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HOW ACCURATE IS THE PULSE OXIMETRY READING IN AN INTENSIVE CARE SETUP?

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ABSTRACT

The pulse oximeter remains a valuable tool in the care of intensive care patients, but an awareness of its limitations is important in enhancing the quality of intensive care. We tried to determine the accuracy of pulse oximeter among Systemic Inflammatory Response Syndrome (SIRS) patients in the presence of various factors and also the reliability of predicting SaO_2 from subsequent SpO_2. Accuracy was analyzed by Bland-Altman analysis. Bias was found to be 2.5%. Subgroup analysis revealed hypoxia and acidosis significantly altered pulse oximeter accuracy. Regression analysis was done to assess reliability of predicting SaO_2 from subsequent SpO_2. Fluctuations in SpO_2 to SaO_2 difference indicated that SaO_2 could not be reliably predicted from SpO_2 after a single ABG analysis. A SpO_2 above 93% appears necessary to ensure a SaO_2 of 90%.

KEY WORDS: Pulse oximeter, SIRS, accuracy, SpO_2, SaO_2

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INTRODUCTION

Pulse oximeter is a device, routinely used for non-invasive monitoring of oxygen saturation (SpO_2) of patients. It is based on photoplethysmographic pulses in two wavelengths, especially in red and infrared regions. The calibration of these signals is performed by measuring the oxygen saturation from arterial blood (SaO_2) by an arterial blood gas (ABG) analyzer simultaneously[1]. Commercial pulse oximeters seem to have an accuracy of around 2% evaluated by the differences between SpO_2 and SaO_2, measured especially among healthy subjects[2]. Systemic inflammatory response syndrome (SIRS) is a frequently encountered complication seen in patients admitted in intensive care units (ICU) and remains as a common cause of mortality in ICUs. The accuracy of pulse oximeter may vary among SIRS patients due to the presence of various micro-circulatory derangements among them[3]. Accurate assessment of SpO_2 value in these patients actually helps in decreasing the likelihood of hypoxia and also helps in better patient management especially those who are mechanically ventilated. With this in mind, the main objective of our study was to evaluate the accuracy and precision of pulse oximetry among critically ill systemic inflammatory response syndrome (SIRS) patients, and also various factors which can potentially contribute to inaccurate SpO_2 readings among them. We also tried to determine whether an initial SpO_2 and SaO_2 difference could be used for prediction of SaO_2 in subsequent measurements.

MATERIALS AND METHODS

The study was conducted for a period of one year from Jan 2014 to Dec 2014 at a tertiary care hospital in south India after getting approval from the Institutional Scientific and Ethical committee. The study sample involved a retrospective cohort that included patients admitted in the Intensive Care Unit (ICU) of age more than 18 years having SIRS as defined by ACCP/SCCM guidelines (Table I)[4]. Patients were excluded if they had signs of left atrial hypertension, congestive heart failure and etiologies of non-septic acute lung injury like pancreatitis, aspiration pneumonia, or traumatic pulmonary contusion. For each selected patient, an arterial sample was drawn from femoral artery and the finger probe of the pulse oximeter was placed on the same side. After waiting for stable plethysmographic waveform, the SpO_2 value was recorded using Comet plus pulse oximeter from Skanray Healthcare. Same probe was used for measurements from all the patients. Arterial oxygen saturation (SaO_2) was measured using GASTAT 600 blood gas analyzer, Techno Medica, from Japan. Hemoglobin concentration (g/dl) and pH were also recorded for each sample. For patients requiring multiple ABGs, subsequent data points were collected during their ICU stay.

Table I

Definitions of Systemic inflammatory response syndrome according to American College of Chest Physicians/ Society of Critical Care Medicine (ACCP/SCCM) guidelines

Systemic inflammatory response syndrome (SIRS) The systemic Inflammatory response to a variety of severe clinical insults. The response is manifested by two or more of the following conditions: (1) temperature >38° C or <36° C; (2) heart rate >90 beats per minute; (3) respiratory rate >20 breaths per minute or $PaCO_2$, <32 mm Hg; and (4) white blood cell count >12,000/cu mm, <4,000/cu mm, or >10% immature (band) forms
Sepsis The systemic response to infection Manifested by two or more of the following conditions as a result of infection: (1) temperature >38° C or <36° C; (2) heart rate >90 beats per minute; (3) respiratory rate >20 breaths per minute or $PaCO_2$, <32 mm Hg; and (4) white blood cell count >12,000/cu mm, <4,000/cu mm, or >10% immature (band) forms
Severe sepsis Sepsis associated with organ dysfunction, hypoperfusion, or hypotension. Hypoperfusion and perfusion abnormalities may include, but are not limited to lactic acidosis, oliguria, or an acute alteration in mental status.
Septic shock Sepsis-induced with hypotension despite adequate fluid resuscitation along with the presence of perfusion abnormalities that may include, but are not limited to, lactic acidosis, oliguria, or an acute alteration in mental status.
Multiple organ dysfunction syndrome(MODS) Presence of altered organ functions in an acutely ill patient such that homeostasis cannot be maintained without intervention.

STATISTICAL ANALYSIS

Data was analyzed using SPSS software 16.0 version for windows. The primary analysis was performed using Bland and Altman analysis. Bias and the limits of agreement were calculated. Bias (inaccuracy), or systematic error, was determined by the mean difference between SpO_2 and SaO_2, whereas imprecision, or random error, was determined by the standard deviation of the mean difference. Positive bias means that pulse oximetry overestimates SaO_2 and negative bias means that it is underestimated. The limits of agreement were the mean difference ± 2SD. The accuracy was also mentioned as 'Root Mean Square' value (A_{rms}) which reports accuracy as a function of both bias and imprecision. It was calculated by square root of the sum of squares of bias and precision**.** Stratified analyses were performed to investigate contributions of hypoxemia (as estimated by a SaO_2 <90%), acidosis (pH<7.36) and decreased hemoglobin levels to the bias and imprecision. A hemoglobin value of less than 25th percentile of our study sample was taken as lower cut-off to assess the role of decreased hemoglobin in contributing to the bias. Parametric data were reported as means with standard deviations (SD) and non-parametric data as medians with inter-quartile ranges (IQR). Means were compared between two independent groups by Student's *t* test and more than two groups by One way Analysis of Variance (ANOVA). A *P*-value of ≤ 0.05 was considered statistically significant. The reproducibility of the difference between SaO_2 and SpO_2 was analyzed graphically using linear regression analysis. For this 15 patients were selected with more than two ABG readings and the first three data points of SaO_2 and SpO_2 were considered. Three SpO_2-SaO_2 differences were taken and were represented as Δ1, Δ2 and Δ3 in chronological order. Two graphs were constructed, the first represents Δ2 (y-axis) versus Δ1 (x-axis) and second Δ3 (y-axis) versus Δ2 (x-axis).

RESULTS

A total of 158 critically ill patients admitted in intensive care unit for more than 24 hours were included in our study. Out of 158 patients 88 (56%) were classified as sepsis patients (38 sepsis, 32 severe sepsis, 18 septic shock patients) and 62 (39%) patients as patients with non-infectious SIRS condition. 8 (5%) patients had multiple organ dysfunction syndrome. 30 (19%) of the 158 patients had succumbed to death in ICU. Table II summarizes the baseline characteristics of all the patients included in our study. Mean age of included patients was 62 years with 63% of male patients and remaining 37% females. Median APACHE II score was 19 for all the selected patients.

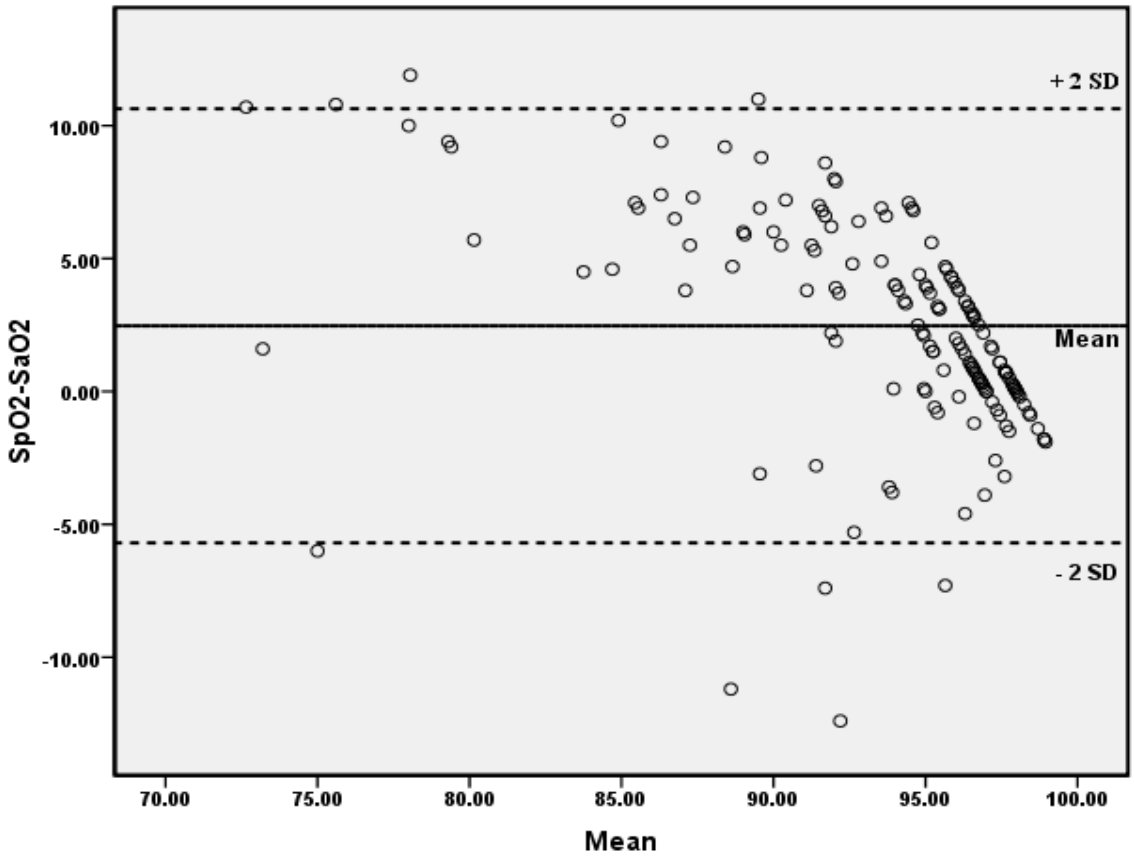
Table II
Summary of general characteristics of patients

Variable	n = 158	Range
Age (Years) Mean ±SD	62 ± 14	20-95
Sex (Males) n (%)	63	NA
pH Mean ±SD	7.36 ± 0.15	6.89-7.58
pCO_2 (mmHg) Mean ±SD	39.9 ± 21.2	7.50-126.60
pO_2 (mmHg) Mean ±SD	83.7 ± 40.5	37.00-330.60
SaO_2 (%) Mean ±SD	92.2 ± 6.6	67.30-99.90
SpO_2 (%) Mean ±SD	94.7 ± 4.8	72.00-98.00
HCO_3 Mean ±SD	21.7 ± 8.9	1.40-59.60
Hemoglobin (mg/dL) Median (IQR)	11.7 (9.6-14.1)	4.60-19.60
APACHE II score Median (IQR)	19 (18-22)	14-32

IQR – Interquartile Range at 25th and 75th percentile; SD – Standard deviation ; APACHE II – Acute Physiology and Chronic Health Evaluation II score ; SpO_2: Pulse oximeter Oxygen saturation ; SaO_2: Arterial oxygen saturation; HCO_3: Bicarbonate; PO2: Partial pressure of Oxygen; PCO2: Partial pressure of carbon dioxide

The mean ± SD of SaO_2 was 92.2% ± 6.6% and that of SpO_2 was 94.7% ± 4.8%. Bland-Altman analysis indicated a bias of 2.5% with limits of agreement -5.7% and 10.7% (Figure I). Accuracy and precision of pulse oximeter saturations at different SaO_2 are summarized in Table III. Pulse oximeter values were most accurate for arterial oxygen saturations of 95% or more (Bias = -0.4%, imprecision = 2.5%, A_{rms} = 2.5%). As the SaO_2 values decreases, the bias of the pulse oximeter readings significantly increases, and have recorded the highest bias at SaO_2 value of <80% (Bias = 7.4%, Precision = 5.6%, A_{rms} = 9.3%) (Table III). The imprecision however remained almost constant even upto 80% of SaO_2.

Figure I
Bland-Altman analysis for Bias (accuracy) and limits of agreement of Pulse Oximeter



n = 158; Bias = 2.5%; Precision = 4.1%; A_{rms}* = 4.8%; Limits of Agreement = -5.7% to 10.7%
A_{rms} – Accuracy as Root Mean Square (calculated by square root of the sum of squares of bias and precision)

Table III
Bias and imprecision across various arterial oxygen saturation values

Arterial Oxygen Saturation (SaO_2) (%)	N	Bias (%)	Precision (%)	A_{rms} (%)*
>95	72	-0.4	2.5	2.5
90-94	45	3.1	3.0	4.3
85-89	20	6.3	1.4	6.5
80-84	11	7.2	2.0	7.5
<80	10	7.4	5.6	9.3

**** A_{rms} – Accuracy as Root Mean Square (calculated by square root of the sum of squares of bias and precision)***

Table IV summarizes the differences in the accuracy and precision of pulse oximetry oxygen saturations between noninfectious SIRS patients, patients with sepsis and the patients having multiple organ dysfunction syndrome. The inaccuracy was highest for patients having multiple organ dysfunction syndrome (4.9%) and highest imprecision was seen in patients with sepsis (4.6%). The mean difference of bias between these three groups was not found to be significant at 5% level (f = 2.12; p = 0.123). A gradual increase in the total error is observed from noninfectious SIRS condition to sepsis and multiple organ dysfunction syndrome.

Table IV
Pulse Oximeter bias and imprecision values among noninfectious SIRS, sepsis patients and patients with multiple organ dysfunction syndrome

Condition	n	Bias (%)	Imprecision (%)	A_{rms}*** (%)
Noninfectious SIRS	62	2.8	3.3	4.3
Sepsis	88	2.0	4.6	5.0
MODS	8	4.9	3.7	6.1
F value*		2.12		
p value**		*0.123*		

One way Analysis of Variance (ANOVA) was done to test the differences of mean between groups
****p value <0.05 considered statistically significant***
***** A_{rms} - Accuracy as Root Mean Square (calculated by square root of the sum of squares of bias and precision)***

The effects of hypoxia (SaO_2<90%), acidosis (pH<7.35) and anemia (Hemoglobin less than 25th percentile of the values taken) on precision and accuracy of pulse oximeter were summarized in Table V. The minimal A_{rms} value was found among patients without hypoxia (3.3%). In case of hypoxic patients A_{rms} value reached as high as 7.4%. But in both the groups, the imprecision remained more or less the same. A similar trend is seen in patients with decreased hemoglobin and acidosis. We defined this difference in bias among the three subgroups of patients statistically using *t*-test for further analysis. Results are summarized in Table VI. The bias among hypoxemic patients was 6.8% in comparison with the patients without hypoxia (0.9%), with a significant difference among them (p < 0.001). Likewise, patients with acidosis showed a significantly higher bias of 3.4% compared to the patients without acidosis (1.9%) (p = 0.03). The accuracy of pulse oximeter does not seem to get affected in patients with less than 25th percentile of median hemoglobin. Results of linear regression analysis of 15 patients with subsequent SaO_2 and SpO_2 readings were shown in Figure II and Figure III. Both Δ1 versus Δ2 as well as Δ2 versus Δ3 did not show any significant correlations among them ($R^2_{\Delta1-\Delta2}$: 0.171; p = 0.125, $R^2_{\Delta2-\Delta3}$: 0.215; p = 0.082)

Table V
Pulse Oximeter bias and imprecision values in various subgroups of SIRS patients

Parameter	Subgroup	N	Bias (%)	Imprecision (%)	A_{rms}** (%)
SaO_2 (%)	>90	117	0.9	3.2	3.3
	<90	41	6.8	3.0	7.4
pH	>7.35	100	2.0	3.6	4.1
	<7.35	58	3.4	4.6	5.7
Hb(g/dL)***	>9.6	114	2.4	4.0	4.7
	<9.6	44	2.6	4.3	5.0

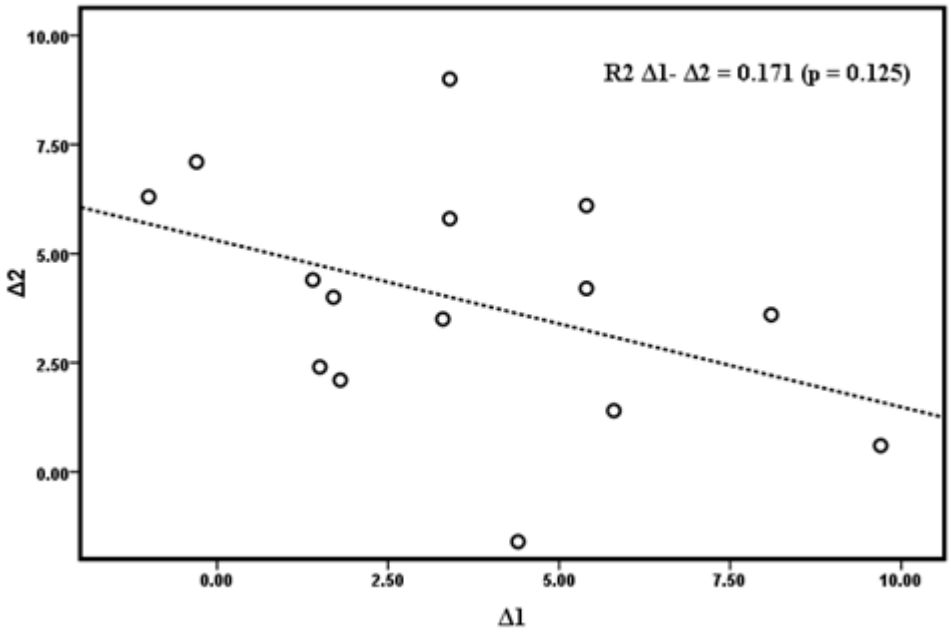
p<0.05 is considered statistically significant
****** A_{rms} – Accuracy as Root Mean Square (calculated by square root of the sum of squares of bias and precision)***
******* 9.6 g/dL was the 25th percentile of hemoglobin concentration present among total patients included in our study***

Table VI
Comparison of inaccuracy (bias) of Pulse Oximeter in various subgroups of SIRS patients

Parameter	Subgroup	n	Bias (%)	*p*	Limits of Agreement
SaO_2 (%)	>90	117	0.9	<0.001*	-5.5 to 7.3
	<90	41	6.8		0.8 to 12.8
pH	>7.35	100	2.0	0.037*	-5.2 to 9.2
	<7.35	58	3.4		-5.8 to 12.6
Hb(g/dL)**	>9.6	114	2.4	0.585	-5.6 to 10.4
	<9.6	44	2.6		-6.0 to 11.2

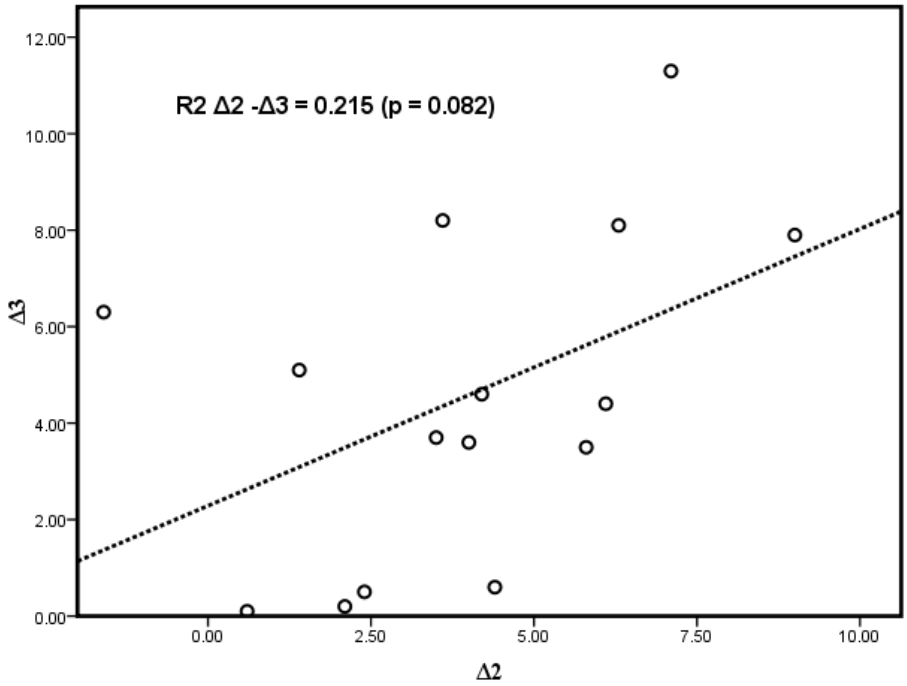
p<0.05 is considered statistically significant
****** 9.6 g/dL was the 25th percentile of hemoglobin concentration present among total patients included in our study***

Figure II
Relationship of changes in SaO_2 and that of SpO_2 between first and second repeated readings (n = 15)



Δ1 – Difference between 1st SpO_2 and SaO_2 reading
Δ2 – Difference between 2nd SpO_2 and SaO_2 reading

Figure III
Relationship of changes in SaO_2 and that of SpO_2 between second and third repeated readings



Δ2 – Difference between 2nd SpO_2 and SaO_2 reading
Δ3 – Difference between 3rd SpO_2 and SaO_2 reading

DISCUSSION

The main aim of this study was to find the accuracy and precision of pulse oximeter among critically ill patients and to assess various factors among them, which can contribute to inaccurate SpO_2 readings. We also tried to find whether subsequent SaO_2 can be predicted from initial SpO_2-SaO_2 difference for the same patient. Our results have shown that the overall bias of pulse oximeter was 2.5%, with limits of agreements ranging from -5.7% to 10.7%. Pulse oximeter saturations were most accurate when the arterial oxygen saturation was

greater than 95% among critically ill. There was no significant difference in bias between the noninfectious SIRS condition, sepsis and multiple organ dysfunction syndrome although the total error was increasing gradually between these groups. Compared to imprecision, it is the bias value which gets significantly affected due to hypoxia and acidosis. Arterial oxygen saturation could not be reliably predicted from pulse oximeter saturation after single ABG measurement. Accuracy of pulse oximeter readings among critically ill patients have so far revealed conflicting results. A retrospective study done by Lee et al[5] among 664 emergency department patients has showed that SpO_2 values actually overestimated SaO_2 values if $CO_{Hb} \geq 2\%$. Studies done by Seguin et al[6] and Wilson et al[7] have also shown that SpO_2 values actually overestimated SaO_2 values by more than 2%. Ironically, some studies have found the opposite that is an underestimation of SpO_2 values with a bias ranging from -1.4% to 2.7% compared to SaO_2 [8, 9]. These wide range of discrepancies may be partially due to the use of different pulse oximeters for each study, as bias is found to be oximeter specific[10]. Inaccuracies in the pulse oximeter readings were due to sepsis induced arteriolar dilation[3] which results in pulsatility being transferred to capillary beds. This, in turn increases venous pulsatility. As the pulse oximeter analyses the pulsatile component of absorption, it will incorporate a systematic error potentially increasing the bias[9]. The lower oxygen saturation in the venous blood potentially could dilute the arterial fraction which may further lead to underestimated SaO_2 values. This, probably is the reason for higher SpO_2 values compared to SaO_2 values in our study. The positive bias of pulse oximeter was found to be the least when the arterial oxygen saturation was more than 95% in our study. Our data also confirms the detrimental effects of hypoxia and acidosis on bias of pulse oximeter with A_{rms} increasing as high as 7.4% and 5.7% in these states respectively. These finding are consistent with the studies done previously by Wilson et al[7] and Van de Louw et al[8]. One possible explanation for this increased bias is due to the lack of reliable human calibration data during extreme hypoxic and acidotic states[11]. There is an increased proportion of reduced hemoglobin in the hypoxic state which increases the error in the absorption ratio, in turn contributing to the bias[12]. It has to be noted that the algorithms incorporated in the pulse oximeter for in vivo analysis of hemoglobin saturation in whole blood will only be tested under physiological conditions and its validity outside the physiological range like hypoxia and acidosis cannot be relied upon[13]. In case of anemia, progressive reduction in the hemoglobin concentration increases the signal to noise ratio from surrounding tissues which can potentially reduce the precision[14]. However the anemic end point where pulse oximetry becomes inaccurate has not yet been established. Various studies have reported cases in which pulse oximeter remained precise even at hemoglobin concentrations at the ranges of 2.7g/dL and 3.0g/dL[15- 17]. Anemia (Hemoglobin value less than 25th percentile of our study population) had only a minor impact on precision and accuracy of measurements using pulse oximeter in our study. It would be valuable to know whether subsequent SaO_2 can be measured from a single SpO_2 measurements to minimize the use of invasive technique. Reason behind considering this is the fact that hypothetically, the factors which might interfere with accuracy of pulse oximetry like skin colour, finger size, carboxyhaemoglobin, methaemoglobin remains fairly constant in the same patient. A study done by Perkins et al on 1132 simultaneous measurements on 41 male patients had concluded that changes in SpO_2 do not predict equivalent changes in SaO_2 among critically ill patients[18]. Our study support this finding and go one step further in stating that the arterial oxygen saturation could not be reliably predicted from pulse oximeter saturation after a single ABG measurement. To our knowledge, we have several limitations in our study. To start with, our study includes all limitations of retrospective observational studies and single centre study. Secondly, we did not classify the patients according to skin colour which has an impact on accuracy of pulse oximeter[19]. Thirdly, we did not control the factors which may influence the bias in pulse oximetry like systemic vascular resistance, cardiac output, temperature and vasoactive agents[2]. Lastly, our study was based only on critically ill systemic inflammatory response syndrome/ sepsis patients and hence the results cannot be generalized to non septic patients admitted to the intensive care unit.

CONCLUSION

To conclude, in a group of SIRS/sepsis patients, pulse oximeter over estimated SaO_2 values by 2.5%. Hypoxia and acidosis alters the accuracy of pulse oximetry quite significantly with most accurate readings are found at arterial oxygen saturation of more than 95%. Arterial oxygen saturation could not be reliably predicted from pulse oximeter saturation after single ABG measurement. The pulse oximeter remains a valuable tool in the care of intensive care patients, but an awareness of its limitations is an important component of enhancing the quality of intensive care.

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