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Reference Values of Nocturnal Oxygenation For Use in Outpatient Oxygen Weaning Protocols in Premature Infants

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Summary. Objective: To define reference ranges for oxygen saturation (SpO_2) values in healthy full-term infants in the first days of life and in preterm infants off supplemental oxygen as they approach neonatal intensive care unit (NICU) discharge. Methods: From April 2009 to March 2010, we enrolled convenience samples of full-term infants from the newborn nursery and former preterm infants who did not require supplemental oxygen at the time of discharge from the NICU. Overnight SpO_2 and signal quality recordings were obtained and analyzed for duration of artifact-free recording time (AFRT), time (s) with SpO_2 less than several different target saturations (90–95%), and number of falls in SpO_2 by $\geq$4% and $\geq$10%. Results: We studied 102 full-term infants and 52 preterm infants. Preterm and full-term infants spent similar amounts of time less than 90%, 91%, 92%, 93%, 94%, and 95% although preterm infants had more falls in SpO_2 by $\geq$4% per hour of AFRT. Over 67% of term and preterm infants spent less than 6% of their time below 93%. Conclusion: These data represent reference SpO_2 ranges for both preterm infants not requiring supplemental oxygen at NICU discharge and full-term infants in the first days of life. As we currently lack guidelines dictating the optimal target oxygen saturations for infants and the acceptable maximal time that they can safely spend below set target saturations, our data may serve as a guide to interpreting SpO_2 recordings of premature outpatient infants who are weaning from supplemental oxygen. **Pediatr Pulmonol. 2012; 47:453–459.** © 2011 Wiley Periodicals, Inc.

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INTRODUCTION

Although neonatal intensive care has improved significantly over the last few decades, the rates of lung disease of prematurity have not substantially decreased.[1–3] In fact, improved survival of extremely low birthweight infants leads to significant numbers of infants who require supplemental home oxygen therapy at time of neonatal intensive care unit (NICU) discharge.[4–6]

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We lack evidence-based protocols to determine appropriate methods for outpatient weaning from supplemental oxygen therapy.[7–10] Even during the inpatient stay in NICUs, there exists significant variability in defining the ideal target oxygen saturations. Thus, a universally accepted definition of oxygen requirement in premature infants is needed.[11,12] Recent trials have attempted to determine optimal target oxygen saturations in the earlier neonatal course for premature infants.[13] Findings demonstrate the advantages and disadvantages of both higher and lower target oxygen saturations in the *early* neonatal course. During the *later* NICU course, we are without data outlining either actual or optimal hemoglobin oxygen saturation status of infants. This leaves the question of when to safely wean infants from oxygen unanswered.

Pulse oximeters with recording capability have become a hallmark technology helpful not only in research, but also in clinical evaluation of sleep-disordered breathing and oxygen saturation levels in neonates. They provide reviewable accurate information about baseline oxygenation levels and the frequency of intermittent falls in oxygenation.[14–17] Furthermore, recent studies suggest that overnight assessment of oxygenation is a common component of outpatient oxygen weaning protocols.[8] In order for clinicians to glean meaning from oximetry data in patient populations, it is essential to obtain reference values in appropriate controls against which they can make comparisons. The development of increasingly motion-resistant pulse oximeters also necessitates the establishment of reference values measured with these more accurate instruments.

We therefore evaluated a series of convalescing preterm infants and healthy full-term infants to establish reference values clinicians can utilize as guidelines when interpreting oximetry studies in preterm infants who are weaning off oxygen.

ABBREVIATIONS:

SpO_2	oxygen saturation
NICU	neonatal intensive care unit
AFRT	artifact-free recording time
TRT	total recording time
D4	continuous SpO_2 decreases by $\geq$4%
D10	continuous SpO_2 decreases by $\geq$10%
SAT5	SpO_2 below which the child spent 5% of AFRT
SAT10	SpO_2 below which the child spent 10% of AFTR
T90	total time in seconds with SpO_2 <90%
T91	total time in seconds with SpO_2 <91%
T92	total time in seconds with SpO_2 <92%
T93	total time in seconds with SpO_2 <93%
T94	total time in seconds with SpO_2 <94%
T95	total time in seconds with SpO_2 <95%
SD	standard deviation
IQR	interquartile range

PATIENTS AND METHODS

This prospective observational study was conducted at two tertiary centers, the Brigham and Women's Hospital (Boston, MA) and Beth Israel Deaconess Medical Center (Boston, MA). Both hospitals have level III NICUs. Infants were recruited from the newborn nurseries and NICUs at these sites between April 2009 and March 2010. The institutional review board at each site approved the study, and the parents of all subjects gave written informed consent.

For purposes of analysis, infants were classified into one of two groups: full-term or preterm. Seventy percent of full-term infants and 54% of preterm infants were enrolled from one site, with the remaining subjects coming from the other site.

Healthy Full-Term Group

Inclusion criteria: (1) gestational age of $\geq$37 weeks at birth; (2) clinically well (defined as Apgar score >4 at 1 and >7 at 5 min; (3) not admitted to a special care nursery; (4) no medications; and (5) $\geq$12-hr old. All infants were studied prior to discharge home, within the first 3 days of life.

Convalescing Preterm Group

Inclusion criteria: (1) gestational age $\leq$32 weeks at birth; (2) current gestational age $\geq$35 0/7 weeks; (3) no supplemental oxygen within the 7 days prior to study; (4) no future anticipated need for supplemental oxygen; and (5) within 2 weeks of anticipated discharge. Requirement for supplemental oxygen was determined by the NICU guidelines; infants who had no recorded episodes of desaturation <90% within 48 hr after weaning off oxygen were determined to not require oxygen by the treating clinicians.

All infants in both the healthy full-term and convalescing preterm groups underwent a nocturnal pulse oximetry test using a Masimo Rad 7 with a new-generation oximeter module (Masimo SET, software version 3.0.2.1; 2-sec averaging mode; Masimo Corporation, Irvine, CA) capable of storing continuous data for pulse oximeter saturation (SpO_2), pulse rate, signal quality ("signal IQ"), and device status for up to 12 hr at a sampling rate of 1 Hz. Signal IQ and device status are data entries developed by the pulse oximeter module and device manufacturer. Signal IQ is derived from the raw plethysmograph indicating the signal-to-noise ratio and, thereby, the confidence of the measured SpO_2 values. In addition to these trend data, desaturation events were recorded separately over a 120-sec period prior to and during the event onto event data memory. A desaturation was defined as SpO_2 decreases by $\geq$4% (D4), as recommended by the American

Academy of Sleep Medicine,[18] or by ≥10% (D10), lasting for at least 10 sec following a prior peak value. For all the infants in both the healthy full-term and convalescing preterm groups, alarms were muted and visual displays dimmed to avoid unnecessary disturbance of sleep during recording.

Data Analysis

Duration of Recording

Following the night of recording, trend and event data were downloaded to a computer. Total recording time (TRT) and artifact-free recording time (AFRT) were determined using data analysis software (Profox, Escondido, CA). For AFRT, recording periods associated with low signal IQ or device status were identified and subtracted from TRT. If AFRT was <6 hr, the recording was excluded because it was unlikely to include at least three full sleep cycles. Oxygen saturation patterns will vary depending on the stage of sleep, and so recordings that did not include sufficient sleep cycles may underestimate desaturation episodes.

Baseline Values

The median SpO_2, the SpO_2 below which the child spent 5% of AFRT (SAT5), and the SpO_2 below which the child spent 10% of AFTR (SAT10) were calculated for each recording using the above-mentioned analysis software. The total time in seconds with $SpO_2 < 90\%$ (T90), 91% (T91), 92% (T92), 93% (T93), 94% (T94), NS 95% (T95) was also calculated.

Desaturation Events

A desaturation event was defined as a drop in oxygen saturation by ≥4% (D4) or by ≥10% (D10) lasting for at least 10 sec following a prior peak value. All desaturation events were visually confirmed to exclude spuriously low values not identified by the software tool. This was done using analysis software provided by the device manufacturer (Profox). Desaturation events were further dichotomized based on duration; desaturations >3 min in duration were quantified separately from episodes lasting >10 sec but ≤3 min.

Statistics

To allow comparisons with published data, values are expressed both as mean and standard deviation (SD), and as median, range, and interquartile range (IQR). Reference ranges were calculated using the 5th and 2.5th percentiles for baseline values and the 95th and 97.5th percentiles for desaturations. The Mann–Whitney *U*-test was used to compare data between subgroups. These analyses were done using statistical software (SPSS version10.0.7; SPSS, Chicago, IL).

RESULTS

All recordings contained analyzable data, but 11 recordings from the full-term infants (9.7%) had to be excluded because of insufficient (<6 hr) recording time. The remaining recordings in the full-term infants were from 50 female and 52 male infants, studied at a mean age of 40.2 hr of life (SD, 20.3 hr). In the preterm cohort, the recordings were from 32 females and 20 males (Table 1). Mean TRT was 707 min (SD, 91), with an AFRT of 679 min (SD, 96); 96.1% (SD, 5.6) of recording time was artifact-free.

Baseline Values

Descriptive statistics for SAT5, SAT10, and median saturation are shown in Table 2. There were no significant differences between the values for the preterm and

TABLE 1— Demographic Characteristics of Full-Term and Preterm Infants

Demographic characteristics	Full-term	Preterm (N = 102)	*P*-value (N = 52)
Gestational age (GA), mean ± SD, weeks	39.3 ± 1.6	29.5 ± 2.1	<0.0001
Age at time of oximetry, mean ± SD, days	1.7 ± 0.8	51.7 ± 28.3	<0.0001
GA at time of oximetry, mean ± SD, weeks	41.0 ± 1.9	36.9 ± 2.9	<0.0001
Birthweight, mean ± SD, g	3359.2 ± 475.9	1349.7 ± 746.9	<0.0001
Gender, n (%)			
Male	54 (54.0)	20 (38.5)	0.07
Female	46 (46.0)	32 (61.5)	
Race or ethnic group, n (%)			
White	68 (69.4)	28 (53.9)	0.97
Black	15 (15.3)	12 (23.1)	
Hispanic	9 (9.2)	7 (13.4)	
Other	6 (6.1)	5 (9.6)	

Full-term infants were studied within the first 3 days of life, and had no respiratory medical issues. Preterm infants were studied no earlier than 35 weeks gestation, and were off supplemental oxygen for at least 7 days prior to study.

TABLE 2— Descriptive Statistics for SpO_2 Baseline Values of the Full-Term and Preterm Cohorts

Variables	Mean ± SD	Median	IQR	Range	5th Centile	2.5th Centile
Full-term cohort (n = 102)*						
SAT_5	92.5 ± 3.9	93	90–95	78–100	86.0	82.1
SAT_{10}	95.3 ± 2.9	96	94–97	84–100	90.1	87.5
Median sat	98.9 ± 1.3	99	98–100	94–100	96.1	96.0
Preterm Cohort (n = 52)*						
SAT_5	92.7 ± 4.7	93	90–96	80–100	85.0	81.3
SAT_{10}	95.1 ± 3.5	96	93–98	85–100	89.0	86.5
Median sat	98.8 ± 1.4	99	98–100	95–100	96.0	95.3

Mean and median values did not vary significantly between the full-term and preterm cohorts.

full-term cohorts. For the 5% of infants who had values below the 5th centile, no obvious pathology or explanation was identifiable from the medical records to explain why these infants had lower values than the rest of the cohort.

The percentages of AFRT spent with SpO_2 less than each value from 90% to 95% are listed in Table 3. Surprisingly, the median values for the preterm infants were slightly lower than those for the full-term infants for all saturation levels analyzed. These differences were not statistically significant but the trend was consistent across all of the SpO_2 targets.

Desaturation Events

Both groups of infants had significantly higher frequencies of shorter (<3 min) versus longer (>3 min) desaturation events per hour of AFRT (Table 3). As expected drops ≥10% were much less frequent than drops of 4–9%. However, the frequency of desaturation

TABLE 3— Descriptive Statistics for SpO_2 Desaturation Events

				Preterm			Full-term		
Variables	Preterm (mean ± SD)	Full-term (mean ± SD)	*P*-value	Median	IQR	Range	Median	IQR	Range
(A) Preterm infants had increased desaturation events compared to full-term infants, although the total time spent less than target saturation levels was comparable									
T90	3.2 ± 3.3	3.6 ± 3.5	0.21	2.2	0.7–4.6	0–14.6	2.6	1.5–4.6	0.2–24.5
T91	4.0 ± 4.0	4.3 ± 3.9	0.29	2.7	0.9–5.7	0–16.8	3.2	1.9–5.2	0.2–27.0
T92	5.0 ± 4.8	5.1 ± 4.7	0.37	3.3	1.4–6.6	0–20.4	3.9	2.2–6.4	0.4–29.5
T93	6.2 ± 6.1	6.3 ± 5.8	0.43	4	1.8–8.9	0–25.5	4.7	2.8–7.5	0.6–31.3
T94	8.0 ± 7.8	8.1 ± 7.5	0.47	5.3	2.3–11.3	0–32.8	5.7	3.6–9.8	0.9–42.4
T95	10.6 ± 10.6	10.5 ± 10.1	0.52	6.8	3.0–15.0	0–43.2	7.1	4.3–13.4	1.1–62.6
D4/hr (<3 min)	11.8 ± 8.1	9.6 ± 5.4	0.0001	10.2	5.5–17.1	0.3–31.5	8.2	6.1–12.3	1.9–25.9
D4/hr (>3 min)	0.7 ± 0.1	0.4 ± 0.4	0.0001	0	0–0.1	0–0.5	0.3	0.1–0.5	0–2.2
D10/hr (<3 min)	4.7 ± 3.8	2.5 ± 1.5	0.0001	4	1.5–6.7	0.1–14.9	2.3	1.4–3.0	0.3–8.5
D10/hr (>3 min)	0.1 ± 0.7	0.1 ± 0.1	0.0001	0	0–0.1	0–0.5	0.1	0.2–0.4	0–0.7

Variables	Preterm (95th %ile)	Full-term (95th %ile)	Preterm (95th %ile)	Full-term (95th %ile)
(B) In this population of healthy full-term and preterm infants who did not clinically require oxygen supplementation, a subset of infants spent significant percentages of time with oxygen saturations less than 93%.				
T90	8.9	10.0	12.2	12.5
T91	10.7	12.4	15.2	14.7
T92	14.3	14.0	17.6	18.4
T93	19.5	17.0	20.9	24.2
T94	25.0	22.6	26.9	30.6
T95	33.8	31.5	39.2	35.2
D4/hr (<3 min)	27.0	21.6	28.5	23.5
D4/hr (>3 min)	0.3	1.3	0.5	1.5
D10/hr (<3 min)	11.5	4.9	12.1	6.2
D10/hr (>3 min)	0.4	0.4	0.4	0.4

events per hour AFRT varied between preterm and full-term babies. These differences were statistically significant (Table 3a).

DISCUSSION

Recorded pulse oximetry is widely utilized to determine when to safely discontinue supplemental oxygen in former premature infants.[8–10] However, proper interpretation of recorded oximetry studies requires comparison with reference values from appropriate control patients. The ideal control cohort to establish this gold standard would be composed of similar patients that do not clinically require oxygen.

In this study, we determined baseline SpO_2 and the frequency of intermittent falls in SpO_2 (desaturations) in a group of full-term and convalescing preterm infants. This study is among the first to utilize newer-generation, motion-resistant pulse oximeters in these populations of infants. These new oximeters have been shown to reduce false alarm rates.[19] The specific oximeter used in this study, the Masimo SET oximeter, has been tested and did not increase the proportion of missed true alarms such as an impaired detection of hypoxemia or bradycardia.[20] While there is no consensus regarding which infants should be the appropriate reference population to provide reference values for use when weaning premature infants from supplemental oxygen, our study populations represent the two most appropriate control groups to consider.

We found that average SpO_2 was comparable between premature infants who did not require supplemental oxygen at approximately 35 weeks post-conceptual age and full-term healthy infants within the first few days of life. In both groups, median oxygen saturation values less than 98% were uncommon. Intermittent desaturations of $\geq$4% were relatively frequent, but desaturations of $\geq$10% were less common. In both groups, the total artifact-free time $\leq$90% was also relatively short, less than 3% in both groups.

Although many reviews suggest 90% as a minimum acceptable saturation, other guidelines suggest using 93% as the oxygen saturation below which supplemental oxygen should be administered.[15,16] This conclusion was made based on a review of the currently available literature. Our data suggest that, in our study populations, there is little difference between the amount of time spent below oxygen saturation of 93% versus the amount of time spent below 90% (4.7% and 2.6%, respectively, of AFRT in the full-term infants). Assessment of clinically significant outcomes will be important to determine which target value (90% vs. 93%), is optimal. In this study, we provide data using multiple target values. We do not have long-term neurodevelopmental or pulmonary outcome data on this reference population, but since all infants in this study were considered clinically healthy without need for supplemental oxygen by their clinical providers, individual infants who have oxygen saturation values comparable to the values provided may be safe for discontinuation of oxygen.

Our study has some important differences from prior studies that sought to identify reference oxygen saturation values in full-term and healthy preterm infants.[21–28]

1. We utilized modern oximeters that reliably measure SpO_2 even during motion and low perfusion, reducing the amount of potentially artifactual readings. We also employed a validated signal quality indicator developed by the pulse oximeter manufacturer. In other studies, limitations of the equipment may have led to false-negative readings of oxygen saturation, particularly during motion.[19]
2. Previous studies of SpO_2 in healthy term and convalescing preterm infants only report median O_2 saturation. In this study, we describe cumulative percentage of time below and number of desaturation events at various threshold values per hour of AFRT. Prior studies also reported episodes of desaturation, but the definition of desaturation used was not clearly validated. We utilized the definition of desaturation (fall in saturation $\geq$4% from baseline) recommended by the American Academy of Sleep Medicine.[18] Recognizing that the definition of desaturation in infants may be different than those for adults, we have also presented data using an alternate, more conservative definition of fall in saturation $\geq$10% from baseline.
3. Finally, the populations of infants reported in prior studies differed from our own population. In the post-surfactant era, the majority of infants who require supplemental oxygen after discharge from the NICU are born less than 32 weeks gestation. In order to employ reference data to interpret oximetry studies in these patients, the reference control group should be of comparable gestational age, that is, less than 32 weeks.

Despite these important differences, our data for baseline (median) measurements in infants appears similar to that previously reported in other studies. As reported in prior studies, a small minority of infants had clinically unrecognized low baseline SpO_2 or a high frequency of episodic desaturations.[21–23]

Our study has a number of limitations. We did not collect data on whether the infants were feeding, sleeping, or awake during recordings, so information regarding possible effects of these factors on the frequency of desaturation is not available. However, recorded oximetry studies in infants who are weaning

off supplemental oxygen similarly include alternating time periods of sleep and activity, making comparisons of this group to our research subjects valid. We also lack information on the later clinical outcomes of the infants described, so the long-term clinical significance of the observed desaturation episodes is unknown. Since all children in the study were determined by their primary medical team to be stable for discharge without need for supplemental oxygen, infants weaning off supplemental oxygen who have comparable or fewer episodes of desaturation during a room air trial may be considered equally as safe to wean off of supplemental oxygen. We also used one specific oximeter; it is possible that different values would have been obtained using other widely used brands of oximeters.[19]

In conclusion, we defined a reference range for SpO_2 in healthy full-term and preterm infants at sea level with a new-generation pulse oximeter. Our data show that almost all children spent most of the night at SpO_2 values $>98\%$ and suggest that intermittent desaturations of $\geq 4\%$ are frequent in this age group, while time spent $<90\%$ SpO_2 is rare. These data may serve as a basis for the interpretation of clinical recordings in preterm infants who have recorded oximetry studies in order to wean off supplemental oxygen.

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