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Original Research Article

To evaluate acceptable range of Pulse oxygen saturation levels to maintain normoxemia in neonates on oxygen therapy

Dr. Pankaj Jain[1], Dr. Usha Acharya[2]
[1]MD Pediatrics, Assistant Professor,
[2]MD Pediatrics, Ex Prof. and Head, Department of Pediatrics,
Division of neonatology, Department of Pediatric Medicine, SMS Medical College, Jaipur, Rajasthan, India

***Corresponding author**
Dr. Pankaj Kumar Jain
Email: pankaj18us2001@yahoo.com

Abstract: The objective of this study was to evaluate acceptable range of Pulse oxygen saturation levels (Spo_2) to maintain normoxemia (Pao_2 40-80 mm Hg) in neonates on oxygen therapy. The subject included were neonates on oxygen therapy admitted in Wards and Neonatal intensive care unit of Sir Padampat Mother and Child Health Institute attached to SMS medical college. 75 paired Pao_2/Spo_2 samples were obtained from total 34 neonates on oxygen therapy. The Pao_2 measurements were obtained from radial arterial blood gas sample; simultaneously pulse oxygen saturation values were recorded if the Spo_2 values changes < 1%, before, during and after the arterial gas sample was obtained. The analysis of 75 samples from neonates on supplemental oxygen revealed that, when Pulse oxygen saturation levels were 85% to 93%, the mean Pao2 was 60.67±15.15 mm Hg. At this Spo2 levels, 84% of the samples had Pao_2 values of 40 to 80 mm Hg, 4% had values of <40mm Hg and 12% had values of > 80mm Hg. When the Spo_2 values were > 93%, the mean Pao_2 was 102±20.31 mm Hg. At this Spo_2 level, 4% of the samples had Pao_2 values between 40 to 80 mm Hg and 92% had values of > 80 mm Hg. We concluded that in neonates on supplemental oxygen therapy, High Pao_2 occurs very infrequently when then Spo_2 values are 85% to 93%. This SPo_2 range is also rarely associated with low Pao_2 values. Spo_2 values of > 93% are frequently associated with Pao_2 values of > 80 mm Hg, which may be of risk for neonates on supplemental oxygen.
Keywords: Neonates, Pulse oxygen saturation, oxygen therapy, normoxemia, hypoxemia, hyperoxemia.

INTRODUCTION

OXYGEN is the most common drug used in neonatology worldwide. There are many pathophysiological conditions that may lead to tissue hypoxia, but the cause of hyperoxemia is the healthcare itself [1].

Pulse Oxygen Saturation (Spo_2) values have been considered the "Fifth vital sign" [2-4]. Spo_2 monitors were introduced into practice since 1980s, but without adequate understanding of health care professionals. Till now, the optimal Spo_2 levels for newborn who receive oxygen therapy are not known. Even, we do not know what 'normal' Pao2 range is for neonates on oxygen therapy. A number of publications and American Academy of Pediatrics suggest that Pao_2 values of 80 to 90 mm Hg may be considered Hyperoxemia, but these values are not based on systematically performed studies [5-7].

For the analyses and comparisons of samples, we selected Pao_2 of < 40mm Hg as a low Pao_2 value based on P_{50}, percentage saturation, and oxygen content calculations. With a Pao_2 value of 40mm Hg, hemoglobin may be 85% saturated. If the hemoglobin concentration is 14g/dl, then the oxygen content would be ~16.2ml/dl. This oxygen content is likely to be sufficient to avoid tissue hypoxia at usual ranges and interactions with neonatal cardiac output, regional blood flow, oxygen consumption, and oxygen delivery. We have chosen Pao_2 of >80mm Hg as a high Pao_2 as above a certain Pao_2, the dissolved Pao_2 adds very little to the oxygen content of the blood and is potentially harmful [8].

With the objective of better defining the relationship between Pao_2 and Spo_2 during routine clinical practice, we have designed this study to analyze Pao_2 values at different Spo_2 ranges among neonates on oxygen therapy. Our hypotheses were that, the Spo_2 range of 85% to 93% would not be associated with Pao_2 levels of 40 mm Hg and that Spo_2 values between 94% and 100% would pose a risk for Pao_2 levels that might lead to oxidative stress in neonates receiving supplemental oxygen.

SUBJECTS AND METHOD

It was a prospective non interventional observational Study conducted among neonates receiving supplemental oxygen therapy admitted in wards and NICU of Sir padampat mother and child health institute (attached to SMS Medical College, Jaipur) over a period of one year.

We included a total of 34 neonates (0-28 days) on supplemental Oxygen therapy from which a total of 75 paired Spo_2 and Pao_2 samples were taken with 25 samples in each of the 3 groups on basis of Spo_2 values -Spo_2 < 85%, Spo_2 85-93% and Spo_2 > 93%.

Finally, each subject included in this study could have ≥ 1 paired Pao_2/Spo_2 sample over the days, but no more that 5 total samples were included for each individual.

Neonates with major congenital malformations, hemoglobin < 14gm% and systolic blood pressure < 50mm hg were excluded. Acute clinical changes/rapid deterioration in clinical condition of neonate or changes in Spo_2 of >1% during arterial blood gas sampling were also among the exclusion criteria.

The arterial blood samples was taken from radial artery of neonate using heparanized dispovan 1ml. or scalp vein set and Pao_2 value is obtained by using blood gas analyzer in emergency laboratory of SMS Hospital, Jaipur.

Following steps were taken to include the paired Spo_2 / Pao_2 samples in the study.

1. The sensor of the Spo_2 monitor had to be in same territory from where arterial sample being taken.
2. The Spo_2 monitor reading was observed and recorded with accuracy by one of the investigators who was present during sampling.
3. Po2 readings had to remain stable for 60 seconds before and 60 seconds after the blood gas sampling, with an accepted maximal variation of Spo_2 of less than 1%.

STATISTICAL METHODS

Quantitative data was summarized by mean and standard deviation and mean difference in all 3 groups was compared by ANOVA and correlation between Spo_2 and Pao_2 was observed by Pearson correlation co-efficient and regression equation. Qualitative data was analyzed by chi-square test and relative variance. The test of significance was done at alpha error 5% and power 80%.

RESULTS

In our study, a total of 75 paired Spo_2 and Pao_2 samples were obtained from 34 subjects with 25 samples in each of the 3 groups on basis of Spo_2 values -Spo_2 < 85%, Spo_2 85-93% and Spo_2 > 93%.

Table-1: Distribution of Pao_2 values among different Spo_2 groups in all 75 paired Spo_2/Pao_2 samples

Pao_2	**Spo_2**			**TOTAL**
	<85	**85-93**	**>93**	
<40	16	1	1	18
40-80	9	21	1	31
>80	0	3	23	26
TOTAL	25	25	25	75

In Spo_2 group <85%, 64% samples had Pao_2 values less than 40 mm Hg (hypoxemia), 36% samples had Pao_2 values between 40-80 mm Hg(normoxemia) and no sample had Pao_2 value more than 80 mm Hg(hyperoxemia). As shown, analyses of the samples with SpO_2 values between 85% and 93% revealed that the majority (84%) were associated with PaO_2 values of 40 to 80 mm Hg, 12% with PaO_2 values of >80 mm Hg, and 4% with PaO_2 values of <40 mm Hg. Table 1 also shows that, when the SpO_2 values were >93%, 92% of the PaO_2 values were >80 mm Hg and 4% of the PaO_2 values were between 40 and 80 mm Hg (P < .001, compared with samples with SpO_2 values of 85%–93%).

Table 2 summarizes the means, medians; interquartile ranges, and ranges for newborns receiving supplemental oxygen. In the 25 samples with SpO_2 values of 85% to 93%, the mean and median PaO_2 values and the proportions of samples with PaO_2 of >80 mm Hg were statistically different from those for the 25 samples with SpO_2 values of > 93% (P < .001, repeated measures analysis of variance) (Table 2). As expected, the mean PaO_2 values (39.2, 60.67, and 102.5 mm Hg, respectively) were significantly different (P <.001, analysis of variance for repeated measures).

The results from the paired PaO_2/SpO_2 samples from this clinical study are plotted in Figure 1. The graphs show a linear correlation and a more-physiologic curvilinear relationship, resembling the oxyhemoglobin dissociation “sigmoid” curve.

Table- 2: Statistical parameters (Mean, Median and Standard deviation) of Spo_2 and Pao_2 values among different groups and their statistical significance (P value)

	Spo_2 <85% (N=25)	Spo_2 85%-93% (N=25)	Spo_2 >93% (N=25)	P value	Statistical Significance
Spo_2 (%)					
Mean±SD*	73.88±12.96	88.08±2.871	97.52±2.064	<0.001	Highly Significant
Median	79	87	98		
Pao_2 (mm Hg)					
Mean±SD	39.2±8.866	60.67±15.15	102.5±20.31	<0.001	Highly Significant
Median (interquartile range; range)	38 (8.1;24.3-65.8)	55.5 (18.4;35.9-95)	106.3 (20.2;38-148.9)		
Proportion of samples with Pao_2 of >80mm Hg (%)	0.0	12.0	92.0	<0.001	Highly Significant
Proportion of samples with Pao_2 of <40 mm Hg (%)	64.0	4.0	4.0	<0.001	Highly Significant

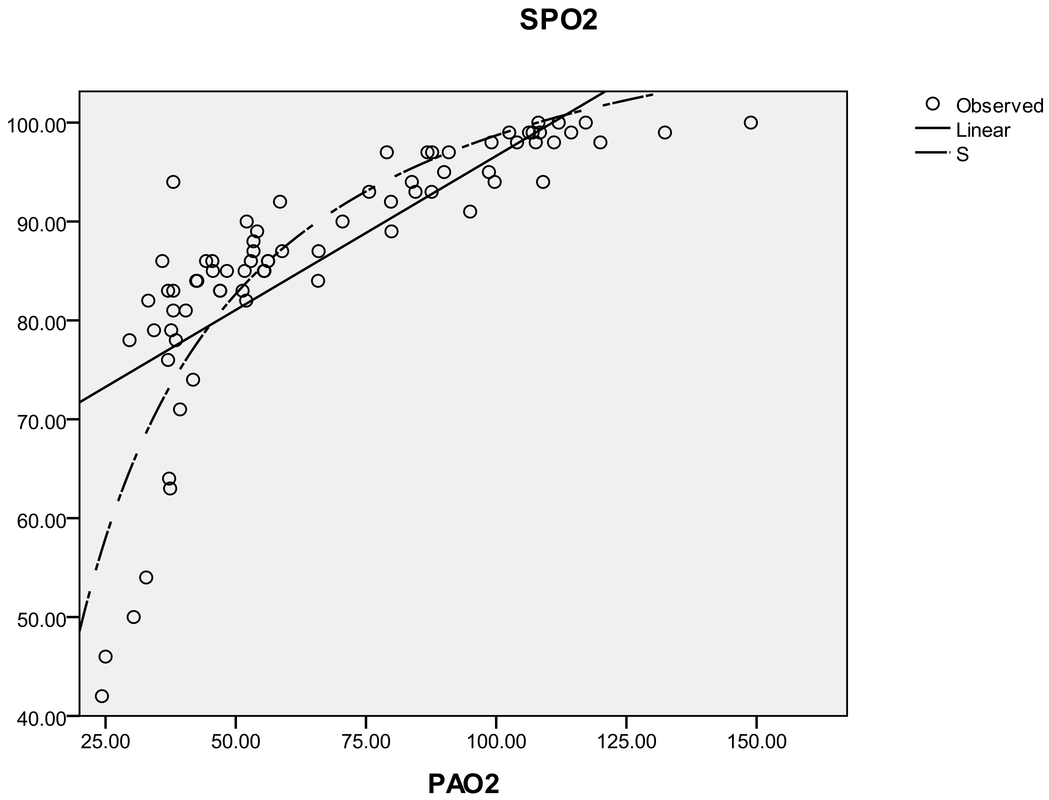

Fig-1: Linear correlation of paired PaO2/SpO2

Fig 2 shows a receiver operating characteristic curve for neonates receiving supplemental oxygen and for samples with SpO_2 values of >93%, considering PaO_2 of >80 mm Hg as positive. The area under the curve was 0.83, with an asymptotic 95% confidence interval of 0.52 to 1.0.

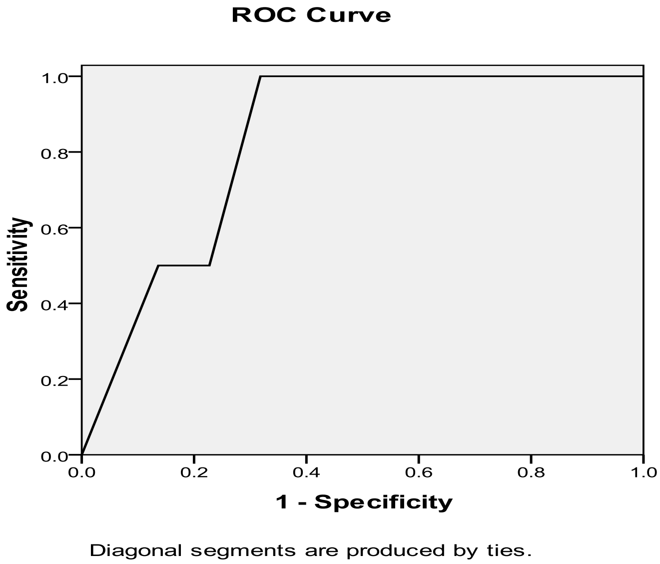

Fig-2: Receiver operating characteristic curve

DISCUSSION

In our study, we observed that among neonates breathing supplemental oxygen therapy, Spo_2 values of 85% to 93% are associated very infrequently with Pao2 values of < 40 mm Hg (4%). In addition, this SpO_2 range is associated with PaO_2 values of >80 mm Hg much less (12%) than when SpO_2 levels are 94% to 100% (92%). Our study suggest that in group with Spo_2 85-93% , Pao_2 values in Normoxemic range(Pao_2 40-80mm Hg) is higher (84%) as compared to other two groups (Spo_2 < 85% - 36%, Spo_2 >93 - 4%)which is significant (P value < 0.001). The mean value of Pao_2 in group with Spo_2 85-93% is 60.67±15.15 which is statistically significant (p value <0.001) as compare to other two groups (Spo_2 <85% - 39.2 ±8.866, Spo_2 > 93% - 102.5±20.31). This suggests that acceptable range of Spo_2 to maintain normoxemia in neonates on oxygen therapy in our study is 85 to 93% with a mean value of 88.08±2.87.

Castillo *et al.;* 2008 [8] in their study, observed that with Spo_2 range 85 -93 %, 86.3% of samples were associated with Pao_2 values of 40-80mm Hg, 4.6 % with Pao_2 values of >80mm Hg, and 8.6% with Pao_2 values of < 40mm Hg. In their study, the mean value of Pao_2 value was 56±14.7 in 85-93% and in more than > 93% group was 107.3±59.3 (p value <0.001). This is in accordance with our study.

As would be expected, the receiver operating characteristic curve demonstrates that SpO_2 values of > 93% are not 100% specific or sensitive for PaO_2 levels of >80 mm Hg. However, the area of 0.83 found supports the concern raised by several researchers regarding potential hyperoxemia with SpO_2 values of >93%. Castillo *et al.* [8] in their study, observed the area of 0.74 under receiver operating characteristic curve which also suggested potential hyperoxemia with SpO_2 values of >93%.

A few studies published in late 1980s [5, 6, 9-12], compared Spo_2 values with Pao_2 values; their main objective was to assess the reliability of Spo_2 values in the detection of hyperoxemia (defined in different studies as > 80 or > 90 mm Hg). All studies suggested the potential benefits of setting high alarm limits at 94% or 95%. The methods and goals of our study were different from those of all of those studies. In Our study, we aimed to define more completely the relationship of Pao_2 and Spo_2 values during routine clinical practice and to define the risk of a Pao_2 value that most health care professionals currently would consider too low (<40mm Hg) when Spo_2 values were 85%-93%. This information may prove to be valuable, because Pao_2 values are measured infrequently in routine clinical practice.

In our study, we have evaluated only correlation between pulse oxygen saturation levels (Spo_2) and partial pressure of oxygen levels (Pao_2), But we did not evaluated the effects that $PaCO_2$, pH, body temperature, fetal hemoglobin concentration & adult hemoglobin concentration separately, 2,3-diphosphoglycerate level, and number of transfusions might have on the relationship between Pao_2 and Spo_2 during routine clinical practice. Furthermore, we did not evaluate the possible relationship between the time after transfusion and the time of Pao_2 and Spo_2 sampling. All of these factors, by themselves and in combination, could have potential effects on hemoglobin affinity for oxygen and shifts of the oxy hemoglobin dissociation curve. In daily clinical practice, however, most clinicians follow the values shown by the Spo_2 monitors and do not analyze the aforementioned factors.

CONCLUSION

In our study, acceptable range of Spo_2 to maintain normoxemia in neonates on oxygen therapy is

85 to 93%. High Pao_2 occurs very infrequently when then Spo_2 values are 85% to 93%. This Spo_2 range is also rarely associated with low Pao_2 values. Spo_2 values of > 93% are frequently associated with Pao_2 values of > 80 mm Hg, which may be of risk for neonates on supplemental oxygen. However, a future goal would be to find even safer Spo_2 limits that can assist health care providers in eliminating both hyperoxemia and hypoxemia during the early neonatal period.

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