ASSESSMENT OF ACCURACY OF PULSE OXIMETRY IN PEDIATRIC AGE GROUPS AND FACTORS AFFECTING IT

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ABSTRACT

Background: Pulse oximetry device is widely used nowadays in both Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU) so assessment of its accuracy is very important as a rapid life saving decisions is taken depending upon its reading.

Objectives: The primary objective of this study was to evaluate the accuracy of simultaneous samples of SpO_2 compared with SaO_2 obtained by CO-oximetry throughout a range of SpO_2 values. Other objectives were to identify factors that may affect the bias of SpO_2 compared with SaO2 such as age, sex, Hb level, PaO_2 level and perfusion state.

Patients and Methods: This study was a cross section observational study. It was carried out at El-Mabarrah hospital in Tanta city. It included Two hundred patients of different pediatric age groups who were admitted to Neonatal Intensive Care Unit (NICU) and pediatric intensive care unit (PICU) from February to December 2015. Patients aged from first day to16 years old and have any indication of NICU or PICU admission were included in our study while patients with major congenital malformations or have traumatic or surgical causes of admission where excluded. They were studied by comparison between SpO2 and SaO2 values. Factors that may affect SpO2 such as age, sex, Hb level, PaO2 level and perfusion state and correlation between SpO2 and ABG findings such as PaO2, pH, PCO2, HCO3 were assessed**.** Confidentiality of data, approval of research ethics committee and informed written consent from parents were obtained before conducting the study.

Results: The study revealed that; there was a statistically significant difference between SpO2 and SaO2 in the whole entire range of SpO2 and in each category of SpO2 in both studied groups. There was no effect of age and sex on the accuracy of pulse oximetry. On the other hand it was affected by Hb level($p=<0.05$), low PaO2 level($p \leq 0.001$), and prolonged capillary refilling time ($p \leq 0.001$).Also there was a statistically significant positive correlation between PaO2 and SpO2 but no statistically significant correlation between SpO2 and pH, PCO2, HCO3.

Conclusion: 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 care. In condition with oxygen saturation ($SpO_2<80\%$) and in critical status, SpO2 is not sufficiently accurate to replace SaO2 measured by arterial blood gases analyzer. Better pulse oximetry algorithms are needed for accurate assessment of children with saturations in the hypoxemic range.

INTRODUCTION

The use of oxygen in the management of critically ill neonates, infants and children admitted to NICU and PICU has been reported for more than a century. Throughout this time, oxygen administration was guided by the clinical observation of skin color, as well as the rate, regularity and work of breathing. It was not until the 1960s and 1970s that technology of micro-sampling of blood gases, transcutaneous oxygen monitoring, and, later pulse oximetry become available for more precise monitoring of physiological effect **(Brian et al., 2009).**

Arterial oxygen saturation (SaO2) and arterial carbon dioxide partial pressure (PaCO2) are two of the most important respiratory parameters in the treatment of critically ill patient. Noninvasive monitoring of these parameters is desirable for continuous estimation of the respiratory status and reducing blood loss due to repeated blood gas analysis **(Buettikker et al., 2005)**.

Pulse oximetry arterial oxygen saturation (SpO2) has become the ***fifth vital sign*** after heart rate, respiratory rate, blood pressure and temperature in the examination of every newborn and infant with respiratory system presentation **(Kugelman et al, 2004).**

AIM OF THE WORK

The primary objective of this study was to evaluate the accuracy of simultaneous samples of SpO2 compared with SaO2 obtained by CO-oximetry throughout a range of SpO2 values. Other objectives were to identify factors that may affect the bias of SpO2 compared with SaO2 such as age, sex, Hb level, PaO2 level and perfusion state and correlation between SpO2and Arterial blood gases (ABG) findings such as PaO2, pH, PCO2, HCO3.

PATIENTS AND METHODS

This study was a cross section observational study. It was carried out at Al-Mabarrah hospital in Tanta city. It included two hundred patients (101 males and 99 females) of different pediatric age groups who were admitted to NICU and PICU by different diseases (38 of them on mechanical ventilation (MV), 16 on continuous positive airway pressure (CPAP), while 104 were receiving O2 through nasal cannula and 42 through room air). It was conducted from February to December 2015.

Approval of research ethics committee was obtained before conducting the study. Informed

written consent was obtained from parents.

With each arterial blood gas sample, SpO2 from pulse oximetry and arterial oxygen saturations from CO-oximetry (SaO2) were simultaneously obtained from each patient.

Accuracy of pulse oximetry was described depending on the bias which was the difference between SpO2 and SaO2. SaO2 as the reference standard from an ABG measured via CO-oximetry.

The probe was placed on the digit of infants and children and across the foot of neonates. Reading of oxygen saturation was observed and recorded. Dragger monitors (Germany, 1979) were used in NICU while UTAS monitors (Ukranie, 1992) were used in PICU. The blood gas machine used in the study was the ABL800 (Radiometer Medical Aps, Bronshoj, Denmark).

Statistical presentation and analysis of the present study was conducted, using the mean, standard deviation and Linear Correlation Coefficient [r] by SPSS V.20. The accepted level of significance in this work was stated at 0.05 ($P < 0.05$ was considered significant).

RESULTS

This study included 200 patients divided into two groups:

Group (1): Patients admitted to Neonatal Intensive Care Unit (NICU).

Group (2): Patients admitted to Pediatric Intensive Care Unit (PICU).

Table (1): Demographic data of the studied groups.

Parameters \ Groups	NICU (n =100)		PICU (n =100)	
	No.	**%**	No.	%
Sex:				
Male	53	53.0	48	48.0
Female	47	47.0	52	52.0
Age:	**In days**		**In months**	
Min. – Max.	1.0 – 28.0		1.0 – 180.0	
Mean ± SD.	7.84 ± 8.20		51.46 ± 48.42	
Median	5.0		36.0	

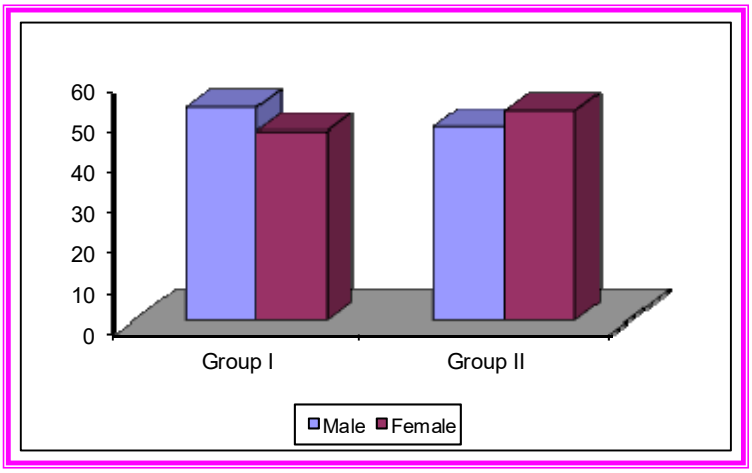

Figure (1): Percentage of gender among the studied groups.

Table (2): Accuracy of pulse oximetry (SpO2 –SaO2) in whole entire range and each SpO2 category in both groups.

SpO_2 categories (%)	NICU			PICU		
	No.	IQR*	Mean ± SD.	No.	IQR*	Mean ± SD.
All	**100**	-0.20 to 3.88	1.87 ± 2.74	**100**	0.88 to 4.38	2.54 ± 2.41
65 - 70	**9**	0.20 to 7.05	3.86 ± 4.04	**6**	4.30 to 6.60	5.23 ± 3.48
71 – 75	**6**	2.98 to 4.85	3.95 ± 1.04	**6**	1.53 to 4.85	2.95 ± 2.36
76 – 80	**6**	2.85 to 4.60	3.67 ± 1.32	**5**	3.75 to 6.05	5.0 ± 1.23
81 – 85	**14**	3.40 to 6.05	4.51 ± 1.68	**16**	3.83 to 6.73	5.53 ± 1.59
86 – 90	**17**	0.50 to 3.80	2.15 ± 1.85	**31**	1.60 to 4.10	2.85 ± 1.43
91 – 95	**23**	-0.20 to 2.50	1.28 ± 1.90	**17**	0.30 to 2.60	1.58 ± 1.42
≥96	**25**	-2.05 to 0.15	-0.88 ± 1.42	**19**	-1.50 to 0.10	-0.46 ± 1.41

**IQR: Interquartile Range.*

Regarding accuracy of pulse oximetry the mean bias in the whole entire range is 1.87 and the local bias is greatest in the SpO2 range of 81% to 85% and smallest in the SpO2 rang of 96% to 97% among NICU group while among PICU group the mean bias in the whole entire range is 2.54 while the local bias is greatest in the SpO2 range of 81% to 85% and smallest in the SpO2 rang of 96% to 97%.

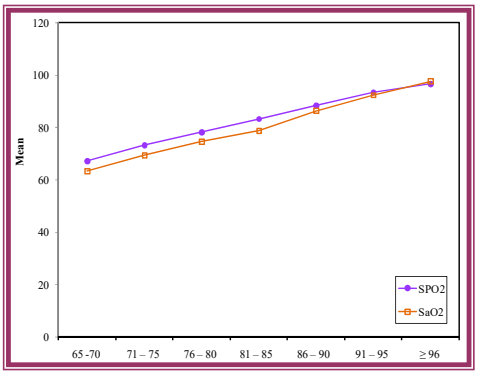

Figure (2): SpO_2 and SaO_2 for NICU group.

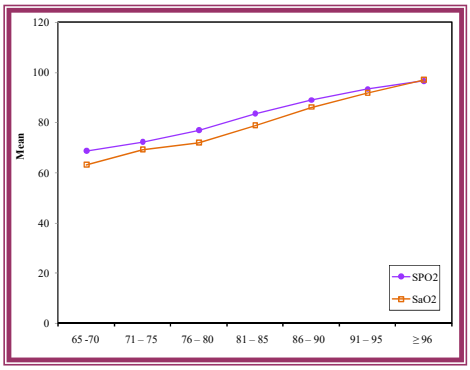

Figure (3): SpO_2 and SaO_2 for PICU group.

Table (3): Accuracy of pulse oximetry regarding Hb level in both groups.

Hb(g/dl) / SpO_2-SaO_2	NICU		PICU	
	≥ 12	< 12	≥ 11	< 11
No.	67	33	82	18
Mean ± SD	0.94 ± 2.79	2.33 ± 2.61	2.40 ± 1.28	3.18 ± 1.92
P. value	**0.016***		**0.036***	

* Statistical significant at $p \leq 0.05$.

Regarding accuracy of pulse oximetry there was statistically significant difference between anaemic and non anaemic patients in both NICU and PICU groups.

Table (4): Accuracy of pulse oximetry regarding PaO2 level in both groups.

PaO2(mm Hg) / SpO_2-SaO_2	NICU			PICU	
	Low (< 60)	Normal (60 – 80)	High (> 80)	Low (< 80)	Normal (80– 100)
No.	45	46	9	75	25
Mean ± SD	3.76 ± 2.28	0.69 ± 1.88	-1.55 ± 1.78	3.39 ± 2.02	0.004 ± 1.55
P. value	**0.001***			**0.001***	

* Highly statistically significant at $p \leq 0.001$

Regarding accuracy of pulse oximetry there was statistically significant difference between PaO_2 levels in both groups where SpO_2 was affected by changes in PaO_2 level.

Table (5): Accuracy of pulse oximetry regarding capillary refilling time (CRT) in both groups.

PaO2(mm Hg) / SpO_2-SaO_2	NICU			PICU	
	Low (< 60)	**Normal (60 – 80)**	**High (> 80)**	**Low (< 80)**	**Normal (80– 100)**
No.	45	46	9	75	25
Mean ± SD	3.76 ± 2.28	0.69 ± 1.88	-1.55 ± 1.78	3.39 ± 2.02	0.004 ± 1.55
P. value	**0.001***			**0.001***	

* Highly statistically significant at $p \leq 0.001$.

Regarding accuracy of pulse oximetry there was statistically significant difference between patients with normal and prolonged CRT in both NICU and PICU groups.

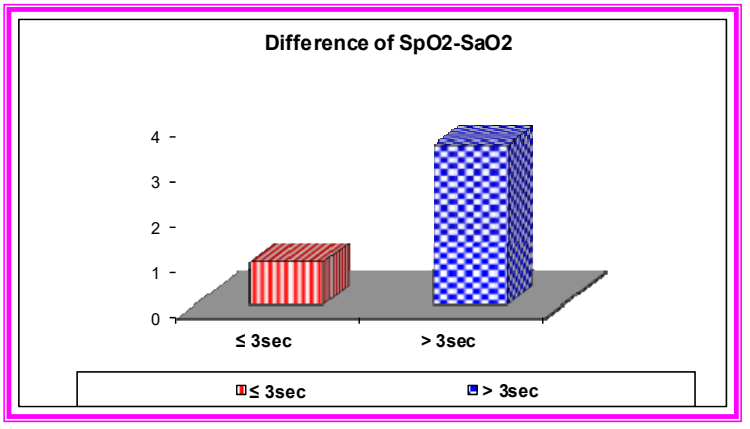

Figure (4): Bias between SpO_2 & SaO_2andCRT in NICU group.

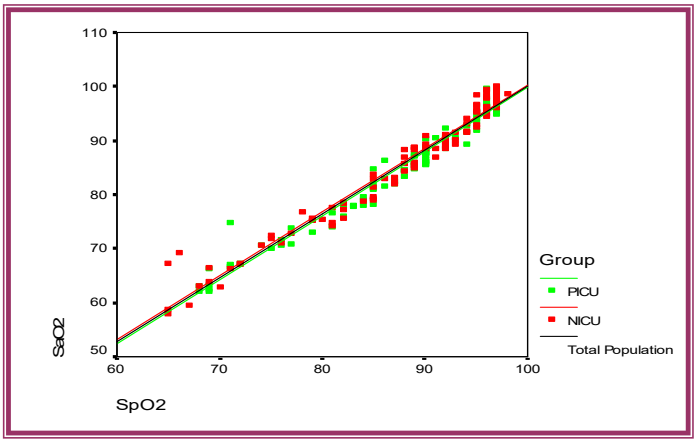

Figure (5): Correlation between SpO_2& SaO_2 in all cases, NICU and PICU groups.

There was positive significant correlation between SpO_2& PaO_2 in all cases, NICU and PICU groups.

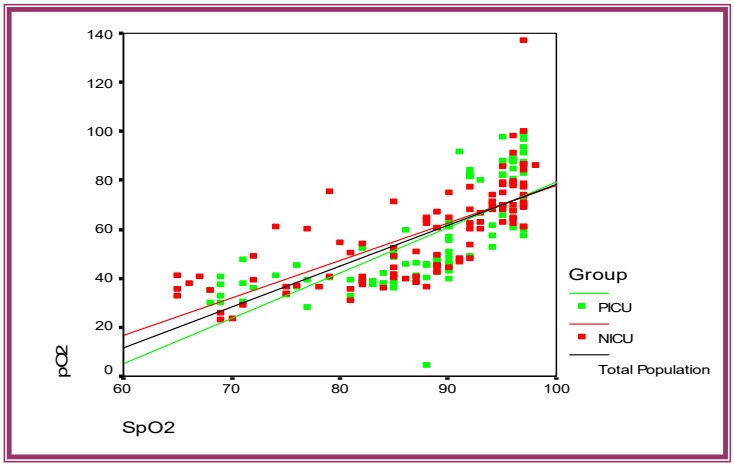

Figure (6): Correlation between SPO_2& PaO_2 in all cases, NICU and PICU groups.

There was no significant correlation between SpO_2 and $PaCO_2$, PH, HCO_3in total samples.

DISCUSSION

Values for SpO2 are plotted against SaO2 for all ABG/SpO2 pairs. The mean bias between SpO2 and SaO2 throughout the whole entire range of SpO2 (65%-97%) was obtained. The accuracy of pulse oximetry varies significantly as a function of the SpO2 range the local bias throughout smaller ranges of SpO2.Were obtained the readings as follow (65%-70%), (71%-75%), (76%-80%), (81%-85%), (86%-90%), (91%-95%) and (96%-97%) in both studied groups.

In NICU group the lowest SpO2 obtained in the study was 65%. In the range of SpO2 65% to 97%, 100 simultaneous values for SpO2 and SaO2 were obtained. The bias (SpO2 – SaO2) varied through the range of SpO2 values. The bias was greatest in the SpO2 range 81% to 85% (14 samples, median 4.90%, mean 4.51%). SpO2 measurements were close to SaO2 in the SpO2 range 95% to 97% (25 samples, median -0.5%, mean -0.88%).

In PICU group the lowest SpO2 obtained in the study was 65%. In the range of SpO2 65% to 97%, 100 simultaneous values for SpO2 and SaO2 were obtained. The bias (SpO2 – SaO2) varied through the range of SpO2 values. The bias was greatest in the SpO2 range 81% to 85% (16 samples, median 5.35%, mean 5.53%). SpO2 measurements were close to SaO2 in the SpO2 range 96% to 97% (25 samples, median 0.50%, mean 0.46%).

The above results regarding accuracy of pulse oximetry were in agreement with the results done by **Ross et al., in 2014**of his a prospective, observational study on 225 patients in 5 units multi-disciplinary PICUs was conducted from August 2009 to October 2010. He found that the lowest SpO2 obtained in the study was 65%. In the range of SpO2 65% to 97%, 1980 simultaneous values for SpO2 and SaO2 were obtained. The bias (SpO2 – SaO2) varied through the range of SpO2 values. The bias was greatest in the SpO2 range 81% to 85% (336 samples, median 6%, mean 6.6%, accuracy root mean squared 9.1%). SpO2 measurements were close to SaO2 in the SpO2 range 91% to 97% (901 samples, median 1%, mean 1.5%, accuracy root mean squared 4.2%).

In our study we found that accuracy of pulse oximetry was not affected by age and sex in NICU and PICU groups. This was in agreement with the results done by **Lee et al.,** in **2000**and**Rabi et**

al., in **2006**.who found the same results.

On the other hand, we found that accuracy of pulse oximery was affected by low Hb level among NICU and PICU groups. This was in disagreement with the results done by **Lee et al., in 2000**.who concluded that accuracy of pulse oximetry was not affected by anemia. This may be right in more old patients with good perfusion.

We found that accuracy of pulse oximetry was poor in patients with prolonged CRT in NICU and PICU groups. This was in agreement with the results done by **Salyer, in 2003** who concluded that low peripheral perfusion often cause in accurately with low SpO2readings.

We found that accuracy of pulse oximetry was affected by low PaO2 level in NICU and PICU groups. This was in agreement with the results obtained by **Muñoz et al., in 2008**who concluded that PaCO2 status can contribute to impairing agreement between SaO2 and SpO2, particularly in patients with hypercapnia.

In this study, there was a statistically significant positive correlation between PaO2 and SpO2. An increase in PaO2 was associated with an increase in SpO2 ($p<0.001$). This was in agreement with **Castillo et al., (2008)** who defined the relation-ship of PaO2 and pulse oxygen saturation values during routine clinical practice and stated that in studying 800 samples from infants breathing supplemental oxygen revealed that, the results from the paired PaO2/SpO2 samples from this study showed a linear correlation and they recommended that; Pulse oxygen saturation values of >93% are frequently associated with PaO2 values of >80 mmHg, which may be of risk for some newborns receiving supplemental oxygen.

On the other hand**, Pamela et al., in (2007)** who studied the validation of pulse oximetry in measuring oxygen saturation in neonates and found that; the range of PaO2 was (50) to (75) mm Hg in relation to SpO2, the range of SpO2 (95%) to (97%), and it is preferable to maintain SpO2 at greater than 95% in neonates to prevent desaturation events.

We found that there was no statistically significant correlation between SpO2 and pH, PCO2, HCO3. This was also in agreement with the results obtained by **Muñoz et al., (2008)** who found that bicarbonate had no significant effect on SpO2 and **Lee et al.,**

(2000) who assessed the accuracy of pulse oximetry in the emergency department and analysis of several variables including age, sex and levels of hemoglobin, bicarbonate, pH, PaO2, PaCO2, and concluded that there was a small effect of pH but not significant.

CONCLUSION

- Pulse oximetry is more accurate at a range of SpO_2readings more than 90% and its accuracy decrease when SpO_2 at a range of (65%-90%) with greatest bias in the SpO_2 range of (81%-85%).
- Accuracy of pulse oximetry was affected by Hb level, low PaO_2 level, and prolonged CRT.
- There was statistically significant positive correlation between PaO_2 and SpO_2, An increase in PaO_2 is associated with an increase in SpO_2.
- There was no effect of age and sex on the accuracy of pulse oximetry.

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تقييم دقة جهاز قياس نسبة الأكسجه النبضيه عن طريق الجلد فى المجموعات العمرية للأطفال والعوامل المؤثرة عليه

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قسم طب الأطفال ـ كلية طب الأزهر

خلفية البحث: فى هذه الأيام أصبح من الشائع استخدام جهاز قياس نسبة الأكسجه النبضية عن طريق الجلد فى وحدة العناية المركزة للمبتسرين و وحدة العناية المركزة للأطفال ، لذا أصبح من الضرورى تقييم دقة هذا الجهاز حيث أنه يتخذ اعتمادا على قراءاته لنسبة تشبع الدم بالأكسجين قرارات سريعة من شأنها إنقاذ حياة المريض. وتعد المقارنة بين قراءة هذا الجهاز لنسبة تشبع الدم بالأكسجين وتلك التى نحصل عليها من خلال قياس غازات الدم الشريانى هى حجر الزاوية فى هذه الدراسة

الهدف من البحث: تقييم دقة جهاز قياس نسبة الأكسجه بالدم عن طريق الجلد عن طريق مقارنة قراءاته بالقراءات التى تم الحصول عليها عن طريق عينة الدم الشريانية والخاصة بنسبة تشبع الدم بالأكسجين فى نفس لحظة قراءة الجهاز ، وتحديد ما إذا كانت دقة هذا الجهاز قد تتأثر ببعض العوامل مثل عمر المريض وجنسه و نسبة الهيموجلوبين بالدم والتغير فى مستوى الضغط الشريانى للأكسجين والحالة الارتوائية لخلايا الجسم بالدم وتقييم العلاقة بين قراءة الجهاز والقيم الأخرى التى نحصل عليها عن طريق تحليل غازات الدم الشريانى مثل ضغط الدم الشريانى لأكسجين وثانى أكسيد الكربون ومؤشر قلوية الدم وبيكربونات الصوديوم.

طريقة البحث: شملت هذه الدراسة مائتى طفل (200 طفل) تتراوح أعمارهم مابين يوم واحد وحتى 16عام والذين تم احتجازهم بوحدتى العناية المركزة للمبتسرين والأطفال بمستشفى المبرة بمدينة طنطا حيث تمت مقارنة نسبة تشبع الدم بالأكسجين التى تم الحصول عليها عن طريق الجهاز بتلك النسبة التى تم الحصول عليها عن طريق عينة الدم الشريانية التى تم سحبها فى نفس اللحظة وتم تحديد مدى تأثر دقة الجهاز بعوامل مثل عمر المريض وجنسه و نسبة الهيموجلوبين بالدم و التغير فى مستوى الضغط الشريانى للأكسجين والحالة الارتوائية لخلايا الجسم بالدم و تقييم العلاقة بين قراءة الجهاز والقيم الأخرى التى نحصل عليها عن طريق تحليل غازات الدم الشريانى مثل ضغط الدم الشريانى لأكسجين وثانى أكسيد الكربون ومؤشر قلوية الدم وبيكربونات الصوديوم.

النتائج: أظهرت تلك المقارنة وجود دلاله إحصائية بين القراءتين ويقل الفارق بينهما حينما تكون نسبة تشبع الدم بالأكسجين فوق 90% ويتسع الفارق كلما كانت نسبة أكسجة الدم تحت 90%، وسجلت الدراسة أكبر فارق بين القراءتين وقصور فى دقة جهاز الأكسجه النبضية حينما كانت نسبة أكسجة الدم بين 81% إلى 85%.وأظهرت الدراسة

أيضا عدم تأثير عمر أو جنس المريض على دقة الجهاز، فيما تأثرت بانخفاض نسبة الهيموجلوبين بالدم وانخفاض الحالة الارتوائية لخلايا الجسم بالدم (CRT)وكذالك التغيرات بمستوى ضغط الأكسجين بالدم الشريانى(PaO_2).

وأظهرت الدراسة أيضا وجود علاقة إيجابيه ذات دلالة إحصائية مباشرة بين قراءة جهاز الأكسجة النبضية وبين قيم ضغط الأكسجين بالدم الشريانى، فيما لم تظهر الدراسة وجود علاقة ذات دلاله إحصائية بين قراءة جهاز الأكسجه النبضية وبين ضغط ثانى أكسيد الكربون بالدم ومؤشر قلوية الدم وبيكربونات الصوديوم (pH,PCO_2,HCO_3).

الاستنتاج: استخدام جهاز قياس نسبة الأكسجة بالدم عن طريق الجلد يظل ذو فائدة، ولكن مع الأخذ فى الاعتبار انه لا يمكن الاستغناء به عن القياس المباشر لغازات الدم عن طريق العينة الشريانية فى المرضى الذين يعانون من نقص تشبع الدم بالأكسجين بنسبة أقل من 80%.