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A Prospective Single Centre Non-Interventional Study Comparing SPO_2 Measured using Pulse Plethysmograph Developed by IIT Palakkad, to that Obtained Standard Multipara Monitor

Sunil P[1], Lakshminarayana GR[2], Vinod AP[3], Arun N[4], Rajagopal R[5], Somanathan C[6]

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Authors Affiliation:
[1,5,6]Consultant, Department of Cardiology, [2]Consultant, Department of Nephrology, EMS Memorial Co-operative Hospital and Research Centre, Perinthalmanna, Kerala, 619322, [3]Professor, Department of Electrical Engineering, Indian Institute of Technology, Palakkad, Kerala 678557, India.

Address for Correspondence:
Lakshminarayana GR, Consultant, Department of Nephrology, EMS Memorial Co-operative Hospital and Research Centre, Perinthalmanna, Kerala, 619322, India.

E-mail: drlng23@gmail.com

Abstract

This is a pilot study done to compare the effectiveness of measurement of arterial hemoglobin saturation (SpO_2), by a newer device manufactured by Indian Institute of Technology (IIT), Palakkad, Kerala and its readings were compared to that measured by Standard multipara monitor by Nellcor/BPL, India, in patients admitted in ICUs. In comparison to standard multipara monitor the pulse plethysmograph oximeter showed a good level of agreement (LOA: mean difference of only -0.2 (95% CI limits -0.59 to 0.13) with statistically significant correlation (0.848), concluding that the study device is effective and reliable in measuring the SpO_2.

Keywords: Arterial hemoglobin saturation (SpO_2); Pulse-plethysmography; Pulse-oximetry; Oxygen fractions.

Introduction

Pulse oximetry has assumed a significant position in management of patients in ICU.[1,2] This non-invasive approximation of SpO_2 is often referred to as fifth vital sign in clinical assessment.[3] Monitoring the SpO_2 is essential for early detection of hypoxia and its treatment; especially in those suffering from disorders associated with cardio vascular system (CHF, DCM, and IHD) and respiratory system (Chronic Obstructive Pulmonary disease (COPD), asthma and pneumonia).[1-3] The patient monitoring with pulse-oximetry has gained more importance during the corona virus disease (COVID 19) pandemic; especially in those under home-quarantine, and for post-discharge monitoring at home.[4, 5] We are conducting this pilot study at EMS memorial co-operative hospital and research centre (Perinthalmanna, Kerala) to study the effectiveness in measurement of SpO_2 by pulse plethysmograph developed by Indian Institute of Technology-IIT, Palakkad, Kerala.

Aims and Objectives

To estimate SpO_2 measurements by using 2 devices in patients admitted in ICUs and to compare their effectiveness and correlation.

a. Pulse-plethysmograph by IIT Palakkad, Kerala, India (Study Method).
b. Multipara monitor by Skanray healthcare (Model-Planet 60), BPL, Philips, India, (Standard method).

Materials and Methods

This was single-centre, prospective, open-label, non-interventional study (NIS) comparing SpO_2 levels as obtained by using two devices in adult patients admitted in ICUs and Cath lab. The SpO_2 was estimated by simultaneously connecting both pulseoximeters to either the index or middle finger of the subject's hand for a minimum of 30 seconds, prior to noting the observations. Data was tabulated and analysed by IBM® SPSS® (Version 24), USA.

Inclusion and Exclusion Criteria

Inclusion criteria: All patients admitted in ICU's of Neurology, Nephrology, Pulmonology, Medicine and Cardiology were included in the study, after explaining the nature of study and after obtaining the written consent.

Exclusion criteria: Those patients with following disorders were excluded from the study.

- Peripheral vascular disease
- Limb amputations
- Cellulitis of upper limb
- Dysmorphic skin or nails, which can impair the recordings of SpO_2 by Pulseoximeter.
- Those not willing for participation in the study.

Results

A total of 160 subjects (Males 108, Females 52) aged 23-91 (mean 62.61) years, admitted in various ICUs at our institute, were recruited for study, the demographic data is shown in table 1. The $SpO_2$was recorded by using the study device and the standard device simultaneously as shown in figure 1. Both devices were effective in measuring SpO_2 with statistically significant correlation (Correlation 0.848, 2 sided p value <0.001) (table 2). Scatter plots of SpO_2 measurements by two devices are shown in figure 1. The Bland-Altman plots showing agreement or equivalence of measured SpO_2 by two devices are shown in figure 2.

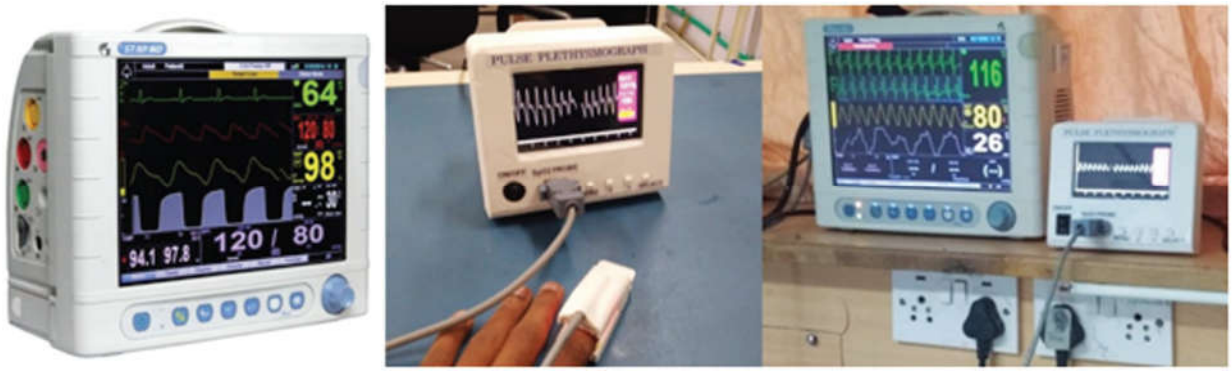

Fig. 1: Photographs of Pulse plethysmograph and Planet 60 multipara monitor used in the study for monitoring SpO_2

Table 1: Demographic data of subjects.

Parameter		Frequency	Percentage
Gender	Females	52	32.5
	Males	108	67.5
Diagnosis	Non-respiratory disease	143	89.4
	Respiratory disease	17	10.6

Table 2: Observations of SpO_2 and its variations based on the device manufacturer.

Parameter	Device for SpO_2 estimation	
	IIT, Palakkad (study method - SpO_2 I)	Nellcor/BPL, India (standard method - SpO_2 S)
Minimum	81	62
Maximum	100	100
Mean	95.13	95.36
Std. Deviation	3.34	4.29
(Spo_2 S + Spo_2 I)/2	72	100
Number of Subjects	160	160

There was no statistically significant difference in measurements of SpO_2 by both devices.

(Paired sample test: 2-sided p-value 0.205).

Both devices were effective in measuring SpO_2 with statistically significant correlation.

(Correlation 0.848, 2-sided p value <0.001).

Table 3: Fit differences in SpO_2 measurements by two devices.

Fit differences of observed SpO_2 by two devices				
Parameter	**Estimate**	**95% CI**		**SE**
Mean difference	-0.2	-0.59	to 0.13	0.18
95% Lower LoA	-4.7	-5.35	to -4.12	0.31
95% Upper LoA	4.3	3.66	to 4.89	0.31
SD	2.3			

SD: Standard Deviation, LoA: Limits of Agreement

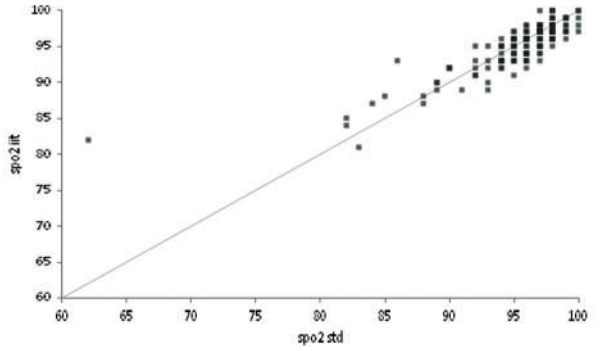

Fig. 1: Scatter plots of SpO_2 measurements by two devices.

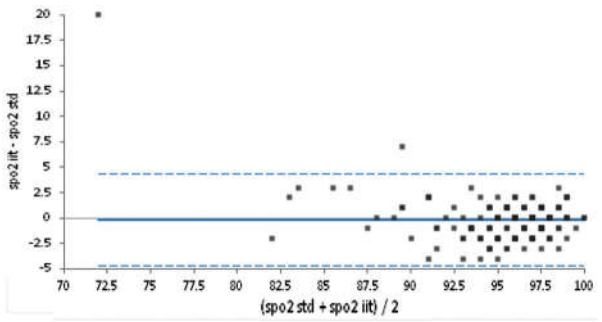

Fig. 2: Bland-Altman plots showing agreement or equivalence in measured SpO_2 by two methods.

Discussion

Pulse-oximetry is an undisputable standard of care in clinical monitoring as they are extremely useful for assessing the respiratory and circulatory status by noninvasively measuring arterial hemoglobin saturation (SpO_2). The information on SpO_2 helps us to maintain patients above the hypoxemic levels by guiding in modifications of ventilator settings and inspired oxygen fractions.[1-5] Study by Seifi S, etal which compared the SpO_2 of earlobe probes with that obtained by ABG analysis had higher accuracy, in patients admitted to the intensive care unit for coronary artery bypass surgery.[6]

Study by Basaranoglu G, on thirty-seven healthy volunteers from operative room staffs (age -18-30 years) showed that right middle finger and right thumb have the most accurate value that reflects the arterial oxygen saturation.[7] The SpO_2 was estimated by simultaneously connecting both pulseoximeters to either the index or middle finger of the subject's hand for a minimum of 30 seconds, prior to noting the observations.

A total of 160 subjects admitted in various ICUs were included in the study (table 1). Both devices were effective in measuring SpO_2 with statistically significant correlation (Correlation 0.848, 2-sided p value <0.001) (table 2). The Bland Altman plot (Figure 2) and fit differences in SpO_2 analysis (Table 3) shows both the study device is comparable to the standard one with good correlation. A similar designed was conducted earlier by comparing wireless Smart Cardia with the ICU-grade monitoring system by Dräger-Healthcare. The SmartCardia device demonstrated clinically acceptable accuracy for HR and SpO_2 monitoring in ICU patients.[8]

Another study which compared two pulse oximeters (a high-quality standard pulse oximeter and an inexpensive pocket pulse oximeter), showed that even though the pocket oximeter was less precise but had agreement limits that were comparable with standard pulse oximeter oximeters. It concluded that the pocket pulse oximeters are powerful allies in clinical monitoring of patients based on a self-monitoring/efficacy strategy.[9]

Another single centre study which compared the 3 lightweight portable pulse oximeters to a standard wall mount pulse oximeter, showed that the portable devices did have good sensitivity using a cutoff value of 94% (sensitivity ranging from 90% to 92%).[10] The study device in present form can be used as portable device for monitoring SpO_2, till other functions are integrated, as it's having a battery backup.

Conclusion

The pulse-plethysmograph developed by IIT, Palakkad has an equivalent efficacy with significant correlation to measure SpO_2 in comparison to multipara monitor. It can be very useful in present form in patients needing only SpO_2 monitoring,

when the other vital parameters are stable, in hospitals facing shortage of multipara monitors. This device will be of significant addition to armamentarium of ICU gadgets for effective patient monitoring if other parameters (BP, ECG, and CVP) are successfully integrated to it.

Limitations

- The present study was conducted by at a single centre with limited number of subjects.
- The device under study (from IIT, Palakkad) can be used to monitor SpO_2 effectively in ICU patients. However, it can't replace the various multipara monitors presently being used in ICU, as present design includes only SpO_2 probe. The research to integrate other parameters to develop pulse-plethysmograph into multipara monitor is under development at IIT, Palakkad.
- Needs another study comparing SpO_2 with ABG analysis.
- Needs large multicentre trials before commercial production.

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