



# Efficacy of Pulse Co-oximeter in Hemoglobin Estimation: A Non Invasive Method

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## ABSTRACT

**Background:** Total Hemoglobin(Hb) measurement is one of the most common and important parameter that is investigated in the laboratory. This non invasive method allows pain free continuous online patient monitoring with minimum risk of infection and facilitates real time data monitoring allowing immediate clinical reaction to the measured data. The objective of the study is to test the efficacy of pulse co-oximeter .

**Methods:** Present study is a prospective comparative study. A total of 261 patients enrolled for the study after their consent. Non invasively measured SpHb values and invasively measured Hb values were then compared by using Bland Altman statistical analysis .

**Result:** Pulse co-oximeter recorded/displayed SpHb in 90.8% patients and did not display SpHb in 9.2% of patients. Out of which 73-75% patients Hb showed variation of less than or equal to 2gms and 20-24% patients Hb showed variation of more than 2 gms. On Bland Altmann comparative analysis of SpHb and Hb revealed bias and limits of agreement was 0.2+3.3gm/d and 95% of the measurements fell within two standard deviation of the mean difference and P value < 0.001 represents good correlation between SpHb and Hb of Lab1 and Lab 2.

**Conclusion:** Pulse co-oximeter can be used as a screening tool for Hb measurement . It determines Hb instantly and non invasively with 73-75% of the values show variation of less than or equal to 2gms. Further studies are needed to determine financial aspects and needs upgradation in terms of accuracy of the instrument.

**Keywords:** Pulse Co-oximeter, Non Invasive Method, Bland Altmann Analysis

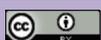
## Introduction

Hemoglobin(Hb) can be measured on a variety of devices using different principles of operation. Non invasive pulse co-oximeter represents the latest development in hemoglobin measuring technology. The technology uses principles similar to pulse oximetry in measuring total hemoglobin, oxyhemoglobin, carboxyhemoglobin and methhemoglobin. The pulse oximeter works by illuminating light into the tissues and sensing the amount of light absorbed. The same methodology is used by laboratory hemoglobinometers to measure hemoglobin concentration. Because both devices work in the same way, efforts were made to modify the pulse oximeter to also measure hemoglobin concentration. Currently there are two commercial pulse co-oximeters (Masimo Rainbow SET and OrSense NBM-200MP) that measure total hemoglobin concentration and one (Masimo) that also measures methemoglobin and carboxyhemoglobin<sup>[1]</sup>. The technology is noninvasive and provides continuous monitoring in comparison to invasive and discrete techniques used in other methods, pulse co-oximeter purportedly provides an advantage in patient care. In present scenario invasive methods are used to measure the Hb concentration, Hb measurement using an automated

analyzer in a clinical laboratory is the gold standard method<sup>[2]</sup>. Apart from the discomfort of ejecting blood samples an added disadvantage of this method is delay between blood collection and its analyses which does not allow real time patient monitoring in critical situations. The purpose of this research is threefold: a) To study accuracy of pulse co-oximeter (Masimo Rainbow SET) by comparing its results with hematology analyzer b) To review the various underlying principles used in measuring Hb c)To discuss issues in implementing pulse co-oximeter into a laboratory or hospital

## Materials and Methods

The present study is a prospective comparative study done over a period of two months during October and November 2016. The study was conducted in central laboratory district hospital VIMS Ballari. After approval from ethical committee VIMS, informed consent was obtained from patients prior to their enrollment. On the basis of previous study performed by Allard<sup>[3]</sup> et al, we did hemoglobin estimation on 261 patients by pulse co-oximeter(SpHb), Lab1-central lab Sysmex hematology analyzer(Hb) and Lab 2-Medall laboratory hematology analyzer(Hb). SpHb estimation by pulse co-oximeter was done while subjects were quiet and sitting upright. Sensor



of pulse co-oximeter was covered with an opaque shield to prevent optical interference.

Immediately following the noninvasive testing, a venous blood sample was obtained by venipuncture of the median cubital vein of the non dominant arm with a disposable syringe and then transferred to 2ml vacuum tube containing EDTA. Venous blood samples were transported at room temperature and analyzed for reference hemoglobin value with Lab1-central laboratory Sysmex hematology analyzer and Lab 2-Medall laboratory hematology analyzer as per clinical and Laboratory Standard Institute guidelines and manufactures directions for use with in 24 hr of collection. The laboratory analyzer was calibrated daily as per the manufacturer's recommendations and good laboratory practice.

This newly developed pulse co-oximeter (Masimo Rad 57) is an optical sensor system uses multiple wavelengths of light for Hb measurement [2]. The Hb sensor developed for this research is fully integrated into a wearable finger clip. The devise is based on technology known as occlusion spectroscopy which uses an optical measurement platform combined with a ring shaped pneumatic probe that fits on the finger [3] (Figure 1).

**Statistical Analysis:** Statistical analysis was performed to determine the relationship between SpHb and the standard laboratory Hb. We calculated the correlation coefficient (r) and coefficient of determination (r<sup>2</sup>). Agreement between the laboratory Hb and SpHb was evaluated as described by Bland and Altman [5]. The accuracy of the SpHb compared with that of the laboratory Hb was calculated using the accuracy root mean square (ARMS) with the formula Square root of( mean bias square + SD square) [6,7]. All statistical analysis was performed with SPSS Version 19.0, with the statistical significance set at P<0.005.

## Results

Conducted prospective study on 261 out patients visiting laboratory for routine hemoglobin estimation . Patients

belonged to varied age group and males were 70.9%, females were 29.1%. Hb estimation was done by 3 different methods on 261 patients

- 1) SpHb by pulse co-oximeter (Masimo)
- 2) Lab1- central lab district hospital by sysmex hematology analyzer
- 3) Lab 2- Medall lab hematology analyzer

These 3 different methods were compared and statistically analyzed. Among 261 patients pulse co-oximeter did not record SpHb values in 24 patients. Pulse co-oximeter can record/display SpHb in 90.8% patients and did not display SpHb in 9.2% of patients due to unknown reasons. Hence a total of n=237 cases were statistically analyzed and 24 patients were excluded from the study. On comparison of SpHb values with Hb of lab1, variation of less than or equal to 2gms is seen in 75% of patients and variation of more than 2gms is seen in 20% patients(Table 1). On comparison of SpHb values with Hb of Lab2, variation of less than or equal to 2gm was seen in 73% patients and more than 2gm in 24.1% patients(Table 2).

The mean laboratory Hb value was  $11.9 \pm 2$  for lab 1 and  $11.5 \pm 2.1$  for lab 2, mean SpHb was  $12.1 \pm 2.1$  which is greater than lab1 and lab 2(Table 3). The correlation coefficient (r) was 0.588(Figure 2) and 0.616 for lab1 and 2 against SpHb and the p value < 0.001 represents good correlation between SpHb and Hb of Lab1 and Lab 2(Table 4). The calculated coefficient of determination (r<sup>2</sup>) was 0.58%. To assess the agreement between the laboratory analyzer and the pulse cooximetry a Bland Altman plot was applied(Figure 3). The bias and limits of agreement was  $0.2 \pm 3.3$ gm/d, using this method 95% of the measurements fell within two standard deviation of the mean difference. The high accuracy(Low ARMS-Accuracy root mean square) was obtained for hemoglobin levels less than 12gm/dl with an ARMS of 2.52gm/dl. For hemoglobin between 12-18gm accuracy was low with an ARMS of 4.5.

**Table1: Comparison of SpHb(Pulse co-oximeter) with Hb of Lab1(Sysmex analyzer).**

Hemoglobin	Percentage of patients
Difference of >2gms	20%
Difference of $\leq$ 2gms	75%
Both showed same values	4.2%

**Table 2: Comparison of SpHb(Pulse co-oximeter) with Hb of Lab 2(Medall laboratory analyzer).**

Difference of >2gm	24.9%
Difference of $\leq$ 2gm	73%
Both showed same values	2.1%

**Table 3: Showing Standard deviation of SpHb, Hb of Lab 1 and Lab2.**

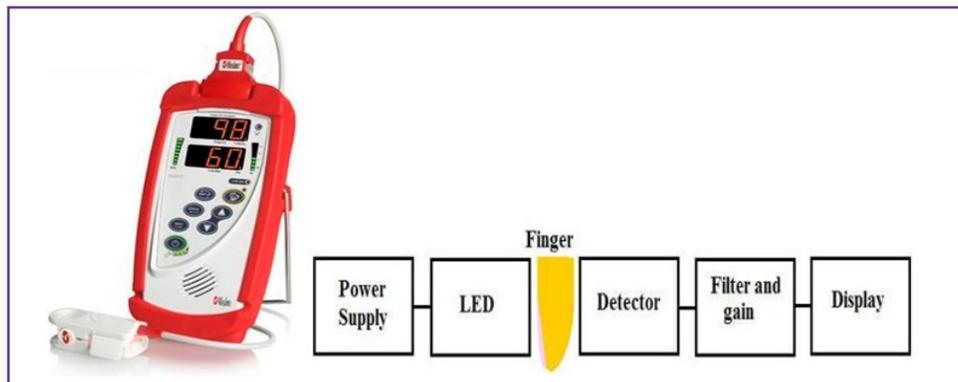
	Mean	SD	Number
SpHb	12.1	1.39	237
Hb Lab1	11.9	2.0	237
Hb Lab2	11.5	2.1	237

**Table 4: Showing correlative values of SpHb, Lab1, Lab2.**

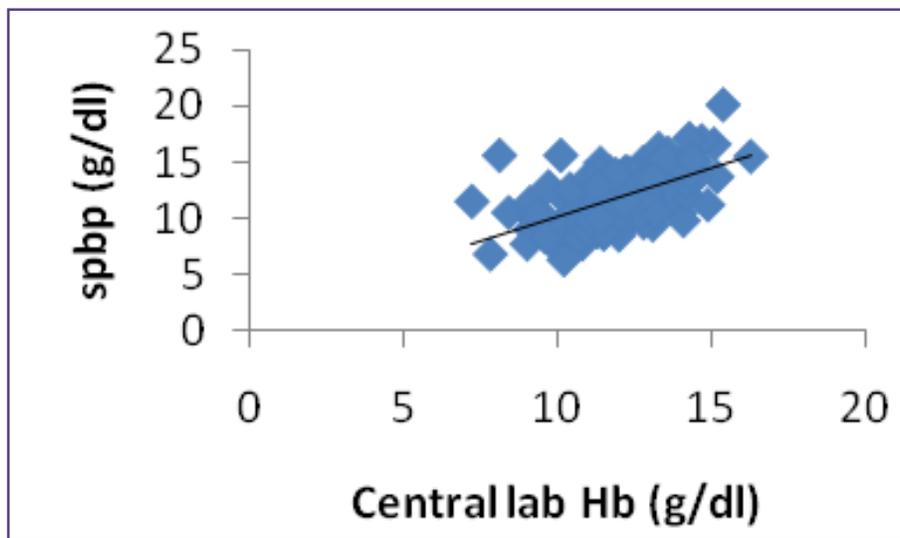
Correlation Values among the Hb of Lab1 and Lab2 with SpHb			
Methods	R	R2	P value
Lab 1	0.589	0.347	<0.001
Lab 2	0.618	0.382	<0.001

**Table 5: Showing different studies and their Bias values.**

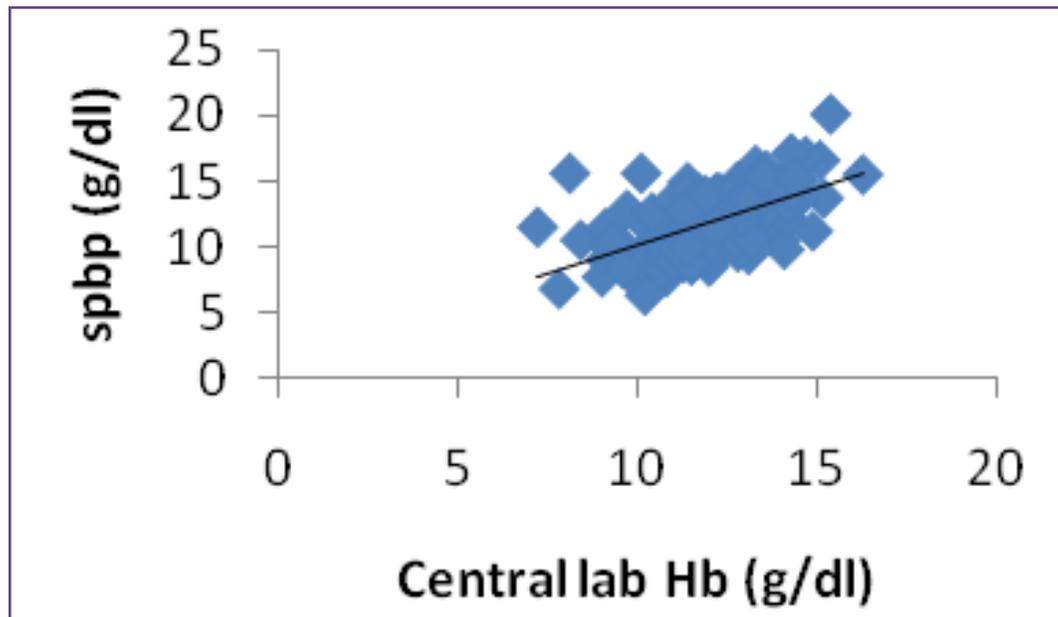
	Number of cases	Bias
Weinstein et al <sup>12</sup>	710	0.03
Hadar et al <sup>13</sup>	63	0.1
Vora et al <sup>14</sup>	76	0.2
Macknet et al <sup>8</sup>		0.15
Present study	237	0.2



**Fig. 1: Pulse Co-oximeter Masimo Rad 57 with displa, figure probe measures SpHb non invasively and basic block disgram<sup>4</sup>.**



**Fig. 2: Scatter plot of hemoglobin values measured by hematology analyzer (lab 1) and pulse co-oximeter. (Correlation coefficient r =0.588).**



**Fig. 3: Bland Altman representation of comparison analysis between hemoglobin measurement by pulse co-oximeter and hematology analyzer (Lab1). The bias(solid line, 0.2) and the limits of agreement (dotted line, bias+1.96SD) are represented on the graph.**

### Discussion

The accuracy of pulse co-oximeter device in measuring Hb was first evaluated in 2007 by Macknet et al<sup>[8]</sup>, SpHb provided clinically acceptable accuracy compared with the laboratory Hb and they were well correlated. In addition there were several reports suggesting that the SpHb was significantly correlated with the laboratory Hb during surgical procedures with substantial blood loss<sup>[9,10]</sup>. The present study revealed that noninvasive SpHb measurement with pulse co-oximetry was significantly correlated with laboratory measurement of Hb.

In 1996, the SET (Signal Extraction Technology) was introduced by Masimo (Irvine, CA) to increase the accuracy of 2 wavelength pulse oximetry under motion and low perfusion conditions<sup>[11]</sup>. Masimo's Rainbow SET technology was later introduced (addition of numerous wavelengths) to measure total Hb, COHb, and MetHb concentrations: CO-Hb in 2005, MetHb in 2006, and noninvasive Hb (SpHb) in 2008<sup>[8]</sup>. It measures SpHb using up to 12 wavelengths. Studies have been published evaluating the performance of the Rainbow SET in measuring SpHb relative to laboratory co-oximeters. The Bland-Altman bias and precision analyses are used to compare 2 technologies. Bias is the mean of the measurement differences between methods, and describes systematic error between measurements (i.e., how closely do results of a new monitor compare to measurements in the

laboratory (Table 5). The limits of agreement are defined as the differences between two methods approximately 95% of the time. The clinically acceptable limits of agreement depend on the variable of interest, the accuracy of the reference standard and what matters clinically.

Nicholas et al<sup>[15]</sup> studied twenty seven newborn with weight less than 3000 gms. His study showed good correlation between SpHb and tHb ( $r=0.75$ ,  $p=0.0001$ ). The bias and precision for the Hb and SpHb values were  $0.10 \pm 1.56$ g/dl. A study by Van Woerkom et al<sup>[16]</sup> using a diffuse optical spectroscopy instrument demonstrated a reliable correlation between tissue haemoglobin and venous haemoglobin before and after a red blood cell transfusion in preterm infants. Torp et al ( $n=471$ ) tested the correlation between the Beckman Coulter lab analyzer and the co-oximeter, he found the correlation between the two devices to be  $0.93(r)$  with a bias of  $0.97$ g/dl.

Beyond the accuracy of SpHb measurement, another concerning issue is the frequency of events where the SpHb monitor did not yield data at all or yielded data of low quality. In present study it did not record SpHb in 9.2% patients. In his study, Macknet<sup>[8]</sup> reported the inability to measure SpHb in 2.4% of the SpHb measurements. Gayat et al<sup>[17]</sup> estimated failure rate to be about 9% (although the investigators of this study did not adhere to the manufacturer directions or use in the conduct of the

study). Miller [18] noticed reduced accuracy when the pulse oximeter indicated a low perfusion index. This finding is supported by Gayat et al [17] study where low blood pressure was associated with reduced accuracy. Similar to pulse oximetry, pulse co-oximetry is susceptible to measurement error from the following sources: ambient light interference, low peripheral perfusion, motion artifact, incorrect sensor positioning, nail polish [19]. Shielding around the finger probe or photodetector helps to minimize this interference. If there is no detectable peripheral pulsation, the pulse co-oximeter cannot function. Hypotension, cold extremities and severe vascular disease are all factors that reduce peripheral pulsations [19]. The association between monitor accuracy and peripheral perfusion should not be a surprise, because all pulse oximeters fail to some degree when the patient is peripherally vasoconstricted or hypotensive.

Pulse co-oximeters are good alternate toward reducing iatrogenic blood loss by venipuncture to obtain a blood count. Other drawbacks of traditional method are painful needle stick operational inefficiency, delayed Hb results, potential injury to patient. Additional studies to establish whether the use of this method will potentially reduce iatrogenic blood loss are required. Pulse co-oximeter is a costly instrument and studies are needed to compare both methods on financial perspective also.

Noninvasive pulse co-oximeters are classified as monitoring devices by the FDA (Food and drug administration) and subsequently do not fall under the CAP (College of American pathologist) and CMS (Centre for medicad services) accreditation of laboratory medicine. Like pulse oximeters, these devices use either a disposable or reusable finger probe. The reusable or "reposable" finger probes are guaranteed for approximately 500 uses. Preventative maintenance is carried out annually using a simulator to verify performance. Routine quality control is not necessary. The device can be operated by a respiratory therapist, registered nurse, certified nursing assistant, or doctor.

## Conclusion

Pulse co-oximeter can be best used as a screening tool for Hb measurement at out patient departments, blood camps, casualty, ICU and labor rooms. It determines Hb instantly and non invasively. Further studies are needed to determine financial aspects and needs upgradation in terms of accuracy of the instrument.

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