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Evaluation of Oxygen Saturation by Pulse Oximetry on Newborn Infant Using Skin Protective Covering

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Background: Pulse oximetry is a convenient method of monitoring oxygen saturation (SpO_2). Pulse oximeter probes have been reported to be associated with injuries in neonates. Objectives: This study was conducted with the objective of examining whether application of a protective covering influences values of SpO_2.

Method: A cross sectional study was carried out in the Neonatology, over a period of one year. Hospitalized 140 neonates within 28 postnatal days were included in the study. Neonates with major congenital malformation, heart disease, severe anemia, shock and deep jaundice were excluded. Readings of SpO_2 were taken on right foot and right hand directly and through micropore by researcher himself when the saturation display was steadied.

Results: The mean readings of SpO_2 on foot directly and through micropore were 94.5±3.4% and 94.2±3.4% respectively. On right hand, the values were 94.3±3.3% and 94.5±3.3% respectively. For each of the 13 subgroups formed on the basis of gestational age, weight and postnatal age of the newborns, oximetry readings of two sites i.e. hand and foot were compared using T-test and 95% confidence interval. Thus there were in all 26 statistical comparisons. Of these, in 22 comparisons the differences in the reading with micropore and without micropore were found statistically not significant. In the remaining 4, differences in 2 cases were significant at 0.04 and 0.05 level. The paired mean differences between readings of SpO_2 by pulse oximeter without micropore and with micropore on foot (0.25±1.11) and hand (0.22±1.12) were very similar to paired mean difference of SpO_2 readings by direct method (0.15±1.22) on hand and foot and were within this limit.

Conclusion: The work concluded that the micropore protective covering did not influence oxygen saturation readings,suggesting that covering can be satisfactorily used for protection of neonates from probe related injuries.

Keywords: Evaluation, oxygen saturation, pulse oximetry, protective covering, neonate.

Introduction

Folic Oxygen supplementation is frequently needed during care of newborn infant specially in neonatal intensive care units (NICU). Oxygen is the most common drug used in neonatology worldwide (1).

Inappropriate supplementation of oxygen may not decrease hypoxia or may leads to development of hyperoxia. Hypoxia may leads to pulmonary vasoconstriction, pulmonary hypertension, neurological and other organ damage (2). This condition may be associated

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with cyanosis, fixed heart rate of 120/mit or bradycardia, lethargy or unresponsiveness, hypothermia and metabolic acidosis (3).

Hyperoxia on the other hand produces complex physical and physiological stress (4). It produces free radical mediated cellular damage through lipid peroxidation, inactivation of enzymes, damage of DNA and structural protein. It is believed that a number of diseases in the newborn may occur as consequences of oxygen free radicals e.g. retinopathy of prematurity, bronchopulmonary dysplasia, necrotizing enterocolitis and patent ductus arteriosus (3).

Deviation from normality during oxygen therapy needs to be prevented through proper monitoring by the clinician. The primary aim of monitoring of oxygen is to reduce hypoxic and hyperoxic episodes and to decrease variability in an infant's oxygen levels (5).

Direct blood gas sampling from arterial lines to measure partial pressure of oxygen in arterial blood (PaO_2) is considered to be the gold standard for accuracy. This method, however, only provides intermittent oxygen monitoring. It is invasive, can lead to significant blood loss and erroneous results may be found if sampling is improper (6). Moreover, such facility is very limited in many developing countries. Transcutaneous oxygen ($tcPo_2$) monitoring is non-invasive but needs frequent calibrations. It is slow in response and needs relocation to different skin sites every 4-6 hourly (7).

The pulse oximeter, on the other hand is easy to use. It is non-invasive, less complex, does not require calibration and provides continuous measurement of hemoglobin-oxygen saturation (Spo_2)(8). Response time of this instrument is fast (9) and accuracy is high (±3%)(8). The technology is regarded as the 'fifth vital sign' due to its enormous advantages and immense utility (10).

Complications associated with use of pulse oximetry have been reported. These include pressure erosion, skin necrosis, digital sensory loss and even burn (11). Complications are due to adverse effect of pulse-oximeter probe on skin. Probe mediated complications may be reported mainly in newborn infants whose skin is very thin and delicate. Chance of trauma may be further increased if probe (sensor) is used for prolonged period for continuous monitoring of critically ill neonates whose cardiac output is low and peripheral circulation is poor (11). Use of a protective covering can prevent probe mediated injury. But it is essential to see whether SpO_2 value recorded through such a covering is similar to the SpO_2 value recorded directly over skin.

Comparative study on values of SpO_2 recorded directly on skin and using a protective covering is not known in our country. It is expected that evaluation of oxygen saturation by pulse oximeter taken through skin protective covering will help to compare percent saturation of hemoglobin (Hb) with oxygen (SpO_2) values recorded through protective covering with values taken directly on the skin. Result of such a study may help to guide regarding use of an easily available, user friendly, low-cost protective covering specially during prolonged pulse oximetry of sick neonate to prevent probe associated injury.

Study Design

A cross-sectional study was conducted in the Department of Neonatology of Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka from December/2008 to November/2009. Convenient sampling technique was used. One hundred and forty neonates constituted study sample. Each neonate was taken

as sample unit. Hospitalized neonates of both sexes within 28 postnatal days of birth were included in the study after obtaining informed consent from their parent(s). Neonates who were getting oxygen therapy and breathing in open air were included. Neonates with major congenital malformation, heart disease, severe anemia, deep jaundice and shock were excluded from the study. Informed consents were taken from legal guardians of newborn infants. Permission of Research Ethical Review Committee of BSMMU was sought through departmental chairman. Pulse oximeter - CIS Criticare USA, 504 Dx Digital oximeter, model no - 902/908; for protective covering - 3M Microporous Surgical Tape, 1530A-16, Hypo allergenic.3M Center, St.Paul, MN55144-1000, USA. made in Taiwan for 3M Healthcare and weighing scale-a digital weighing scale of TANITA Corporation, Tokyo, Japan, BD-585, US Patent No 5415176 Max 0-20kg d=10g were used. A pre-tested simple proforma (data sheet) was designed as research instrument.

Data were collected by face-to-face interview of the responsible attendant, transferring information from hospital records and pulse oximetry readings on newborn babies. Pulse-oximetry oxygen saturation reading was first taken on right foot of neonate applying pulse oximeter probe directly on skin of neonate without any protective covering. Then a piece of micropore (surgical tape) was wrapped around the same part of neonate as a protective covering. Reading of oxygen saturation was taken by pulse oximeter over the covering when the saturation display was steadied. Micropore was used on each neonate only for the time needed for pulse oximetry. Reading with micropore was compared with reading taken directly over skin (standard method). Similarly, readings were taken on right hand of neonates with protective coverings and without covering.

After collection, data was checked and cleaned to reduce error. Descriptive and statistical methods were used in analyzing data. Important variables e.g. readings of SpO_2, methods of reading of SpO_2, gestational age, weight of neonates and their postnatal age were considered. Standard statistical methods like t test, 95% confidence interval (CI), Bland-Altmon's method for assessing agreement were adopted. All analyses were done using 'Statistical Package for Social Science (SPSS)'.

Results

About half (50.7%) of newborns in this study had gestational age of ≤34 weeks. Only 25% of neonate were of normal weight and 75% were low birth weight (LBW) or very low birth weight (VLBW). Two-third neonates had post natal age of ≤14 days. The observed mean SpO_2 value by direct method of recording (without micropore), on right foot was 94.5± 3.4% and with micropore covering 94.2±3.4%. On hand, directly and through micropore the values were 94.3±3.3% and 94.5±3.3% respectively.

The neonateswere divided into 13 subgroups on the basis of gestational age, weight and postnatal age of the newborns. For each of the 13 subgroups, oximetry readings of two sites i.e. hand and foot were compared using t test and 95% CI. Thus there were in all 26 statistical comparisons. Considering SpO_2 recorded on hand of neonates with gestational age ≤32 weeks, the calculated value of paired-T was 1.66 (df=54, p=0.1). Hence, the differences between readings of SpO_2 by direct method (without micropore) and over micropore (modified method) was statistically not significant. Again, 95%CI of paired difference was

-0.546 to 0.051 (included 0), indicating that the difference was not significant Differences between SpO_2 recorded by both methods in all other groups were also not significant ($p>0.05$) (Table-1). Gestational age wise SpO_2 values on foot were also compared (Table-2). Mean values with gestational age of ≤32 weeks without micropore and with micropore were 94.4±4 and 94.3±3.1 percent respectively. The calcu-lated value of paired-T was 0.93 (df=54, p=0.35), which was lower than table value. Again, 95% CI was -0.155 to 0.424.

These signified that difference between the two values were statistically not significant. Considering gestational age of neonates and SpO_2 recorded on hand and foot, out of 8 statistical comparisons only 1 showed significant difference (Table-2). On the basis of weight and postnatal age of neonates, excepting 3 subgroups, in 18 comparisons the differences in SpO_2 readings between two methods were not found statistically significant. In the remaining 3, differences in 2 cases were only significant at 0.04 and 0.05 level.

When SpO_2 values of two methods on foot were plotted according to 'Bland-Altmon method of assessing agreement between systems', a line of equality was seen. This indicated that SpO_2 values by both methods were clinically same. A strong correlation ($r=0.947$, $p<0.01$) between both method was observed (Fig-1). Again, a plot with difference between two methods against their means was constructed. It was seen that almost all differences lied within mean difference±2SD (Fig-2). The mean difference of SpO_2 was 0.25 with SD±1.11%.

Similarly, a line of equality was also observed when two types of data in case of hand were plotted. The observed correlation coefficient(r) between two types of data was 0.943 ($p<0.01$) (Fig-3). Mean difference of SpO_2 values was 0.22±1.12 percent. A plot of differences between SpO_2 values by both methods against their means showed observation similar to that of foot (Fig-4).When SpO_2 values by direct (conventional) method on foot and hand were plotted, a line of equality was seen. This indicated that SpO_2 values by this method

Table-1. Gestational age wise Spo_2 readings on hand of neonates (n:140)

Gestational age (weeks)	Spo_2 readings (%)		95% CI of paired difference		t /p value
	Direct x± SD	Over micro-pore x± SD	Lower value	Upper value	
≤32 (n=55)	94.2±2.9	94.4±2.8	-0.546	0.051	-1.66/ 0.10 NS
33-34 (n=16)	95.3±2.0	95.8±1.9	-1.207	0.082	-1.86/ 0.08 NS
35-36 (n=25)	95.1±3.1	95.3±2.9	-0.561	0.217	0.91/ 0.37 NS
≥37 (n=44)	93.7±4.1	93.7±4.2	-0.443	0.293	-0.41/ 0.68 NS

NS: not significant, p>0.05; **n:** number of subject

Table-2. Gestational age wise Spo_2 readings on foot of neonates (n:140)

Gestational age (weeks)	Spo_2 readings (%)		95% CI of paired difference		t /p value
	Direct x± SD	Over micro-pore x± SD	Lower value	Upper value	
≤32 (n=55)	94.4±3.0	94.3±3.1	-0.155	0.424	0.93/ 0.35 NS
33-34 (n=16)	95.6±2.1	95.5±1.5	-0.596	0.721	0.20/ 0.84 NS
35-36 (n=25)	95.3±3.1	94.6±3.4	0.432	0.944	5.55/ 0.0001 S
≥37 (n=44)	93.6±4.1	93.4±4.0	-0.161	0 .624	1.19/ 0.24 NS

NS: Not significant, **S**: Significant p>0.05; **n:** number of subject

recorded simultaneously on two sites in this work was clinically same. A strong correlation (r=0.935, p<0.01) between readings of SpO_2 values by direct method on these two sites of studied neonates was observed (Fig-5). The mean difference of SpO_2 values in that case was 0.15±1.2 (Fig-6).

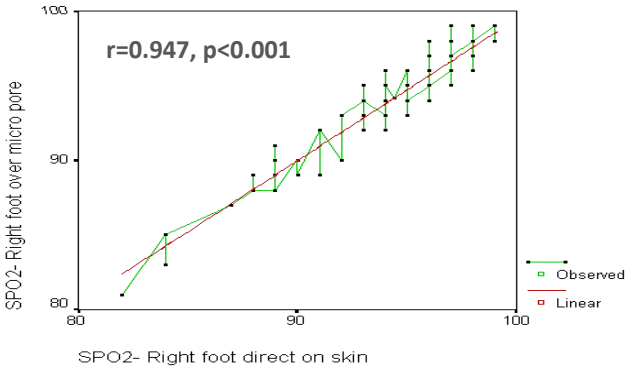

Figure-1. Relationship of SpO_2 by direct and through micropore on foot.

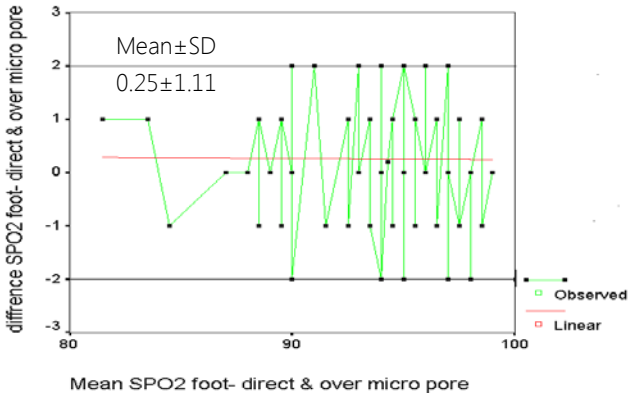

Figure-2. Relationship of mean SpO_2 direct and through micropore with paired differences of SpO_2 on foot.

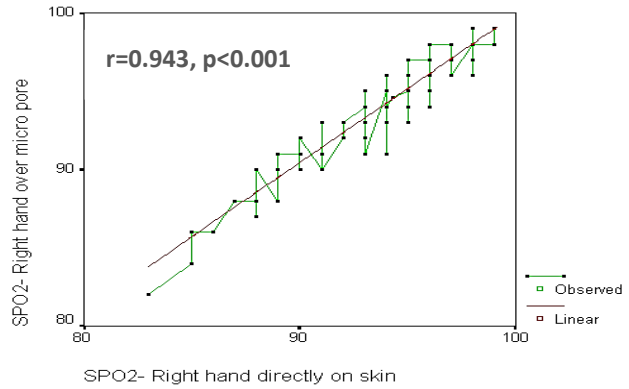

Figure-3. Relation of SpO_2 by direct and through micropore on hand.

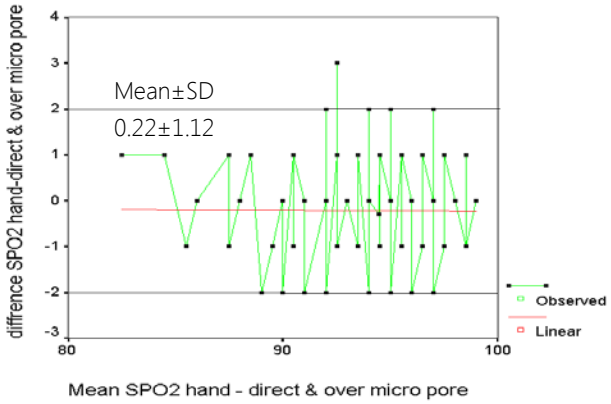

Figure-4. Relation of mean SpO_2 direct and through micropore with paired differences of SpO_2 on hand.

Again, a plot with difference between simultaneously taken two time's SpO_2 readings by direct conventional method against means was made. It was seen that almost all differences lied within mean difference ±2SD (Fig-6).

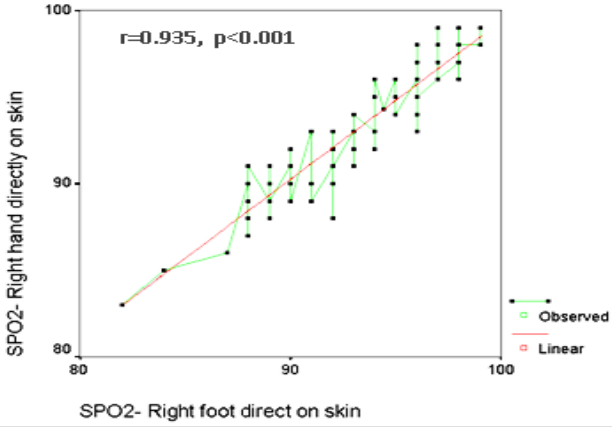

Figure-5. Relation of SpO_2 by direct method on foot&hand.

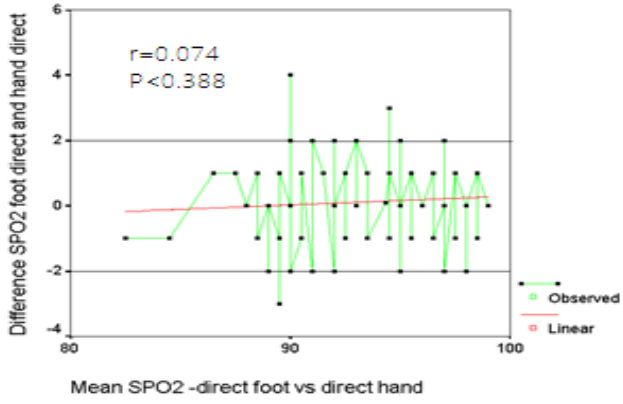

Figure-6. Relation of mean and paired differences of SpO_2 by direct method on foot and hand.

This was test of repeatability of direct conventional method and clinically acceptable. Here, it was seen that difference between readings of SpO_2 taken through micropore and readings taken directly on both sites (hand and foot) of neonates were very close and within limit of differences seen on testing of repeatability by direct method (Fig-2,4,6). It implied that SpO_2 values by both methods were very similar to each other and clinically interchangeable.

Discussion

Hypothesis that insisted the researchers to conduct the study was 'skin protective covering on the probe site does not influence oxygen saturation reading by pulse oximeter'. A logical preliminary step before selecting and advising use of a protective covering, it is important to test whether such a covering influences the SpO_2 readings. In this work, an attempt was made to find out the effect of protective covering (e.g. micropore) on the reading of SpO_2 in neonate and not on to see whether micropore influences injury on neonate. Micropore was chosen as a protective covering on the ground that this simple, low-cost, easily available, user friendly material is already in common use for fixation of I.V. canula, nasogastric tube etc. for considerable length of time even on neonates. Moreover, in our daily practice it is observed that micropore on skin surface does not causes skin injury.

In this study, reading of SpO_2 was taken on two sites of neonates (hands and feet) instead of one site. Importance of recording SpO_2 readings on two sites was three-folds: (i) The finding of SpO_2 readings without and with micropore covering recorded on two sites were not statistically different confirmed that micropore did not influence the readings. (ii) Repeated comparisons substantiated each other and (iii) Result was analysed by T-test, 95%CI and Bland-Altmon's method for assessing agreement between two clinical methods. Readings of two times recording of a conventional method is needed for analysis data by Bland-Altmon's method. Virtually, Bland-Altmon's method is useful for assessing the acceptability of a new clinical method (recording of SpO_2 readings with micropore covering in this study) in relation to conventional (recording of SpO_2 readings without micropore here) method.

In this work reading of SpO_2 by direct method was compared with reading with micropore covering in terms of gestational age, weight and postnatal age of newborn. Again, from practical points of view SpO_2 was recorded both on hand and foot of neonates. For each of the 13 subgroups formed on the basis of gestational age, weight and postnatal age of the newborns, oximetry readings of two sites i.e. hand and foot were compared using t test and 95%CI. Thus there were in all 26 statistical comparisons. Of these, in 22 comparisons the differences in reading with micropore and without micropore were not found statistically significant. In the remaining 4, differences in 2 cases were only significant at 0.04 and 0.05 level. Some confounding factors like surface temperature of neonate, clinical conditions, observer bias or other factor might interplay in these marginal discrepancies.

Considering means of differences of SpO_2 recorded by both methods on foot, it was seen that mean±2SD which covered 95% paired differences was -2% to 2.5%. Similarly, areas that covered 95% paired differences of both methods on hand were -2% to 2.5%. But, the area that included 95% of paired differences by direct method on foot and hand was -2.3% to 2.6%. The range of paired differences of both methods on both parts of neonates was less and within the difference of

repeatability of direct conventional method on two parts (hands and foots) of neonates. However, the value of repeatability of conventional method on these two parts is clinically acceptable. In this work, the difference between conventional and modified method was within the range of difference of test of repeatability of conventional method.

Hess and colleagues found that the standard error on using the probe directly was 2% (95% CI was about±4%)(12). Alexander et al found that the 95% prediction limit of a single pulse oximeter reading was ±6% throughout 70–100% saturation range (13). In this work, the agreement of variations between readings taken by both methods was less than the variations taken as acceptable by previous workers. Finding of present study was consistent to the finding of James et al (14). These researchers worked with micropore and gauze piece as protective covering on foot of neonates and observed that difference between 'with covering' and 'without covering' in both cases were not significant. In this study, it was seen that the value of reading of SpO_2 was not influenced when a micropore was used on the probe site of pulse oximeter. Hence, the result of modified method in this work might be considered as clinically acceptable.

Conclusion

Oxygen supplementation needs a reliable monitoring system. Pulse oximetry is regarded as the 'fifth vital sign' due to its enormous advantages in monitoring of oxygen in neonate. Complications in form of various injuries are associated with use of pulse oximeter. Probe mediated injury may be overcome using a micropore covering on probe site. From the present work it is evident that values of readings of percent saturation of haemoglobin with oxygen (SpO_2) are not influenced if a micropore is applied over the recording sites on neonates. A piece of micropore may thus conveniently be wrapped around the skin under probe on neonate during recording of SpO_2 by pulse oximeter. Hopefully, this simple, easily available but reliable covering might protect neonate from undesirable injuries.

Recommendations

On the basis of the study, the authors put forward the following recommendations: Pulse oximetry is a very useful noninvasive, convenient reliable method of monitoring oxygen saturation, but there is chance of probe related injury specially during prolonged recording. As the work shows that a micropore covering does not influence readings of pulse oximetry, micropore may be wrapped around the part of neonate where pulse oximeter probe is attached. Study on a wide scale, covering all postnatal age groups should be carried to substantiate present findings.

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Jagadish C Das took part in conception and design of study, data collection, analysis and interpretation of data, drafting and revising the manuscript critically. Mohammad Shahidullah took part in conception, design of study and interpretation of data. Sadiqa Tahera Khanam conceptualized and designed the study, interpreted data and revised the manuscript critically. M.A Mannan conceptualized the study, interpreted data. M.A Hafez took part in conception and design of study, analysis and interpretation of data. Nibedita Paul took part

in conception and design of study, interpretation of data and revision of the manuscript.

All authors read and approved the manuscript for publication. The authors declare that they have no competing interests. Permission of Research Ethical Review Committee of BSMMU was sought through departmental chairman. Informed consents were taken from legal guardians of newborn infants who participated the study.

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List of Abbreviations

SpO_2: Percent saturation of hemoglobin (Hb) with oxygen, PaO_2: Partial pressure of oxygen in arterial blood, NICO: Neonatal intensive care unit, DNA: Deoxy ribonucleic acid. Hb: Hemoglobin. BSMMU: Bangabandhu Sheikh Mujib Medical University.

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