4.4%)	
On inotropes	2 (4.4%)	
Seizures	2 (4.4%)	

Notes: *Including culture positive sepsis.

CPAP—continuous positive airway pressure, °C—degree Celsius, HHHFNC—heated humidified high flow nasal cannula, mm Hg—millimeter of mercury, NIV—noninvasive ventilation, SD—standard deviation.

Table 2. Comparison of Heart Rate and Saturation by Forehead Pulse Oximeter and Peripheral Pulse Oximeter.

Parameter (n = 540)	Forehead pulse oximeter	Peripheral pulse oximeter	Difference	p-Value
Heart rate (per minute) Mean ± SD	148 ± 4.5	144.1 ± 4.8	3.8 (95% CI 3.3 to 4.3)	< 0.0001
SpO2 (%) Mean ± SD	95.9 ± 0.9	93.4 ± 0.7	2.5 (95% CI 2.3 to 2.7)	< 0.0001

Notes: CI—confidence interval, Spo2—oxygen saturation, SD—standard deviation.

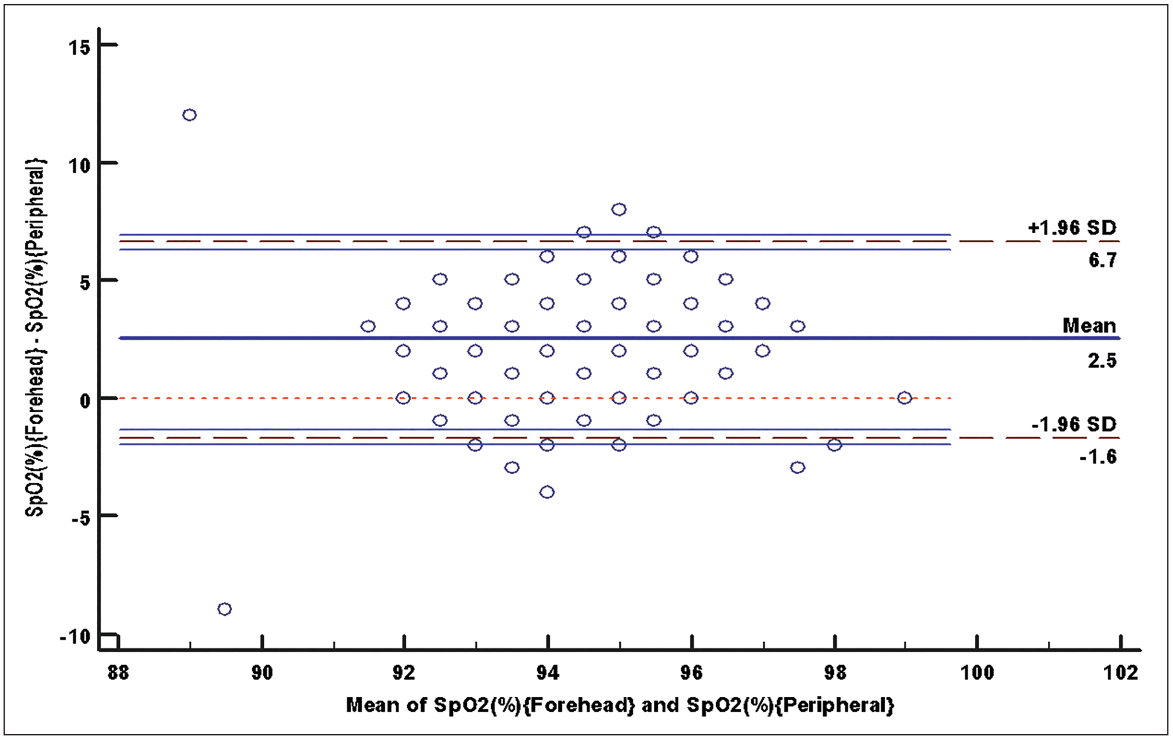

Figure 4. Bland–Altman Plot for Comparison of SpO_2 (%) Measured by Forehead Pulse Oximeter and Peripheral Pulse Oximeter.

Table 3. Difference of Heart Rate and SpO2 by Forehead Pulse Oximeter and Peripheral Pulse Oximeter in Preterm and Term Babies.

Parameter (*n* = 540)	**Difference**	***p*-Value**
Preterm (*n* = 360)		
HR (/minute)	+ 4	<.0001
SpO2 (%)	+ 2.6	<.0001
Term (*n* = 180)		
HR (/minute)	+ 3.4	<.0001
SpO2	+ 2.4%.	<.0001

Notes: HR—heart rate, Spo2—oxygen saturation.

Table 4. Comparison of Blood Pressure and Temperature in Two Groups with Heart Rate Differences of More or Less Than Five Beats Per Minute Between the Forehead and Peripheral Pulse Oximeters.

Parameters	**No** ***n* = 322**	**Yes** ***n* = 218**	***p*-Value**
Systolic blood pressure (mm Hg) Mean ± SD	71.7 ± 7.32	70.99 ± 7.3	0.272†
Diastolic blood pressure (mm Hg) Mean ± SD	39.46 ± 6.13	39.34 ± 6.56	0.824†
Mean blood pressure (mm Hg) Mean ± SD	48.43 ± 6.8	47.3 ± 6.69	0.057†
Temperature (^{0}C) Mean ± SD	36.59 ± 0.1	36.59 ± 0.12	0.998†

Notes: † Independent t test

^{0}C—degree Celsius, mm Hg—millimeter of mercury, SD—standard deviation.

Table 5. Comparison of Blood Pressure and Temperature in Two Groups with SpO2 Differences of More or Less Than 2% Between the Forehead and Peripheral Pulse Oximeters.

Parameters	No *n* = 271	Yes *n* = 269	*p*-Value
Systolic blood pressure (mm Hg) Mean ± SD	71.5 ± 7.17	71.32 ± 7.46	0.782†
Diastolic blood pressure (mm Hg) Mean ± SD	39.5 ± 6.09	39.33 ± 6.52	0.753†
Mean blood pressure (mm Hg) Mean ± SD	47.94 ± 6.63	47.92 ± 6.94	0.969†
Temperature (^{0}C) Mean ± SD	36.58 ± 0.09	36.6 ± 0.12	0.111†

Notes: † Independent t-test.

^{0}C—degree Celsius, mm Hg—millimeter of mercury, SD—standard deviation.

Table 3 shows the difference of HR and SpO2 by the forehead and the peripheral pulse oximeter in term and preterm babies. Bland–Altman comparison for the HR and SpO2 in preterm and term babies is shown in supplementary Figures 2–5.

To assess whether there was any variation in blood pressure or temperature when the difference was more than 5 beats per minute in the HR or more than 2% in SpO2 between the forehead and peripheral pulse oximeter, subgroup analysis was done (Tables 4 and 5). No significant difference was there in either of the values between the two groups.

Out of 45 patients, 4 patients had redness at the site of application of forehead sensor over the course of the study. This was comparable to five patients who had redness in the hands due to peripheral application of the sensors.

Discussion

RPO sensors have been developed that enable oximetry measurements at various body locations. These recently developed reflectance sensors may offer advantages over conventional digit-based oximetry. The demand for RPO sensors has been continuously increasing because they can be used on diverse measurement sites such as the feet, forehead, chest, and wrists.[12]

TPO sensors are still most widely utilized, particularly the finger sensor. But it can be less effective in poor peripheral circulation as it can be more prone to the effects of vasoconstriction and this can decrease accuracy of readings due to reduced photoplethysmography signal.[13] RPO, as used in the forehead sensor, is less vulnerable to vasoconstriction.[9] Additionally, it can be more securely attached which could make it less prone to motion artifact and therefore more reliable during exercise testing.

A study was published in January 2022 in which SpO2 and HR were compared between forehead and finger sensors during the six minute walk test (MWT). Sensor readings were also to be compared for signal quality and with capillary blood gas (CBG), pre and post 6MWT. The results were that the forehead sensor recorded higher values for SpO2 ($p < 0.001$) and HR ($p < 0.01$) compared with the finger sensor during the 6MWT.[4]

However, RPO is costlier and not easily available. Therefore, a new innovative method of applying the transmittance type of sensor over the forehead is being studied. This method of forehead pulse oximetry would provide an affordable option in the low socioeconomic settings. An experimental exploratory work was done by Gupta et al, where in transmittance sensor of peripheral pulse oximetry was used on forehead of neonates with encouraging result.[14] To the best of our knowledge, no other study has been done on the use of TPO peripheral pulse oximeter sensor as RPO for forehead pulse oximetry in newborn. This study is the first to evaluate the accuracy and validity of transmittance pulse oximeter for forehead pulse oximetry.

In the 45 subjects, the mean value of HR (per minute) and SpO_2 (%) measured from the forehead monitor was 148 ± 4.5 and 95.9 ± 0.9, respectively. However the mean value of HR (per minute) and SpO_2 (%) of study subjects by peripheral pulse oximeter was 144.1 ± 4.8 and 93.4 ± 0.7, respectively. A difference of 3.8/minute was seen in the measurement of HR between forehead pulse oximeter and peripheral pulse oximeter (p-value < 0.0001). The reason for this difference may be that some pulses were missed by the peripherally placed pulse oximeter as compared to forehead pulse oximeter. This difference, although statistically significant, is not considered significant clinically.

A significant difference of 2.5% was seen in the measurement of SpO_2 between forehead pulse oximeter and peripheral pulse oximeter (p-value < 0.0001). This difference in SpO2 may be explained by the proximal position of the forehead pulse oximeter compared to the peripheral pulse oximeter. Significant difference in the PI between the two sites, with forehead PI more than peripheral PI, demonstrates the better signal strength in the central area. Therefore, it is expected that the forehead probe may have higher sensitivity compared to conventional peripheral pulse oximeters for saturation monitoring. This difference in SpO2 is also clinically significant. Therefore, nomograms for the forehead pulse saturation should be established before they are used to titrate the oxygen requirement of the baby.

This difference persisted on subgroup analysis of the HR and SpO2 in term and preterm babies.

In the two groups where the difference in HR was more or less than 5/minute or SpO2 was more or less than 2% in the forehead and peripheral pulse oximeters, there was no significant difference in the blood pressures or the temperature. This shows that the difference might be due to the signal intensity rather than shock or hypothermia in the index population.

It was also observed that the forehead pulse oximeter was well tolerated by the neonates. In few study subjects, skin on the forehead area of the sensor became erythematous, which normalized after removing the band. This was comparable to the peripheral sensors, which sometimes resulted in the local reaction. It is suggested that the sensor site should be assessed and the sensor removed every six hours for a few minutes to prevent skin injury.

This study suggests that forehead pulse oximetry gives a viable alternative monitoring site when access to patient extremities is limited, such as in patients with intravenous (IV) cannulation, and under conditions of poor perfusion, such as during shock or hypothermia, or when there are a lot of motion artifacts. In such cases, peripheral pulse oximetry may not function appropriately.

The strength of the first of its kind study is that the study cohort had a diverse population in terms of gestational age and birth weight. Large numbers of readings were recorded. Selection bias was avoided by using the chit system. However, there are some limitations. Forehead pulse oximetry can be done only with peripheral pulse oximeter if both the ends of the sensors are free. Sample size was small and therefore definitive conclusions cannot be made. Also, independent clinical researches which can evaluate the accuracy and reliability of HR and SpO2 readings on a variety of patients in the clinical setting are required before the conclusion can be applied to a larger population. Also, since the signal extraction technology (SET) oximeters (Masimo) were used in the study, generalizability for the conventional pulse oximeters cannot be made.

Conclusion

In this study, we demonstrated the use of peripheral pulse oximeters for forehead pulse oximetry in newborns. It was observed that transmittance type peripheral pulse oximeters when applied to the forehead in newborns could measure the HR and saturation. HR readings from forehead pulse oximetry were more than the peripheral pulse oximeter, though they were not clinically significant. Forehead saturation was more than the peripheral pulse oximeter.

Further studies with a larger sample size are required to confirm the findings, before this innovative strategy of using transmittance type of oximeters for forehead pulse oximetry can be used as a standard of care.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

The study was approved by the institutional ethics committee (Himalayan Institute of Medical Sciences, Swami Rama Himalayan University) (Ref. No: HIMS/RC/2022/22).

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Informed Consent

Newborns admitted were enrolled after obtaining informed, written consent from the parents.

Supplemental Material

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