Pulse Oximetry in Children With Congenital Heart Disease: Effects of Cardiopulmonary Bypass and Cyanosis

Adalberto Torres Jr, MD, FAAP*
Kelly M. Skender, MSN, PNP†
Julie D. Wohrley, MD*
Jean C. Aldag, PhD*
Gary W. Raff, MD*
G. Kris Bysani, MD*
Dale M. Geiss, MD*

The objective of this prospective, observational study was to assess the reliability, bias, and precision of Nellcor N-395 (N) and Masimo SET Radical (M) pulse oximeters in children with cyanotic congenital heart disease and children with congenital heart disease recovering from cardiopulmonary bypass–assisted surgery admitted to a cardiovascular operating suite and pediatric intensive care unit at a tertiary care community hospital. Forty-six children with congenital heart disease were studied in 1 of 2 groups: (1) those recovering from cardiopulmonary bypass with a serum lactic acid > 2 mmol/L, and (2) those with co-oximetry measured saturations (SaO₂) < 90% and no evidence of shock. Measurements of SaO₂ of whole blood were compared to simultaneous pulse oximetry saturations (SpO₂). Data were analyzed to detect significant differences in SpO₂ readout failures between oximeters and average SpO₂ – SaO₂ ± 1 SD for each oximeter. A total of 122 SaO₂ measurements were recorded; the median SaO₂ was 83% (57–100%). SpO₂ failures after cardiopulmonary bypass were 41% (25/61) for N versus 10% (6/61) for M (P < .001). There was a significant difference in bias (ie, average SpO₂ – SaO₂) and precision (± 1 SD) between oximeters (N, 1.1 ± 3.3 vs M, −0.2 ± 4.1; P < .001) in the postcardiopulmonary bypass group but no significant difference in bias and precision between oximeters in the cyanotic congenital heart disease group (N, 2.9 ± 4.6 vs M, 2.8 ± 6.2; P = .848). The Nellcor N-395 pulse oximeter failed more often immediately after cardiopulmonary bypass than did the Masimo SET Radical pulse oximeter. SpO₂ measured with both oximeters overestimated SaO₂ in the presence of persistent hypoxemia.

Key words: monitoring, pediatrics, cardiac surgery, oxygen saturation, pulse oximetry, arterial blood gases

Pulse oximetry is considered by many clinicians as the fifth vital sign and is widely used in many clinical settings [1]. Intensivists rely heavily on this non-invasive instrument to continuously assess the adequacy of oxygenation and to track the need and response to therapy. However, it has been well documented that pulse oximetry is less reliable and less accurate under certain conditions, such as poor peripheral perfusion and in children with hypoxemia [2-11]. Using various hypoperfusion models (eg, tourniquet, decreased ambient temperature), multiple investigators have demonstrated in adult volunteers that pulse oximeters increasingly fail and become less accurate, that is, > 2% difference in pulse oximeter saturation (SpO₂) and co-oximeter measured saturation (SaO₂) [2,7,8]. Others have demonstrated that pulse oximeters become less accurate in patients with hypoxemia, including both children [4,5,9] and adults [6,10]. Clinicians caring for patients with severe shock or hypoxemia (eg, children with cyanotic heart disease) are often required to obtain arterial blood gases to accurately assess the patient’s oxygenation or make a less than adequately informed medical decision.

Manufacturers of 2 newer generation pulse oximeters, the Masimo SET Radical and the Nellcor N-395, claim an accuracy of ± 3% during periods of poor peripheral perfusion and with arterial oxygen saturations as low as 70% [12,13]. These 2 oximeters have not been validated in children with poor...
perfusion or hypoxemia. We hypothesized that SpO\textsubscript{2} measured with the Nellcor N-395 and the Masimo SET Radical pulse oximeters were neither accurate nor precise when compared with SaO\textsubscript{2} of the whole blood of children immediately recovering from cardiopulmonary bypass, a transient period of poor peripheral perfusion, or in children with persistent hypoxemia (ie, an SaO\textsubscript{2} < 90%).

Materials and Methods

A prospective observational study with consecutive sampling was proposed to the community institutional review board and approved. The study was deemed exempt from requiring informed consent by the community institutional review board.

Two groups of children with congenital heart disease were studied: (1) children undergoing cardiopulmonary bypass–assisted cardiac surgery and (2) children with persistent hypoxemia. Twenty-five children with congenital heart disease undergoing surgical repair (n = 13) or palliation (n = 12) using cardiopulmonary bypass, arterial catheter in place, and a serum lactic acid ≥ 2 mmol/L (ie, evidence of insufficient tissue perfusion) were recruited between February 27, 2001, and August 6, 2001. Patients were excluded if pulse oximeter readings within 2% of each other prior to the start of cardiopulmonary bypass were unobtainable and if the serum lactic acid was < 2 mmol/L after cardiopulmonary bypass.

Twenty-one children with cyanotic congenital heart disease, an arterial catheter in place, and a measured SaO\textsubscript{2} consistently less than 90% on serial blood gases were recruited between August 7, 2001, and December 18, 2002. Four children were enrolled on 2 separate occasions following distinct operations. To avoid recruiting patients in a state of poor perfusion similar to the postcardiopulmonary bypass period, patients in this group were excluded if they displayed any clinical features of shock (eg, tachycardia, cool peripheral extremities, oliguria, serum lactate acid ≥ 2 mmol/L, etc).

The pulse oximeters tested were the Masimo SET Radical (version 3, Masimo Corporation, Irvine, Calif) and the Nellcor N-395 (Nellcor Puritan Bennett, Inc, Pleasanton, Calif). The whole-blood co-oximeter used to measure SaO\textsubscript{2} in the postcardiopulmonary bypass group was the IL Synthesis 1725 (Instrumentation Laboratories, Lexington, Mass). Because of an institutional change in laboratory equipment, the whole-blood co-oximeter used to measure SaO\textsubscript{2} in the cyanotic congenital heart disease group was the IL 682 (Instrumentation Laboratories, Lexington, Mass).

A pulse oximeter probe attached to each oximeter was attached to the same distal extremity: one on a digit and the other on the palm or sole. Probes were not attached to extremities with arterial catheters in place to avoid potential interference from diminished arterial blood flow. Palliative shunts were positioned centrally, that is, aorta to pulmonary artery confluence, when placed in certain patients (eg, hypoplastic left heart syndrome, unbalanced atrioventricular canal), making it feasible to obtain an SpO\textsubscript{2} measurement for comparison from an extremity different from the extremity with the arterial catheter. The probes were optically shielded. SpO\textsubscript{2} displayed on each pulse oximeter at the time routine arterial blood SaO\textsubscript{2} measurements were recorded. Cardiopulmonary monitor heart rate, pulse oximeter heart rate, and failure of pulse oximeter to display SpO\textsubscript{2} at the time of the blood gases measurement were also recorded for analysis.

Core temperature, cardiopulmonary bypass time, and aortic cross-clamp time were recorded for analysis in the cardiopulmonary bypass group. None of the subjects in the cyanotic congenital heart disease group were hypothermic (ie, core temperature < 36°C) at the time of study measurements, and therefore, core temperature was not measured.

Bias and precision, measures of agreement described by Bland and Altman [14], were used to compare SpO\textsubscript{2} measurements by both oximeters with the co-oximetry SaO\textsubscript{2} measurements. Bias is defined as the average of the differences between the method being tested and the gold standard (SpO\textsubscript{2} − SaO\textsubscript{2}), and the precision is the standard deviation of that difference. The expected range of that difference between the 2 measurements, that is, the limits of agreement, are then calculated as the bias ± 1.96 × SD. These data points were graphically displayed as bias plots. The vertical axis represented the SpO\textsubscript{2} − SaO\textsubscript{2} difference, and the horizontal axis represented the average saturation [(SpO\textsubscript{2} + SaO\textsubscript{2})/2]. χ\textsuperscript{2} test was used to detect a significant difference in data readout failures between oximeters at the time of the SaO\textsubscript{2} measurements in the postcardiopulmonary bypass group. A Wilcoxon signed ranks test was used to detect differences in matched data (ie, pulse oximeter heart rate and cardiac monitor heart rate), and the Mann-Whitney U test was used to detect differences in unmatched data. Spearman rank correlation was used to detect significant relationships between the absolute SpO\textsubscript{2} − SaO\textsubscript{2} differences and patient characteristics (eg, hematocrit, core temperature, aortic
cross-clamp time). Mean differences ± 1 standard deviation were reported. A $P$ value < .05 was considered significant.

**Results**

Table 1 contains the characteristics of the 46 patients enrolled. There were a total of 122 SaO$_2$ measurements obtained, 61 measurements obtained in each group. The median (range) SaO$_2$ measurement was 83% (57%-100%). Seventy-seven of the 122 (63%) SaO$_2$ measurements obtained were less than 90%. The median serum lactic acid concentration was 1.8 mmol/L (0.4-12.7). The median hematocrit was 40% (19%-54%).

### Postcardiopulmonary Bypass Group

The Nellcor N-395 pulse oximeter failed to measure the SpO$_2$ during 41% (25/61) of the SaO$_2$ measurements compared to 10% (6/61) for the Masimo SET Radical pulse oximeter ($P < .001$). There was a significant difference in bias ± precision but no significant difference in heart rate between oximeters (see Table 2).

There was a significantly negative relationship between absolute SpO$_2$ – SaO$_2$ difference of Masimo SET Radical and aortic cross-clamp time ($r = -0.29$, $P = .03$) and core temperature ($r = -0.42$, $P = .001$). Both pulse oximeters had significantly positive relationships between absolute SpO$_2$ – SaO$_2$ difference and hematocrit (Nellcor N-395: $r = 0.46$, $P < .01$; Masimo SET Radical: $r = 0.35$, $P < .01$). There was no significant relationship between pulse pressure and absolute SpO$_2$ – SaO$_2$ difference for the Nellcor N-395 ($r = -0.03$, $P = .9$) or the Masimo SET Radical ($r = 0.22$, $P = .1$).

Seventeen of the 61 (28%) SaO$_2$ measurements were less than 90%. There was a significant difference in bias ± precision when comparing SaO$_2$ < 90% versus SaO$_2$ ≥ 90% measurements for the Nellcor N-395 (4.9 ± 4.7 vs 1.4 ± 1.6; $P = .02$) and the Masimo SET Radical (4.1 ± 2.9 vs 1.3 ± 1.6; $P < .001$).

### Cyanotic Congenital Heart Disease Group

There were no SpO$_2$ failures for either oximeter in any of the subjects in this group. There was no significant difference in bias ± precision between oximeters in this group (see Table 2). The mean heart rate differences were not significantly different ($-0.1 ± 2.0$, Nellcor N-395 vs $-0.05 ± 1.8$, Masimo SET Radical; $P = .973$).

Neither pulse oximeter had a significant relationship between absolute SpO$_2$ – SaO$_2$ difference and hematocrit in this group (Nellcor N-395: $r = 0.04$, $P = .76$; Masimo SET Radical: $r = 0.24$, $P = .07$).

Figures 1 and 2 are bias plots for each oximeter.

### Discussion

Manufacturers of the 2 newer generation pulse oximeters tested assert recent technological advances have overcome 2 of the obstacles to adequate clinical performance: motion and low perfusion. Nellcor’s Oxismart XL Advanced Signal Processing technology functions by locking onto a pulse signal and then multiple algorithms work together to track the pulse rate and SpO$_2$ [12]. They assert that this advanced microprocessing technology will filter out corrupted signals caused by motion, environmental noise, and low perfusion...
Masimo’s Signal Extraction Technology (SET) applies multiple algorithms to filter the pulse signal and to extract the arterial from the venous signal and report the true SpO2 and pulse rate during motion and low perfusion conditions [13]. We compared these 2 technologically advanced pulse oximeters to the gold standard, measured SaO2, to evaluate their performance under 2 conditions prone to inaccuracies: low perfusion and hypoxemia. Children who have undergone cardiopulmonary bypass with subsequent lactic acidosis are considered comparable to children with a pathologically caused low perfusion condition [15]. The major difference between the Nellcor N-395 and the Masimo SET was the proportion of readout failures in the postbypass group (41% vs 10%, respectively). A study comparing percentage of nonfunctional monitoring time after coronary artery bypass surgery in 86 adults revealed that the Masimo SET Radical but not for the Nellcor N-395. The high failure rate for the Nellcor N-395 during low perfusion conditions would likely result in a greater number of arterial blood gases being performed to ensure adequate SaO2.

Another significant finding of our study was the increase in bias and precision, that is, loss of accuracy and increase in scatter, for both oximeters when SaO2 was < 90%. Both manufacturers assert that their pulse oximeter is “accurate” even at a low SaO2 of 70% [12,13]. Bell and colleagues [9] reported a significant increase in precision for 3 oximeters (Ohmeda 3700, Novametrix 520A, and the Nellcor N-200) when the SaO2 was < 90% in children undergoing major operations including cardiac surgery. Jubran and Tobin [10] found a significant increase in bias and precision for a Nellcor brand pulse oximeter and an Ohmeda 3700 pulse oximeter when the SaO2 was ≤ 90% compared to an SaO2 > 90% (5.1% ± 2.7% vs 1.7% ± 1.2%; P < .001). Results of 2 studies of pulse oximetry in children with cyanotic congenital heart disease are conflicting: one reported an increase in bias and
precision with an $\text{SaO}_2 < 80\%$ [5], and the other reported no difference with an $\text{SaO}_2$ of $< 80\%$ [20]. The increase in scatter on the bias plots appears to occur at $(\text{SpO}_2 + \text{SaO}_2)/2 < 90\%$ for the Masimo Radical SET compared to $(\text{SpO}_2 + \text{SaO}_2)/2 < 80\%$ for the Nellcor N-395. Algorithms used by the manufacturers probably do not contain adequate numbers of patients with hypoxemia, which might explain these findings. The apparent increase in bias and precision when $\text{SaO}_2$ was $< 90\%$ in the postcardiopulmonary group versus the persistent hypoxemia group may have been secondary to the combination of low perfusion and hypoxemia in the postcardiopulmonary group or the different co-oximeter methodology used in each group (light scatter [IL Synthesis 1725] vs spectrophotometry [IL 682]). Published data comparing the 2 technologies were lacking. Nevertheless, the results in both groups confirmed diminished pulse oximeter performance when $\text{SaO}_2 < 90\%$.

It has been well documented that different pulse oximeters do not perform similarly when tested under other adverse conditions [2-11]. For example, Van de Louw and colleagues [21] reported a statistically significant (but not clinically significant) difference in bias for 3 pulse oximeters (Nellcor N-200, Ohmeda 3700, and the Hewlett Packard Viridia 24C) when vasoactive agents were being administered to children admitted to a pediatric intensive care unit. Other studies of older generations of pulse oximeters still widely used have reported variable performances when tested under different, low perfusion conditions [15,22]. Macnab and colleagues [15] reported a bias $< 2\%$ for the Biox 3700 in 58 children recovering from deep hypothermia for cardiac surgery regardless of core temperature, while Ibáñez and colleagues [22] reported an absolute bias of $> 4\%$ for the Biox 3700 pulse oximeter in 9 of 24 (37%) adult patients receiving vasoactive agents.

The absolute bias and precision for both oximeters correlated best with the patients’ hematocrit in the cardiopulmonary bypass group but not in the persistent hypoxemia group. One study examining the accuracy of the Nellcor N-100 pulse oximeter in children with cyanotic congenital heart disease did not demonstrate a correlation between high hematocrit concentrations and the oximeter’s bias and precision [5]. Hematocrit of the whole blood may have a greater impact on the rheology of the red blood cells under low perfusion conditions and therefore alter the reflective characteristics of capillary blood. The lack of a correlation between pulse pressure and the absolute bias and precision are similar to the findings of Villanueva and colleagues [3], who found only a weak correlation between pulse pressure and the bias of the Nellcor N-200 pulse oximeter.

One limitation of our study was the lack of peripheral skin temperature monitoring. Studies have reported conflicting data regarding the relationship between peripheral skin temperature and pulse oximeter performance as mentioned previously. Barker and colleagues demonstrated that sensor malpositioning during pulse oximetry testing under conditions of hypoxemia significantly altered accuracy [23]. Although sensor positioning could not be checked during the study in the cardiopulmonary bypass group, the patients were all neuromuscularly blocked during the testing, making it unlikely that patient motion caused sensor malpositioning. Probes were examined for sensor positioning after the measurements were made, and none of the probes appeared displaced. And finally, probe position may have influenced the results of our study. No data were available regarding differences in accuracy based on probe position (eg, toe vs sole of the foot). Since no attempts were made to randomly place the different probes in the different positions, it is possible that probe position may have influenced our results.

**Conclusions**

The Masimo Radical SET and Nellcor N-395 pulse oximeters have an acceptable accuracy but unacceptable precision in children with congenital heart disease. The Nellcor N-395 pulse oximeter failed significantly more often than the Masimo SET Radical pulse oximeter did in children with lactic acidosis recovering from cardiopulmonary bypass. Performance of both oximeters worsened when $\text{SaO}_2$ was $< 90\%$ compared to $\text{SaO}_2$ of $\geq 90\%$. Clinicians should refrain from altering management of the child with cyanotic congenital heart disease based solely on pulse oximetry readings with the pulse oximeters studied.

**Acknowledgments**

This study was supported in part by the Department of Pediatrics, University of Illinois College of Medicine at Peoria. We are grateful to the cardiovascular surgery and pediatric intensive care unit staff for their patience and are especially grateful to the perfusionists for their unselfish assistance. We are also grateful to the Masimo.
Corporation for the unreimbursed supply of Masimo SET pulse oximeter probes. This study was presented in part at the Society of Critical Care Medicine’s 32nd Society of Critical Care Medicine Congress, San Diego, California, January 28, 2002, and at the 31st Society of Critical Care Medicine Congress, San Antonio, Texas, January 30, 2003.

References