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Original Research

To estimate accuracy and feasibility of Paediatric Pulse Oximeter for use in newborns by comparing it with cardiac monitor as gold standard

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Abstract
Objectives : To evaluate the possibility of paediatric pulse oximeter (finger) recommended for age more than 2 years for pulse oximetry in newborns comparison to gold standard cardiac monitor recommended for newborns.
Methods : Pulse oximetry of 100 normal newborns was done with Dr Trust USA Pediatric pulse oximeter by applying it on index fingers along with ring and index finger of both upper limbs and in big toe along with part of foot of newborn. HR, SpO_2 and PI data was collected and compared with Philips goldway GS20 2020 cardiac monitor applied almost simultaneously and the results were compared to estimate efficacy, feasibility and sensitivity of pulse oximeter.
Results : It was feasible to apply pulse oximeter in 61 babies in all four limbs and partially in one, two or three limbs in 19 and in 20 babies it could not be applied in any limb. Mean response time was higher in pulse oximeter than cardiac monitor as expected, although statistically significant but clinically acceptable. Heart rate showed a linear correlation among two instruments signifying that sensitivity of pulse oximeter is acceptable clinically. Oxygen saturation in all four limbs, difference was statistically significant but clinically acceptable. However, the difference in perfusion index in all four limbs was statistically significant as well as clinically unacceptable.
Conclusions : Studied Pulse oximeter can be used in areas where dedicated cardiac monitors for newborns are not available for measuring heart rate and oxygen saturation only if it could be applied.
Keywords- Newborn,Pulse oximeter, Pulse oximetry, Perfusion index, Oxygen saturation

Introduction

Pulse oximetry is a non-invasive method to measure arterial oxygen saturation continuously. It has become a preferred instrument for monitoring and accessing vital parameter of adults as well as children(1). It quickly evaluates oxygen concentration (SpO2) and guides required actions to achieve normal saturation easily. Pulse oximetry measures heart rate, oxygen saturation and gives estimation of arterial oxygen saturation through sensor placed on the body part from where red or infrared lights are sent by two light emitting diodes which detect oxygenated and deoxygenated haemoglobin proportions in blood (2). The change in absorption of light during pulsatile and non-pulsatile flow is analysed, which gives value of SpO2, as with each heartbeat flow surge of blood is detected, heart rate is also detected (3). Its precision has improved with developing technology to a great extent, especially the ability of pulse oximeter to work where low perfusion is there has also improved (4). This is the most common reason for the usage of cardiac monitor and special probes in paediatric setting but the availability of cardiac monitor and special probes is limited to tertiary care centres at high cost. They cannot be made available at lower levels and cannot be used for screening purpose especially in developing countries.
Most common site used for this process is fingers in adults and children and special probes for neonates that is applied on wrist and feet (5). Finger pulse oximeter designed for a newborn is not yet available. This creates a barrier for diagnosing and examining the neonate at periphery. Although pulse oximeter is being widely used worldwide from tertiary hospitals to periphery especially after COVID 19 pandemic, however newborns, the most vulnerable population remains undiagnosed due to non-availability of this screening and monitoring tool in far off areas, leading to mortality and morbidity. Dr Trust USA paediatric finger oximeter is meant for children from 2 to 12 years of age. We evaluated its feasibility of application on middle finger and big toe and evaluated its efficacy and reliability in neonates by simultaneously applying the gold standard cardiac monitor and compared the results, with a mindset of extrapolating the results between the neonate to 2 years of age (6).

Material and methods

After obtaining approval from the Institutional Ethical Committee, a cross sectional study was done where Pulse oximetry of 100 normal newborns was done with Dr Trust USA Paediatric pulse oximeter. HR, SpO_2 and PI was measured by applying pulse oximeter on index fingers along with ring and index finger of both upper limbs and in big toe along with part of foot of newborn. Similar data was collected with Philips goldway GS20 2020 almost simultaneously and the results were compared. Term babies more than 37 weeks gestation were included irrespective of mode and place of delivery. Master sheet for data was prepared in Microsoft Excel. Statistical analysis was done on IBM Statistical Package for the Social Sciences (SPSS) 28.0.1 latest version to estimate the efficacy, feasibility and sensitivity of pulse oximeter. Paired t test was used for measuring response time. Heart rate, Oxygen saturation and Perfusion index was compared using Pearson correlation coefficient and scattered diagram.

Results

Characteristic	Distribution	Number & Percentage
SEX	Males	45
	Females	55
GESTATIONAL AGE	37- 38 Weeks	68
	39- 40 weeks	32
BIRTH WEIGHT	Less than 2000	1
	2000G – 2500G	17
	2500G – 3000G	55
	3000G – 3500G	17
	3500G – 4000G	9
	More than 4000G	1

Table: 1 – Demographics of neonates, numbers given are same as percentages as total subjects are 100

100 neonates were studied, maximum number of neonates were in weight band of 2500-3000gm (55%). Gestational age wise maximum number of neonates were between 37-38 weeks gestation (68%) with female preponderance. Male female ratio being 4.5: 5.5. Readings were recorded by applying cardiac monitor probe in all four limbs and compared with results of readings recorded with pulse oximeter junior. Feasibility was assessed by applicability record ability of pulse oximeter. 95% of subjects were within the age bracket of 72 hours. In 61% neonates probe could be applied in all four limbs and in rest of 39% it could not be applied. Out of these 39 probes, it could not be applied in any of the limbs in 20 and in rest 19 it could be applied partially, it was successful in 3 limbs in 10, 2 limbs in 7 and 1 limb in 2 babies with same percentage. Response time was recorded and it always took longer time for getting readings to display in pulse oximeter than cardiac monitor and the difference was highly significant statistically with a p value of <0.001 on paired t test. The minimum maximum range for response time by cardiac monitor was 24.18 - 24.90 seconds, whereas minimum time required for generation data was 35.85 and maximum 42.95 seconds for pulse oximeter. (Figure 1). Further data analysis was done for 61 cases only as pulse oximeter data was available for all 4 limbs in 61 cases only corresponding to the cardiac monitor data. Heart rate was showing positive correlation in between cardiac monitor and pulse oximeter in all four limbs, with a Pearson co- relation coefficient of 0.901 and P value 0.000 for right upper limb, 0.921 and 0.000 for left upper limb, 0.928 and 0.000 for right lower limb and 0.931 and 0.000 for left lower limb defining accuracy and sensitivity. Clinically the observed values were either same or differed by 1-2 (figure 2) Oxygen saturation showed good correlation in all four limbs with a Pearson co-relation coefficient of 0.683 and P value 0.000 for right upper limb, 0.685 and 0.000 for left upper limb, 0.527 and 0.000 for right lower limb and 0.501 and 0.000 for left lower limb defining accuracy and sensitivity. Clinically the observed values were either similar or differed by 1-3 % (figure 3) Perfusion index did not show a good correlation, it was quite variable in pulse oximeter with a mean value of 3-4 against a mean value of 1 on cardiac monitor with variability in decimals. On statistical analysis Pearson creation coefficient of 0.277 and p value of 0.032 was found for Right upper limb, 0.208 and 0.111 for left upper limb, 0.130 and 0.323 for right lower limb 0.130 and 0.323for left lower limb (figure 4)

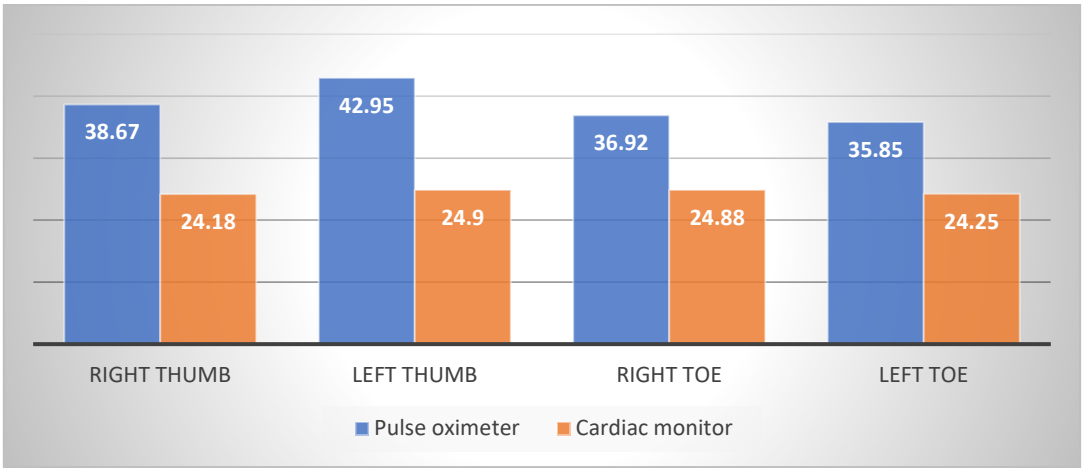

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Figure: 1- Response time of pulse oximeter versus gold standard cardiac monitor

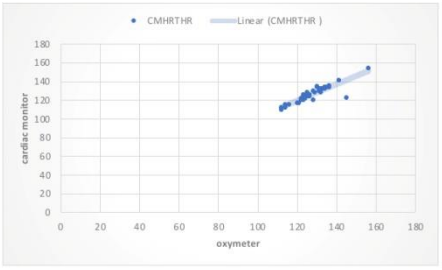

Chart A Cardiac monitor relation to oximeter with respect to heart rate in right thumb

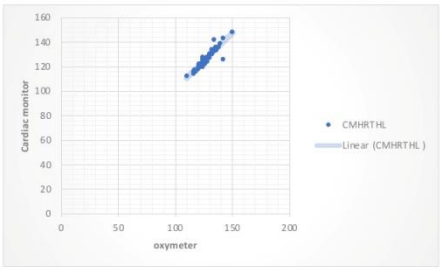

Chart B Cardiac monitor relation to oximeter with respect to heart rate in left thumb

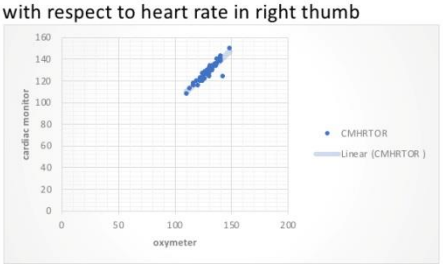

Chart C Cardiac monitor relation to oximeter with respect to heart rate in right toe

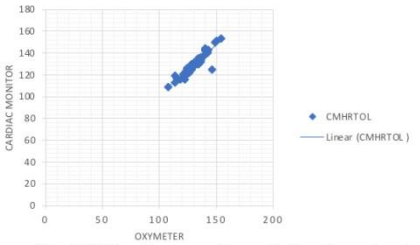

Chart D Cardiac monitor relation to oximeter with respect to heart rate in left toe

Figure: 2- Scatter diagram and correlation of cardiac monitor and pulse oximeter data for heart rate

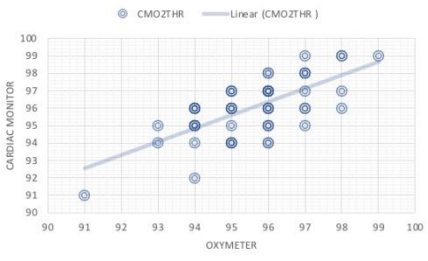

Chart A Cardiac monitor relation to oximeter with respect to oxygen saturation in right thumb

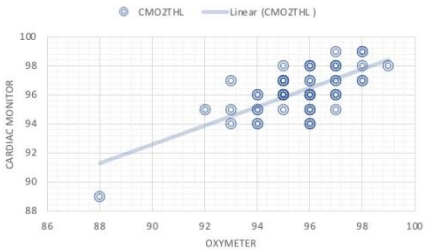

Chart B Cardiac monitor relation to oximeter with respect to oxygen saturation in left thumb

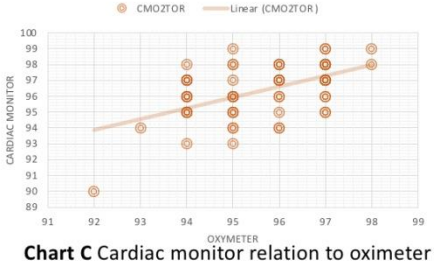

Chart C Cardiac monitor relation to oximeter with respect to oxygen saturation in right toe

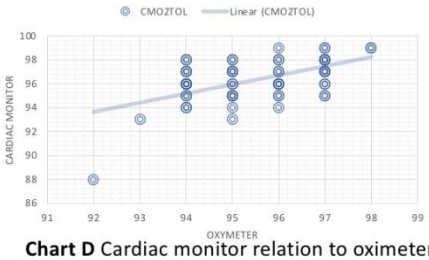

Chart D Cardiac monitor relation to oximeter with respect to oxygen saturation in left toe

Figure: 3- Comparison of pulse oximeter and cardiac monitor in reference to oxygen saturation

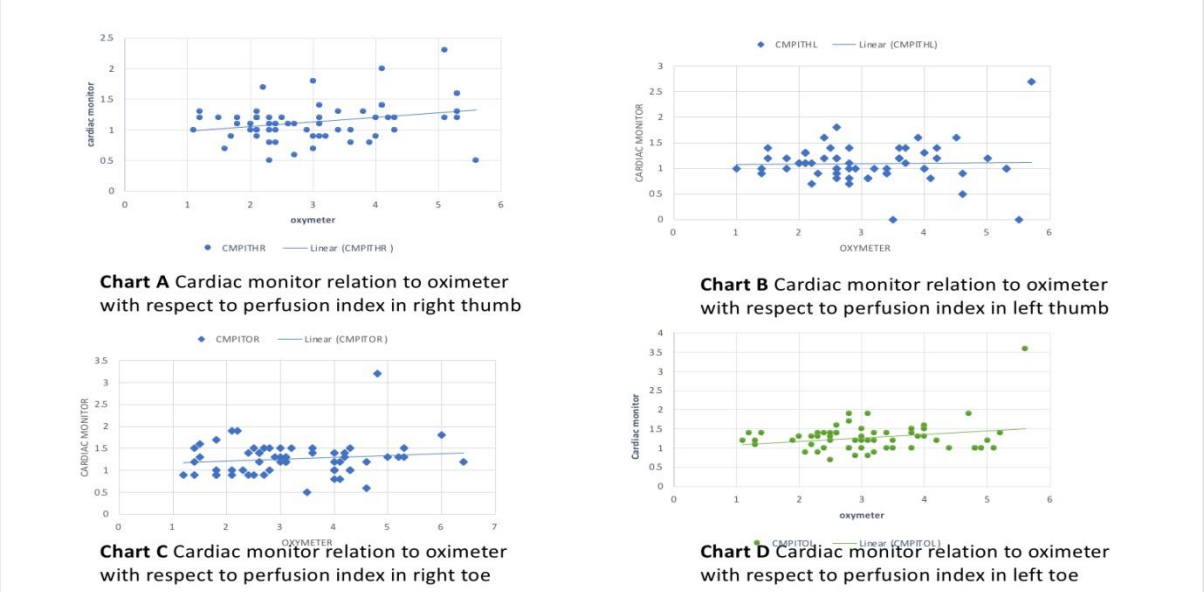

Figure:4- Comparison of pulse oximeter and cardiac monitor data in reference to perfusion index

Discussion

Finger pulse oximeter is a non-invasive method to measure vitals(7). It is also used where cardiac monitors are not available but its applicability in infants is not feasible as cardiac monitors are expensive, not portable and not available in low-income setups (8).Pulse oximeters are widely available for adults in post covid era. Pulse oximeters are now available for up to 2-3 years and older children also but less than 2 years the most vulnerable population including new-borns are deprived of this vital monitoring in most of the setups. This affects the detection of sick infants and children at appropriate time, who later present in serious condition. It also affects oxygen supplementation at the outset, if they are in need (9). In our study response time of cardiac monitor ranged between 24-25 seconds and was consistent in reading with a variability of less than 1second between different subjects, whereas pulse oximeter response time was definitely delayed with a highly significant difference statistically. It ranged between 35 to 43 seconds with a variability of 8 seconds between different subjects. This difference of about (11-18 seconds) in recording data may be statistically highly significant but clinically it hardly matters if we get a reliable data few seconds later at a peripheral setup, which helps in taking a medically indicated actions. Moreover, considering the huge difference in cost and portability one weighs over the other (8).This study focused on comparing applicability and feasibility with accuracy and sensitivity of child pulse oximeter which was designed for age 2years to 12 years in term neonates. Applicability or feasibility was 61% in our study. Main hindrance noticed for applicability was length of middle finger of new-born, which was not able to reach to cover the light emitting area in pulse oximeter and hence became unrecorded or inapplicable. we used middle finger the longest instead of traditional index finger for this reason only (4). Mizukoshi et al also confirmed middle finger gives the highest perfusion when compared (5). Study done by Hinkelbein and Ibrahim et al showed saturation in finger and toe shows similar results which was also seen in our study. In a study done by Aaron louie et al. used four types of pulse oximeters comparing them for their accuracy and reported that motion decreases the perfusion performance (10). In our study we also found that excessive mobility and crying of baby decreases the stabilisation and affects saturation as well as perfusion index. In our study, data collected from pulse oximeter gave clinically useful almost similar results about heart rate and oxygen saturation but perfusion index was not reliable. The slight variability in heart rate and SpO2 can be attributed to sequential process of application and variability in respiration of newborn. The perfusion index is a newer entity for newborns and there is paucity of data on this dynamic value, so we cannot say much about its clinical reliability or non-reliability but statistically it was found to be unreliable (8). The vulnerable group with nonavailability of a pulse oximeter is from 0-2 years. We targeted the lowest end of the age group that is new-born and that too 95% data was collected in first 72 hours of age. we therefore extrapolate if the feasibility

is 61 % in this age group when they are in an institution, the feasibility will definitely improve with increase in their size and length of finger later in infancy. Further studies are required in this direction.

Limitations of study: The study was conducted on a convenient sample of 100 subjects. It did not cover the whole age group of 0-2 years. The matched data for partial application was not analysed.

Conclusions:

Pulse oximeter (junior) can be used to at periphery to measure heart rate and oxygen saturation in new-borns almost accurately if it could be applied, but perfusion index measured is not reliable. If the reading is recorded, it can be used for clinical judgment like supplementation of Oxygen, or immediate referral etc. as an aid to other clinical parameters.

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