eNeonatal Review

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In this issue...

The clinical application of blood gas analysis and pulse oximetry is regulated in the United States, with new guidelines enforcing the use of these technologies to monitor the baby in the delivery room and special care nursery. To date, the practice of delivery room resuscitation of the newborn in the United States has varied widely, with pulse oximetry gaining in popularity. However, the data used by the manufacturers of these technologies relies on test reagents, adult data, and controlled environments; indeed, every effort is taken by these technology manufacturers to isolate and limit variables in order to develop steady-state conditions during which reference data is collected. Unfortunately, the environs of caring for the sick newborn and physiological aspects unique to the infant make for circumstances less conducive to accurate data acquisition. To that point, a recent report of clinical use found the accuracy of pulse oximetry SpO_2 values in neonates was appreciably worse than manufacturers' claims.

In this issue, we review the current literature describing how manufacturers establish instrument accuracy, examine factors that can degrade accuracy, and provide tools for maximizing blood gas analysis and pulse oximetry performance in neonatal care.

This Issue

Guest Editor of the Month

Commentary & Reviews:
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Robert J. Kopotic
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No faculty member has indicated that their presentation will include information on off label products.

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April 15, 2006

Commentary

A long established measure of the degree and duration of fetal hypoxia has been blood pH, drawn either from the scalp or the cord, a practice carried into newborn care with pH analysis of heel puncture blood. Because of the stability of this value, factors such as the length of sampling time, the degree of exposure to air, and mixing of blood sources (arteriolar, capillary and venous) have little affect on measurement accuracy. However, of relevance to the topic at hand, blood gases (PaO_2 and $PaCO_2$), blood CO-oximetry (SaO_2), and pulse oximetry (SpO_2 and pulse rate) values are highly volatile in neonates and affected by many variables. In addition, blood analyzers are technically sophisticated devices, requiring a great degree of skilled maintenance to be kept in optimal working order. Conversely, a pulse oximeter requires little sophistication to operate, and the typical sensor is quite intuitive to place. Pulse oximetry is largely trouble-free, and requires minor user interface (other than the occasional changing of the sensor site). Perhaps the simple nature of pulse oximeter operation is cause for the lack of end-user understanding and results in badly interpreted data.[1-4]

The clinical application of blood gas analysis (BGA) and pulse oximetry (PO) is regulated in the United States by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). However, JCAHO requires compliance with the guidelines of other groups, primarily the Clinical and Laboratory Standards Institute (CLSI) and its predecessor NCCLS, prior to accrediting an institution. Relevant to this discussion, these guidelines focus on measurement via analytical instruments, such as analyzers for measurement of blood CO-oximetry, gas and pH.[5-8] These guideline documents primarily describe principles for collecting, handling, transporting, and analyzing arterial blood specimens, as well as instrument quality control matters, with the aims of reducing collection hazards, ensuring integrity of the arterial specimen, and achieving reliable data.

The standards emphasize that PO SpO_2 values are not a direct measure of the percent of arterial hemoglobin saturated with oxygen.[9-11] The current pulse oximeters in neonatal use cannot differentiate nor quantify dyshemoglobins. It is important to note that the *calculated* SaO_2 value reported via a blood gas analyzer is not a reference for SpO_2. Rather, only the *functional* SaO_2 value from CO-oximeter analysis of an arterial blood specimen can provide a reference for SpO_2. The CO-oximeter also provides a measure of the content of fetal versus adult hemoglobin. Table 1 reviews the user interventions and rationale associated with optimizing accuracy in comparing SaO_2 and SpO_2 values in neonates.

Download Optimizing comparison of a CO-oximetry SaO_2 value with pulse oximetry (PO) SpO_2 values in neonates.

The accuracy of PO SpO_2 values is derived by testing healthy adult human volunteers under controlled laboratory conditions (CLC). In CLC, every effort is taken to isolate and limit variables, and to seek steady-state conditions during which reference data can be synchronized. In the NICU, when the infant is the least stable, concurrence of BGA and PO data is most desired and expected. Table 2 details why the NICU environment is less conducive to accurate data acquisition than the CLC used by PO manufacturers. It is safe to assume that in contrast to the NICU, the collection of this data in the delivery room setting would be far more difficult and prone to patient and caregiver variables.

Download Comparing SaO_2 to SpO_2 data in an NICU versus that from controlled laboratory conditions.
Note: *Author Comments in Parentheses*

New guidelines for neonatal resuscitation have been promulgated.[12] Care of the sick newborn requires the best instrumentation complemented by thorough clinical vigilance. Pulse oximetry data derived immediately post-delivery have prompted comparative interventional studies.[13] Lack of PO was a contributing factor of poor outcome during infant sedation.[14] Some have suggested close-looping SpO_2 values to maintain normoxemia in mechanically ventilated infants.[15,16] With this degree of reliance on basic and advanced newborn care, PO accuracy is essential. Unfortunately, in clinical use, the accuracy of SpO_2 values in neonates

was found appreciably worse than manufacturers' claims. Caregivers should recognize multiple sources of compounding error in the clinical setting that can corrupt correlation of SaO_2 to SpO_2 values versus the claimed accuracy data of PO manufacturers. There is dissimilarity in populations (the ill neonate versus healthy adult) and an SpO_2 plateau at the time of blood sampling may not occur in the NICU, whereas SpO_2 plateaus are an expectation in the laboratory setting. Without controlling such influences, comparison between blood analysis and pulse oximetry values is fraught with error and the potential for misinterpretation. Owing to an avoidance of invasive risk, SpO_2 data are often relied upon in conditions where direct arterial access for corroboration of SpO_2 values does not exist, so the data go unchecked.

At the moment, it appears that while pulse oximetry is included in the updated resuscitation guidelines, clinical use data reveal oximeters currently used in neonatal care can lack the precision claims of their manufacturers. Given that, caution may be warranted in using pulse oximetry for a discrete value of SpO_2. Rather, a trend of stability or declining and increasing SpO_2 values may prove more beneficial to clinical care. Suggestions and rationale for optimizing blood gas and pulse oximetry data were included in this review to provide a common denominator for future comparative studies and maximize accuracy in the assessment of oxygenation in the acute care of newborns.

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16. Claure N, Gerhardt T, Everett R, Musante G, Herrera C, Bancalari E. Closed-loop controlled inspired oxygen concentration for mechanically ventilated very low birth weight infants with frequent episodes of hypoxemia. *Pediatr* 2001;107(5):1120-1124.

UPDATED GUIDELINES FOR RESUSCITATING THE NEONATE

International Liaison Committee on Resuscitation.
Part 13: Neonatal resuscitation guidelines.
Circulation 2005:112(24, suppl):IV188-IV195.

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The AAP News, the official newsmagazine of the American Academy of Pediatrics, recently reported that the AAP has adopted new guidelines for resuscitating neonates and will publish them in the May 2006 issue of the journal *Pediatrics*[12]. These revised guidelines, based on the 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, suggest the use of pulse oximetry in the periodic evaluation at 30-second intervals. They stress that the normal newborn may take >10 minutes for post-ductal SpO_2 values to reach 95%. Several paragraphs discuss room-air resuscitation versus 100% oxygen and note that: "Administration of a variable concentration of oxygen guided by pulse oximetry may improve the ability to achieve normoxia more quickly." Additional recommendations include advising facilities that electively deliver babies at less than 32 weeks' gestation to provide both oxygen blenders and pulse oximeters in delivery rooms. They also recommend starting mechanical ventilation with room air-diluted oxygen; the level should be adjusted up or down until oxyhemoglobin concentration increases to near 90%. (Practitioners should note that oxyhemoglobin is measured directly via CO-oximetry of arterial blood and estimated with the SpO_2 displayed by a pulse oximeter.)

The guidelines are based on a review of the latest scientific evidence, and affirm assessment of oxygenation status and management of supplemental oxygen therapy via pulse oximetry. Lacking, however, is specificity for resuscitation with airway concentrations of 100% oxygen or less, as well as adequate caution regarding the subjectivity of pulse oximetry data, and the need for performance optimization in the resuscitation setting (where challenges to instrument accuracy can be extreme).

VARYING U.S. PRACTICES OF RESUSCITATING THE NEWBORN POST DELIVERY

Leone TA, Rich W, Finer NN.
A survey of delivery room resuscitation practices in the United States.
Pediatrics 2006(2);117:164-175.

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This study addressed delivery room resuscitation practices in the United States with the aim of determining the extent of variation among neonatal programs. In 2004, the authors designed a 15-question survey about resuscitation staff, tools, and techniques. It was mailed to 795 neonatal directors; 450 surveys were completed (response rate of 63%), representing all 50 States.

The authors captured a snapshot of current NRP practices across the Unites States. Among their results, pertinent to the subject of this review, is that 52% of program directors used pulse oximetry, with 23% indicated that they had useful readings within 1 minute of placing a sensor. The authors remark that while the time to data acquisition may vary, pulse oximetry is useful for monitoring subsequent care of infants and is essential if clinicians wish to use a blender and to provide <100% oxygen. They further comment that their experience in evaluating neonatal resuscitation suggests that infants spend far more time in the resuscitation area than is anticipated, and the use of blenders and oximeters in such circumstances can reduce unnecessary exposure to excessive supplemental oxygen. While they suggest that in the delivery room the oximeter should be set to its lowest averaging time and highest sensitivity, the rationale and consequences of such settings are not discussed. Moreover, the shortcomings of pulse oximetry are not mentioned nor is reference made to means of reducing error.

The authors conclude that substantial variations exist in neonatal resuscitation practices, some of which are not addressed in existing guidelines. They recommend that future guidelines include the use of blenders, oximeters, continuous positive airway pressure/PEEP, and plastic wrap during resuscitation. Further, the authors express their hope that the widespread dissemination of these survey results will encourage re-evaluations of practice efficacy, so that future resuscitation practices will be evidence based.

DO NEONATAL SpO_2 VALUES CORRELATE WITH MEASURED ARTERIAL SATURATION?

Gerstmann D, Berg R, Haskell R, et al.
Operational evaluation of pulse oximetry in NICU patients with arterial access. Journal of Perinatology 2003;23(5):378-383.

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This wide-ranging study by Gerstmann et al sought to analyze available data recorded during the process of providing routine neonatal care. They performed a historical evaluation, a prospective evaluation, a procedural evaluation, a verification evaluation, and an evaluation of corroborating data from NICUs at several institutions.

Of particular note is their determination that a calculated SaO_2 via a blood gas analyzer was not appropriate for comparing SpO_2 accuracy; rather, they measured functional SaO_2 with the corresponding pre-blood draw baseline SpO_2. Multiple brands of CO-oximeters (ABL, Beyer, and Instrumentation Laboratory) and pulse oximeters (Datex-Ohmeda, Masimo, Nellcor and Spacelabs) were used. In order to contrast the neonatal performance of the models of pulse oximeter for which data were available, operational performance was defined as the frequency with which, at any given SaO_2 value, the corresponding SpO_2 reading was within a manufacturer's specified accuracy for neonates (typically, ±3 digits (1 SD) between 70% and 100% saturation).

Nearly 32 thousand data sets of SaO_2 to SpO_2 values collected during routine care were compared. While the range of SaO_2 was from 57% to 100%, most data were between 85% to 100%. As a point of measurement consistency between the two brands of CO-oximeters, 52 arterial blood samples were drawn from 10 neonates and run simultaneously on both CO-oximeters. The average difference in SaO_2 values was 0.07, which proved to be not statistically significant. However, none of the pulse oximeters provided a consistent bias of SpO_2 values across the range of SaO_2 of 70% to 100%. While SpO_2 accuracy was device dependant between an SaO_2 of 92% to 97%, performance declined for all manufacturers above and below this range. Indeed, a rapid drop in operational performance was seen in all pulse oximeters as SaO_2 decreased. As an example, at an SaO_2 of 80%, SpO_2 will typically read approximately 90%.

This study is the largest collection of neonatal data comparing SaO_2 and SpO_2 values. Notably, the period of data collection was nearly concurrent with the survey of neonatal directors by Leone et al (as above). Gerstmann et al suggest that the poor SpO_2 accuracy seen in their data seems at a level inconsistent with pulse oximetry's perceived importance, role and use in the NICU. Elaborating on the results, concerns of both over- and under- treatment were raised. They conclude, pending improvement in SpO_2 accuracy, that adjustments to supplemental oxygen and ventilator settings in the NICU patient "must be based on and re-evaluated by arterial blood analysis." Further, the authors demonstrated that some variables were not evident, e.g. the difference in CO-oximeter brand.

It must be noted that while the multi-center, multi-caregiver design of this study doubtless introduced inconsistencies, those inconsistencies accurately replicate the environment typical to the daily care of neonates in centers across the Nation.

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Ask the Author

Ask a Question about this Newsletter

LAST MONTH'S Q & A March 2006 - Volume 3 - Issue 7

Last issue we reviewed the clinical application of blood gas analysis and pulse oximetry, discussed the new guidelines enforcing the use of these technologies, and compared PO manufacturers' accuracy claims vs the

reality of caring for the sick newborn.

Commentary & Reviews:
Robert J. Kopotic, MSN, RRT, FAARC

Director of Clinical Programs

ConMed Corporation
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We received the following questions one of our subscribers.

Q Regarding the limitations of pulse oximetry technology: although we strive for a reliability value ±3%, we are still unclear on what our target saturations should be. Can you provide more clarification on this topic?

A The purpose of this review was to caution endusers on the shortcomings of blood analysis and pulse oximetry with a focus of optimizing their accuracy. Target SpO_2 values in neonatal care are a different matter, and are the subject of on-going investigation. Following are links to several recent papers on the subject, which should prove of interest.

Cole CH, Wright KW, Tarnow-Mordi W, Phelps DL; Pulse Oximetry Saturation Trial for Prevention of Retinopathy of Prematurity Planning Study Group. Resolving our uncertainty about oxygen therapy. Pediatrics. 2003 Dec;112(6 Pt 1):1415-9.

Lloyd J, Askie L, Smith J, Tarnow-Mordi W. Supplemental oxygen for the treatment of prethreshold retinopathy of prematurity. Cochrane Database Syst Rev. 2003;(2):CD003482. Review.

Saugstad OD. Optimal oxygen therapy in the newborn period. Pediatr Pulmonol Suppl. 2004;26:112-3.

The eNeonatal Review Team asked the March faculty a few questions.

Q Given the degree of caution raised in the Gerstmann et al paper (e.g., "use of the pulse oximeters tested could lead to over treatment...and...a neonate could be under treated"), is there a place for pulse oximetry in neonatal care?

A Perhaps pulse oximetry's greatest contribution to neonatal monitoring is as an indicator of the trend of oxygenation, and not a measure of absolute SaO_2 values. Consequently, it is essential that endusers understand, identify, and (hopefully) avoid blood components or external factors that may cause sustained erroneous SpO_2 readings.

Q Of the two blood oxygenation extremes (i.e., hyper- and hypoxemia), what is the role of SaO_2 versus SpO_2 monitoring?

A Numerous publications have warned that hyperoxemia is not well assessed with pulse oximetry, but observing trends of SpO_2 can be a helpful means of avoiding hypoxemia. However, monitoring blood specimens from direct arterial access for SaO_2 and/or PaO_2 values can be useful for managing either extreme.

Baeckert P, Bucher HU, Fallenstein F, Fanconi S, Huch R, Duc G. Is pulse oximetry reliable in detecting hyperoxemia in the neonate? Adv Exp Med Biol 1987;220:165-169.

Beresford MW, Parry H, Shaw NJ. Twelve-month prospective study of oxygen saturation measurements among term and preterm infants. J Perinatol. 2005 Jan;25(1):30-2.

Poets CF, Wilken M, Seidenberg J, Southall DP, von der Hardt H. The reliability of a pulse oximeter in the detection of hyperoxemia. J Pediatr 1993;122:87-90.

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At the conclusion of this activity, participants should be able to:

- Discuss the new guidelines for resuscitating neonates and the current lack of uniformity in resuscitation practices in the United States.
- Identify the means for establishing accuracy of blood gas analysis and pulse oximetry instrumentation.
- Describe, as they specifically relate to neonatal care, the issues that challenge the accuracy of blood gas analysis and pulse oximetry data.

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- Dr. Nogee has indicated a financial relationship of grant/research support with Forest Laboratories and has received an honorarium from Forest Laboratories.
- Dr. Lawson has indicated a financial relationship of grant/research support from the NIH. He also receives financial/material support from Nature Publishing Group as the Editor of the Journal of Perinatology.
- Dr. Lehmann has indicated a financial relationship with the Eclipsys Corporation.

All other faculty have indicated that they have not received financial support for consultation, research, or evaluation, nor have financial interests relevant to this e-Newsletter.

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