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ORIGINAL ARTICLE

Reevaluating Reference Ranges of Oxygen Saturation for Healthy Full-term Neonates Using Pulse Oximetry

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Background: We compared our clinical experience with currently available reference oxygen saturation level (SpO_2) values from the American Academy of Pediatrics/American Heart Association (AAP/AHA) neonatal resuscitation program guidelines.
Methods: We enrolled 145 healthy full-term neonates; infants showing respiratory distress and those with serious congenital anomalies were excluded. SpO_2 values at every 1 minute until 10 minutes after birth were measured and recorded. Infants were classified into the cesarean section (CS) and normal spontaneous delivery (NSD) groups for evaluating differences. The 10th percentiles of SpO_2 at each minute were used as the lower limits of normal oxygen saturation, and these were compared with the lowest target values recommended in the AAP/AHA guidelines.
Results: Overall, 130 vigorous full-term neonates (median gestational age: 38 5/7 weeks; body weight at birth: 2405—3960 g) were analyzed. The median SpO_2 were 67% and 89% at the 1st and 4th minute, respectively. On average, SpO_2 values reached >90% at the 5th minute. No statistical differences were noted in the SpO_2 values between the CS and NSD groups after 5 minutes; however, a trend of higher SpO_2 was observed in the NSD group. We noted a gradually increasing

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trend for SpO_2 values over time, similar to that noted in the AAP/AHA guidelines. However, SpO_2 values at the 10^{th} percentiles of each minute within the first 5 minutes in our study were equal to or significantly lower than those in the AAP/AHA guidelines; moreover, at the 10^{th} minute, SpO_2 values at the 10^{th} percentiles were significantly higher than those in the guidelines.
Conclusion: The delivery modes did not affect the SpO_2 values of full-term healthy neonates. Discrepancies in SpO_2 changes in full-term neonates not requiring resuscitation between this study and the AAP/AHA guidelines were significant. SpO_2 ranges for each time point within the first 10 minutes after birth should therefore be reevaluated locally.

1. Introduction

Although the passage through the birth canal is a hypoxic experience for the fetus, few neonates require breathing assistance at birth.[1–3] Timely successful ventilation may determine the future life of the neonate; however, no indicator can completely indicate the exact status of neonatal pulmonary oxygenation during ventilation. The oxygen saturation level (SpO_2) is one of the common parameters measured during neonatal ventilation. However, the range of SpO_2 in healthy neonates after cesarean section (CS) or normal spontaneous delivery (NSD) varies greatly,[4–8] which leads to confusion and ambiguity regarding the optimal reference range.

Kattwinkel et al[3] recommend that, for full-term neonates in need of resuscitation at birth, the goal should be to achieve an SpO_2 value in the interquartile range (IQR) of preductal saturations measured in healthy term babies following vaginal birth at sea level. They proposed a panel of SpO_2 values at each minute within the first 10 minutes after birth; these values were summarized based on the Consensus on Resuscitation Science and Treatment Recommendations (CoSTR) to set clear and easily accessible guidelines for clinicians for use in the delivery room (DR), along with threshold values for determining whether the infant requires ventilation.[3] This systematic review and well-organized algorithm for directing the decision for the initiation of active ventilation as well as for conducting resuscitation procedures conveys objective and scientific information in this regard. However, several studies have reported SpO_2 changes in term or near-term infants not requiring resuscitation in the first few minutes after birth.[5,6,8] It is possible that genetic variations,[9] considerable interobserver and intraobserver variability, and different settings and facilities for monitoring neonates[3,8] may have led to these changes.

In our experience, the threshold values within the first 5 minutes after birth in the American Academy of Pediatrics/American Heart Association (AAP/AHA) guidelines appeared to be relatively lower than the values observed for full-term healthy neonates delivered in our hospital. To clarify the noted discrepancies, we conducted a prospective study to reevaluate the SpO_2 values of vigorous full-term neonates in the first 10 minutes of life using a new-generation pulse oximeter for minimizing interobserver and intraobserver errors at various settings to represent our data as percentile curves; the 10^{th} percentile SpO_2 values were then used as cutoff points for comparing the data with the lowest SpO_2 limits specified in the AAP/AHA guidelines. We considered that it may be necessary to reevaluate the threshold SpO_2 values provided in the AAP/AHA guidelines used for guiding ventilatory assistance, while taking into account various ethnic and regional differences.

2. Materials and methods

This prospective study was conducted at the DR of the Tri-Service General Hospital, a tertiary center in Taiwan, from November 2011 to May 2013. This hospital has a tertiary neonatal intensive care nursery, with 85–125 full-term and preterm births every month. The inclusion criteria were defined as full-term gestational cases with a single fetus and no maternal or fetal pathologic changes during gestation. All newborn infants were dried, suctioned, and stimulated properly by a senior pediatric resident according to the AAP/AHA guidelines after birth. Any neonate that showed signs of distress,[3] including persistent central cyanosis, apnea, gasping, or bradycardia, which may require supplemental oxygen, assisted ventilation, or expected resuscitation in the first few minutes after birth were excluded. Infants were also excluded if they had congenital anomalies that might interfere with the normal transition to extrauterine life. Before birth, all the prospective parents were required to sign an informed consent form for participation in the study. The design and conduct of this study was approved by the local Institutional Review Board.

Enrolled infants born through either CS or NSD were placed on a resuscitation trolley. The time after birth was measured using a chronometer, and a pulse oximeter sensor (Masimo Radical; Masimo Corporation, Irvine, CA, USA) was attached onto the infant's right wrist and secured with a Coban wrap (3M Health Care, St. Paul, MN, USA) immediately and then connected to an oximeter (LNOP Neo Masimo SET; Masimo Corporation) after birth. For all infants, the pulse oximeter was set to acquire data with better sensitivity. The data were recorded at 1-minute intervals for a 10-minute duration to closely monitor any changes in the SpO_2 and heart beats.

We used SPSS Statistics version 20.0 software (SPSS, Chicago, IL, USA) for all statistical analyses. The characteristics of all infants are presented as proportions and numbers (range) for categorical variables, mean $\pm$ standard deviation for normally distributed continuous variables, and median and IQRs for variables with skewed distribution. The

SpO_2 values were acquired for each infant at 1-minute intervals and for both the delivery groups (i.e., CS and NSD), and are shown as median (IQR) in the tables and figures. The two-tailed Mann–Whitney *U* test was used to compare the CS and NSD groups. A p value < 0.05 was taken to be significant.

All data were inputted into an Excel spreadsheet (Microsoft, Redmond, WA) for analysis. The skewness–median–coefficient of variation (LMS) method[10] was used to calculate the SpO_2 percentiles and to summarize the changing distribution of SpO_2 measurements after delivery. This method uses three curves, representing the skewness (L), median (M), and coefficient of variation (S); the first one is expressed as a Box–Cox power. The modified LMS method was used for the truncated SpO_2 percentage scale; SpO_2 values of 100 were also changed to 99.9. Subsequently, all SpO_2 values were logistically transformed according to the following formula:

$$\text{logit} = \log[SpO_2/(100 - SpO_2)] + 5$$

Thereafter, the logit percentile values were back-transformed to SpO_2 values based on the following formula:

$$SpO_2 = [100\exp(\text{logit} - 5)]/[1 + \exp(\text{logit} - 5)]$$

At last, all the references and available data from COSTA, which were cited by Kattwinkel et al[2] in 2010, were used for comparison with our results.

3. Results

A total of 145 full-term newborn births were evaluated; of these, 15 infants were excluded from analysis as they required intubation for meconium aspiration syndrome ($n = 2$), oxygenation with self-inflating bags due to poor spontaneous breathing ($n = 4$), oxygen supplementation due to persistent central cyanosis ($n = 8$), and resuscitation due to shock from cord strangulation ($n = 1$). Overall, 130 full-term, healthy, and vigorous neonates were enrolled in this study.

The median gestational age of all full-term infants was 38 5/7 weeks. Of these, 67 infants (52%) were delivered vaginally and 63 (48%) were delivered through CS. The mean birth weight of the studied patients was 3132 ± 342 g. The other characteristics of the infants are presented in Table 1. There were no significant differences in the characteristics of infants born through CS and NSD.

The median time from birth to first data collection was 72 seconds (range: 43–86 seconds); therefore, the number of data points collected in the 1st minute after birth is lower than that for other time points. The median SpO_2 values (IQR) of each minute from birth to 10 minutes after delivery are listed in Table 2. The median SpO_2 values at each minute were as follows: 1st minute, 67%; 2nd minute, 75%; 3rd minute, 83%; 4th minute, 89%; 5th minute, 94%; 6th minute, 96%; 7th minute, 97%; 8th minute, 98%; 9th minute, 98%; and 10th minute, 99%. Figure 1 shows the SpO_2 values for the 3rd, 10th, 25th, 50th, 75th, 90th, and 97th percentiles for all infants, with a trend of gradually increasing oxygen saturation over time after birth.

The median SpO_2 values (IQR) at each minute of age are delineated as box plots based on the mode of delivery in Figure 2. The p values at the 1st, 2nd, 4th, and 5th minute were less than 0.05. The SpO_2 values did not significantly differ between the CS and NSD groups at any time point after 5 minutes. Nonetheless, a trend of higher SpO_2 values was noted in the NSD groups as compared with the CS group.

In this study, in most full-term healthy neonates, the SpO_2 levels reached 90% at the 5th minute after birth. Our results and the data from the references and COSTA, as cited by Kattwinkel et al in 2010,[2] are summarized in Table 3.

4. Discussion

To avoid bias and to acquire corrective data in the measurement of SpO_2 in the first 10 minutes after birth in a safe and accurate manner, we used a new-generation pulse oximeter calibrated for its higher sensitivity and accuracy for each minute; furthermore, in accordance with the technique described by O'Donnell et al and Mariani et al, the Masimo sensor was attached onto the right wrist of the infant before being connected to the oximeter.[7,11–13] With this method, the preductal SpO_2, which is considerably

Table 1 Characteristics of the infants.

	All infants (N = 130)
Gestational age (wks)	38 5/7 (37 1/7–41)
Birth weight (g)*	3132 ± 342
Maternal age (y)*	31.3 ± 3.4
General anesthetic, n (%)†	0 (0)
Normal spontaneous delivery, n (%)†	67 (52)
Cesarean section, n (%)	63 (48)
Apgar score at the 1st min	8 (8–9)
Apgar score at the 5th min	9 (9–10)
Time from birth to first data collection (s)	72 (43–86)

Data are presented as median (range).
Times are measured from the point of cord clamping.
* Mean ± standard deviation.
† Number (percentage).

Table 2 Comparison of SpO_2 values from the 1st to the 10th minute after birth for full-term births.

Time after birth	SpO_2, median (IQR), %
	All infants
1st min	67 (59–78)
2nd min	75 (65–84)
3rd min	83 (74–87)
4th min	89 (82–94)
5th min	94 (86–96)
6th min	96 (91–97)
7th min	97 (91–98)
8th min	98 (95–99)
9th min	98 (96–99)
10th min	99 (97–99)

IQR = interquartile range.

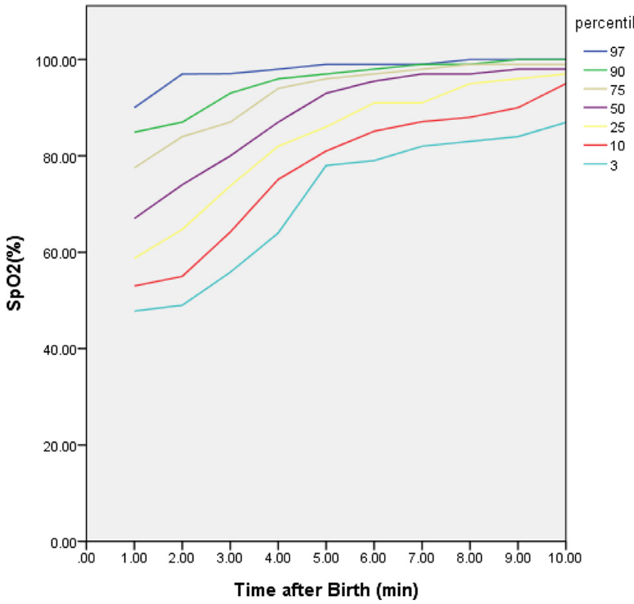

Figure 1 Third, 10th, 25th, 50th, 75th, 90th, and 97th oxygen saturation level (SpO_2) percentiles for all vigorous full-term infants with no medical intervention in the first 10 minutes after birth.

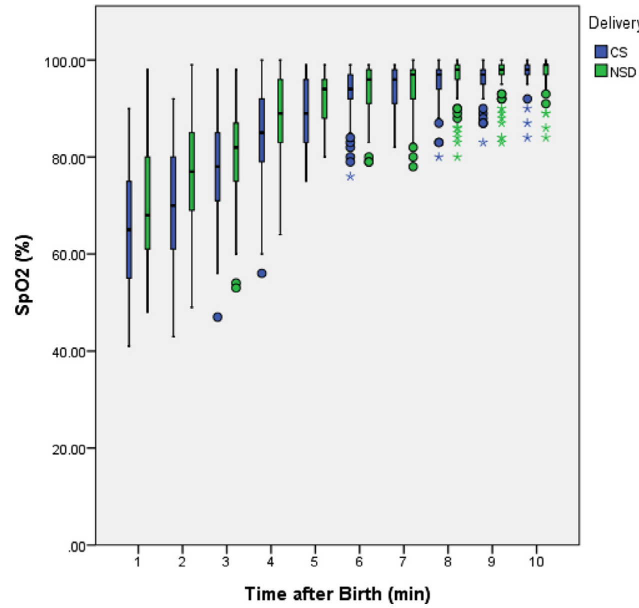

Figure 2 Median oxygen saturation level (SpO_2) values in the cesarean section (CS) and normal spontaneous delivery (NSD) groups in the first 10 minutes after birth. The median is represented by a horizontal line within each box. Boxes represent the data between the 25th and 75th percentiles. Circles and stars represent outliers and extreme values, respectively. 1st minute: $p = 0.021$; 2nd minute: $p = 0.005$; 3rd minute: $p = 0.075$; 4th minute: 0.014; 5th minute: $p = 0.034$; 6th minute: $p = 0.233$; 7th minute: $p = 0.62$; 8th minute: $p = 0.231$; 9th minute: $p = 0.225$; and 10th minute: $p = 0.466$.

higher than postductal SpO_2, could be recorded rapidly following delivery.[6,13–15] A Masimo pulse oximeter with Masimo signal extraction technology and 1-minute continuous measurements were used to attenuate the noises caused by motion and to calibrate low perfusion. Both factors are well-known to cause artifacts in SpO_2 measurements in the DR. In addition, data were collected only when the plethysmographic waves and signal quality were excellent. Thus, we optimized our data such that they were least likely to be affected by artifacts.

Dawson et al showed that SpO_2 values exceeded 90% in vigorous full-term infants at or around the 5th minute after birth; the median SpO_2 values at each minute reported were as follows: 1st minute, 68%; 2nd minute, 76%; 3rd minute, 81%; 4th minute, 88%; and after the 5th minute, all values were above 92%.[16] In this study, our recorded intervals were longer than those used by Dawson et al because we intended to have more detailed data. However, our results focusing on healthy full-term neonates were similar to theirs.[16] The study by Dawson et al as well as most reports published in 2010 showed results compatible with ours, supporting the hypothesis that the SpO_2 values for the first few minutes after birth in the AAP/AHA guidelines, which used references published before 2008, were lower than the normal values.[3] These attracted our interest in exploring the discrepancies between our experience and the results of Kattwinkel et al.[3]

To investigate whether the mode of delivery may affect neonatal respiration,[8,17] we divided the infants in the present study into the CS and NSD groups. Some reports have suggested that infants born through CS show significantly lower SpO_2 values than those born through NSD.[8,13,17] Our results demonstrated no significant differences in SpO_2 values after the first 5 minutes following birth in the CS and NSD groups. These findings are also in agreement with those of House et al. and Dimich et al.[4,14,18] However, in the present study, we noted a global trend for higher SpO_2 values in infants born through NSD than those born through CS. These findings might be explained by the delayed clearance of pulmonary fluid in the CS group. Moreover, our small sample size may have caused this nonsignificant difference in the results.

Kattwinkel et al reported that 10 minutes were required to achieve SpO_2 levels greater than 90%.[3] However, our data revealed that $SpO_2 > 90\%$ was achieved at or around the 5th minute in most healthy full-term infants included in this study. This finding is also supported by Dawson et al.[16] To examine the data and references cited by Kattwinkel et al,[3] we have listed most of them in Table 3, including five studies belonging to COSTA (marked with an asterisk).[3,6,8,13,17,19] We found that Kattwinkel et al included data from these papers, which were not specific for full-term infants but also included data for preterm neonates.[6,8,13,17,19] Therefore, a combination of preterm and full-term infants in a study focusing on full-term infants may have reduced the overall levels of SpO_2 at each time point in the first 10 minutes. For example, House et al, Rao and Ramji, and Rabi et al observed an $Spo_2 < 90\%$ at 5 minutes of age and SpO_2 more than 90% at 8–10 minutes of age.[4,5,8] In studies enrolling only healthy full-term neonates, SpO_2 reached 90% at 4–5 minutes of age; furthermore, most median SpO_2 values were greater than 70%.[6,13,17,19] Studies focusing on full-term infants[13,17,19] as well as ours showed consistent SpO_2 values at each time

Table 3 Observational studies measuring SpO_2 during the first few minutes after birth in the delivery room with no medical intervention.

Study	Numbers	Gestational age	Type of oximeter	Sensor location	Birth weight (mean), g	Apgar score at		SpO_2 (%) at					$SpO_2 \geq 90\%$ (min)
						1st min	5th min	1st min	2nd min	3rd min	4th min	5th min	
House et al[4]	28	Term and preterm	Nellcor N-100 or Ohmeda BIOX 3700	Preductal	850–5230	Not reported	Not reported	78 (9) †	—	—	—	84 (14) †	10
Rao and Ramji[5]	30	Term and preterm	Novametrix 515A	Preductal	>2499	Not reported	Not reported	70 (16) †	—	82 (14) †	—	89 (9) †	10
Rabi et al[8,*]	115	Term and preterm	Masimo Radical	Preductal	Not reported	9 (8–9) ‡	9 (8–9) ‡	77 (72–82) ‡	76 (71–82) ‡	83 (72–83) ‡	79 (74–84) ‡	81 (75–83) ‡	8
Toth et al[6,*]	46	Term	Nellcor N-3000	Preductal	3436 (2450–4290) ‖	10 (8–10) ‖	10 (8–10) ‖	—	73 (44–95) ‖	—	—	84 (48–99) ‖	10
Kamlin et al[19,*]	205	Term	Masimo Radical	Preductal	3393 (560) †	8 (8–9) ‡	9 (9–9) ‡	63 (53–68) ‡	70 (58–78) ‡	76 (64–87) ‡	81 (71–91) ‡	90 (79–91) ‡	4.7 (3.3–6.4) ‡
Dimich et al[14,*]	110	Term	Masimo Radical	Preductal	3380 (2745–3865)	Not reported	Not reported	—	—	75 (11) †	84 (77–78) ‡	89 (83–93) ‡	5
Altuncu et al[17,*]	150	Term	Nellcor N-550B	Preductal	2500–4200	Not reported	Not reported	71 ¶	77 ¶	83 ¶	—	92 ¶	4
Lu et al	100	Term	Masimo Radical	Preductal	3132 (342) †	8 (8–9) §	9 (9–10) §	67 (59–78) ‡	75 (65–84) ‡	83 (74–87) ‡	89 (82–94) ‡	94 (86–96) ‡	5
Ref[3]	COSTA	Term? (Preterm?)	COSTA	Preductal	COSTA	COSTA	COSTA	60–65% #	65–70% #	70–75% #	75–80% #	80–85% #	10

SpO_2 = oxygen saturation level.
* Studies belonging to COSTA.
† Mean (standard deviation).
‡ Median (interquartile range).
‖ Median (range).
§ Mean (range).
¶ Median.
\# Range.

point in the first 10 minutes after birth. Interestingly, at the 3rd minute after birth, the SpO_2 value in these three papers was almost identical, being higher than 75%. The present study showed a trend of gradually increasing oxygen saturation over time after birth. Moreover, the median SpO_2 at the 3rd minute was 83% and more than 94% at the 5th minute. Therefore, all the available evidence supports our hypothesis that the discrepancies between the present results and those of Kattwinkel et al may have arisen because the data were affected by the inclusion of both full-term and preterm infants rather than full-term infants alone.

To be objective and scientifically accurate, we plotted our data to a percentile curves chart, because percentile curves—instead of a given SpO_2 value at a specific time point—are a better choice for evaluating the range of SpO_2 at the same time point after birth in healthy full-term neonates with different ethnicities, different phenotypes, and variable responses to environmental stimuli.[16] We then compared these curves with those based on data from the AAP/AHA guidelines. We found that the SpO_2 ranges at each minute in our study were wider than those specified in the guidelines.[3] These results supported the data presented by Dawson et al.[16] Furthermore, for a more accurate comparison, we constructed a 10th percentile for SpO_2 values to assess the accuracy of the lowest limits[16]; our data demonstrated that the 10th percentiles for SpO_2 at each minute after birth were considerably lower than the lowest limits of SpO_2 specified in the guidelines for the first 5 minutes, but far higher than those at the 10th minute.[3,16] Moreover, the lowest SpO_2 limits specified in the guidelines were similar to the 10th–50th percentiles in the first 5 minutes and to the 2nd percentile at the 10th minute in our percentile curves. Kattwinkel et al recommend that clinicians should initiate active respiratory intervention for full-term newborns if SpO_2 values at any time point were below the threshold levels suggested therein.[3] Based on our findings, full-term neonates may receive unnecessary ventilatory support to reach the 10th percentile of SpO_2 values in the first 5 minutes after delivery and may possibly be at risk for hyperoxia exposure. By contrast, if the 2nd percentile values for SpO_2 at the 10th minute of childbirth are targeted, full-term neonates may be at potential risk for hypoxia exposure. The adverse effects of both hyperoxia and hypoxia may damage the brain, lung, myocardium, and/or kidney.[20–23] Because too much and too little oxygen are both harmful to neonates, caution should be exercised when following the AAP/AHA guidelines, without tailoring it for local differences.[3]

The small sample size is a limitation of this study. A large-scale prospective study may further clarify the discrepancies noted here and provide objective and scientific information for the appropriate resuscitation of neonates.

5. Conclusion

This study was designed to reevaluate the optimal levels of oxygen saturation for healthy full-term neonates after birth by comparing data from our center with the limits recommended by the AAP/AHA guidelines. We aimed to present local reference values of SpO_2 in full-term healthy neonates. Although we have no contention with the existing AAP/AHA guidelines, the purpose of this study was to verify our clinical experience and its agreement with currently available reference values for SpO_2, such as those recently presented by Kattwinkel et al.[3] We consider that the threshold recommendations of the AAP/AHA guidelines for initiating ventilatory support for full-term neonates need to be locally reevaluated based on the present findings, because too much as well as too little oxygen may be harmful. We believe that a well-designed large-scale prospective study will provide objective and scientific information for the optimal resuscitation of neonates.

Conflicts of interest

There are no conflicts of interest to declare.

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