Published in final edited form as:

J Cardiothorac Vasc Anesth. 2016 October ; 30(5): 1167–1171. doi:10.1053/j.jvca.2016.03.148.

Non-Invasively Measured Hemoglobin Concentration Reflects Arterial Hemoglobin Concentration before but not after Cardiopulmonary Bypass in Patients Undergoing Coronary Artery or Valve Surgery

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Abstract

Objective—This study compared non-invasively measured hemoglobin and arterial hemoglobin before and after cardiopulmonary bypass in patients undergoing coronary artery or valve surgery.

Design—Observational study with retrospective data analysis.

Setting—Veterans Affairs hospital.

Participants—Thirty-five men.

Interventions—None.

Measurements and Main Results—We compared hemoglobin values measured non-invasively by co-oximetry (Radical-7 Pulse CO-Oximeter; Masimo, Irvine, CA) to corresponding arterial hemoglobin concentrations taken at clinically relevant time points chosen at the discretion of the cardiac anesthesiologist. Thirty-five and 27 pooled pairs of data were obtained before and after cardiopulmonary bypass, respectively. Arterial hemoglobin concentration was analyzed using i-STAT CG8+ test cartridges (Abbott Point of Care, Princeton, NJ) routinely used in our operating rooms and those of other institutions. Linear regression and Bland-Altman analysis revealed a significant positive bias, wide limits of agreement, and low correlation coefficients between the non-invasive and arterial hemoglobin measurements. These findings were especially notable after compared with before cardiopulmonary bypass.

Conclusions—The results suggest that non-invasive measurement of hemoglobin overestimates arterial hemoglobin by almost 1 g/dL when compared to iSTAT. A lack of precision was also

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observed with non-invasive measurement of hemoglobin especially after cardiopulmonary bypass. These findings support the contention that sole reliance on non-invasive measurement of hemoglobin for transfusion decisions in cardiac surgery patients may be inappropriate.

Keywords

Masimo Radical-7; i-STAT; non-invasive hemoglobin monitoring; instrumentation; cardiac surgery; cardiopulmonary bypass

Introduction

Non-invasive, continuous hemoglobin (Hb) measurement without blood sampling offers several potential advantages including almost instantaneous, rapidly repeatable results without pain, exposure to blood-borne pathogens, and avoidance of needle stick injuries.¹ These and other features make non-invasive Hb measurement especially attractive for patients in the intensive care unit and the operating room. The Masimo Radical-7 Pulse Co-oximeter (Masimo Corporation, Irvine, CA) is a multi-wavelength spectrophotometer that allows continuous, non-invasive Hb monitoring (SpHb) as a component of its pulse oximetry platform. Since the device's release a few years ago, many studies have investigated the accuracy of the device in a variety of clinical settings, often with widely variable conclusions.¹⁻³

To the authors' knowledge, the intraoperative accuracy of the Radical-7 in patients undergoing cardiac surgery has not been examined. The authors compared SpHb CO-oximetry values with Hb obtained directly from arterial blood samples in cardiac surgery patients before and after cardiopulmonary bypass (CPB). We tested the hypothesis that SpHb measured using the Masimo Radical-7 device closely correlated with arterial Hb during coronary artery or valve surgery.

Methods

This study was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The study was approved (7435-3) by the Institutional Review Board of the Clement J. Zablocki VA Medical Center, Milwaukee, WI; the requirement for written informed consent was waived. Thirty-five consecutive men between the ages of 18 and 85 undergoing coronary artery bypass grafting (CABG) with or without valve repair or replacement or valve surgery alone were used to compare simultaneously collected SpHb values and arterial Hb obtained at clinically relevant time points chosen at the discretion of the attending cardiac anesthesiologist before and after CPB. Hb values from arterial samples were measured with i-STAT Handheld devices (calibrated every 8 hours) using CG8+ test cartridges (Abbott Point of Care, Princeton, NJ), routinely used in the cardiac operating room of the Clement J. Zablocki VA Medical Center. SpHb values were measured and recorded concurrently with a Masimo RDS-1 Radical-7 Signal Extraction Pulse CO-Oximeter with Rainbow Technology (Version 7.7) and disposable R2-25a Pulse Oximeter Adult Optical Sensors connected through a reusable R2-25r cable (Masimo, Irvine, CA). Cardiac anesthesiologists were blinded to the SpHb readings, and clinical care decisions were not influenced by SpHb measurements.

Statistical Analysis

A power analysis revealed a minimum sample size of 30 patients for an alpha of 0.05, a power of 0.9, and a correlation coefficient of $r = 0.5$. All data are expressed as mean $\pm$ standard error of the mean (SEM) or as percentages. Linear regression analyses were conducted with SigmaPlot for Windows (version 12.0; Systat Software, Inc.; San Jose, CA). Data were also analyzed to calculate bias and limits of agreement using Bland-Altman analysis. While the traditional Bland-Altman technique assumes independent sampling and that only one measurement per subject is obtained under constant conditions,⁴ in the current investigation, more than one observation per patient was obtained under changing physiological conditions resulting from surgery and CPB. Thus, measurement of each subject more than once and under different conditions may violate the original assumptions of independent sampling as described by Bland and Altman. Multiple (dependent) measurements from multiple (independent) patients require a different approach.⁵ To properly account for this sampling strategy, the use of pooled data that can account for multiple measurements is recommended.^{6,7} Therefore, the authors used a method in which the average means and differences for each subject before vs after CPB were pooled; these values were then used for subsequent Bland-Altman analysis to calculate bias and limits of agreement. The data are plotted using hemoglobin error grids that allow direct comparisons of concurrently measured hemoglobin concentrations while also considering the clinical context of the values as they relate to professional guidelines regarding packed red blood cell transfusion.⁸⁻¹⁰ Percentages were compared using Chi-Square testing. The null hypothesis was rejected when the p value (two-tailed) was less than 0.05 (*).

Results

All data were normally distributed. The patients were 65.8 ± 1.2 years old, had an average height and weight of 176.3 ± 1.3 cm and 90.9 ± 3.5 kg, respectively. Twenty-nine (83%) of the 35 patients underwent CABG surgery, 14 (40%) had valvular surgery. Their preoperative hemoglobin concentration was 13.3 ± 0.3 g/dL and bypass duration was 168 ± 11 min in average.

Thirty-five and 27 pooled data pairs were obtained from 35 patients before and after CPB, respectively. Before CPB, the regression was $\text{SpHb} = 3.85 \pm 2.05 + 0.73 \pm 0.18 \text{ Hb}$, $R^2 = 0.33$, $P < 0.001$ (Fig 1, upper panel); Bland-Altman analysis showed a bias of $+0.88$, a precision (one standard deviation) of ± 1.82 , resulting in upper and lower limits of agreement of $+4.45$ and -2.69 , respectively (Fig 1, lower panel). After CPB, this worsened to $\text{SpHb} = 5.78 \pm 2.28 + 0.50 \pm 0.25 \text{ Hb}$, $R^2 = 0.13$, $P = 0.062$ (Fig 2, upper panel) with Bland-Altman analysis showing a bias, precision, and upper and lower limits of agreement of $+1.33$, ± 1.64 , $+4.53$ and -1.88 , respectively (Fig 2, lower panel).

Using a clinically relevant hemoglobin error grid introduced by Morey et al.,⁸ there was a significant increase from 5/35 (14.3%) of all value pairs being outside zone A (green) from before CPB to 15/27 (55.6%) after CPB ($P = 0.002$). In case of a standardized transfusion trigger of, e.g., 10 g/dL, a commonly used value in cardiac surgery patients, non-invasive hemoglobin measurement would have led to unnecessary transfusions in 3/35 patients (8.6%) pre-CPB (Fig 1, solid arrows) and in 1/27 patients (3.7%) post-CPB (Fig 2, solid

arrows). Conversely, in 5/35 patients (14.3%) pre-CBP (Fig 1, dashed arrows) and in 13/27 patients (48.1%) post-CBP (Fig 2, dashed arrows) an indicated transfusion would have been missed.

Discussion

The consistently positive bias observed in the current investigation indicates that SpHb not only overestimates Hb in cardiac surgery patients by almost 1 g/dL pre CPB, but also demonstrates a lack of precision in SpHb measurement because of wide limits of agreement and low correlation coefficients. As displayed in the pre-CPB Morey plot (Fig 1), this observation may not be clinically relevant before CPB because most Hb values were above 10 g/dL, a common trigger for transfusion of red blood cells in cardiac surgery patients. After CPB, non-invasively measured SpHb deviates to an even greater extent as indicated by an even larger positive bias. SpHb also demonstrated wide limits of agreement and no significant correlation with arterial Hb. These data suggest that SpHb may be unreliable as non-invasive measurement of Hb and cannot be used to guide clinical care, especially after CPB. Indeed, the post-CPB Morey plot (Fig 2) shows a similar number of points in zone B (yellow) compared with zone A (green). This observation confirms that SpHb overestimates Hb measured by iSTAT in a majority of cases and emphasizes that solely using SpHb to make a clinical decision about transfusion may be inappropriate.

Since its introduction on the market more than half a decade ago, non-invasive SpHb has been the focus of numerous studies in pediatric,^{11–15} spine,^{16–18} trauma,^{19, 20} obstetric,^{21–23} urological,²⁴ abdominal surgery,^{25, 26} emergency,^{27–29} critically ill^{30–32} and other patient groups^{33–40} as well as a few review articles.^{1–3}

Calculating merely the correlation between SpHb and Hb alone (as is often reported as a single outcome) is insufficient to describe the accuracy of an alternative technique compared with a commonly used technique.⁴¹ When using Bland-Altman analysis a considerable positive and negative biases with wide limits of agreement between SpHb and Hb have been reported in many previous studies.^{19, 22, 24, 25, 27, 31, 32, 42} These data emphasize that the Radical-7's usefulness may be limited for clinical decision making under a variety of conditions. Our findings confirm and extend these past results in an additional population, cardiac surgery patients. The increase in bias with a continuously wide interval between limits of agreement between SpHb and Hb makes SpHb unreliable for determining the need for red blood cell transfusion after CPB, a time period in which anemia is common. The post-CPB Morey plot with many measurements outside the zone A (Fig 2) and the number of theoretically missed transfusions clearly demonstrate this limitation of SpHb. Although anemia, increased peripheral vasoconstriction, not completely recovered temperature in the fingers, and other physiological changes during the immediate post-CPB period may explain the observed differences from before to after CPB, this is a period of the operation where accuracy is most important, and the Masimo device appears to overestimate Hb measured by iSTAT even more than before CPB.

The current results should be interpreted within the constraints of several limitations. First, this is a single center, observational study with a quantitatively limited and specific patient

population, that is 35 male patients at a Veterans Hospital undergoing CABG or valve surgery; thus, the current conclusions cannot necessarily be translated to other patient populations, other cardiac procedures, or different clinical conditions. As an observational study it was not designed or approved to alter the anesthetic care for our patients by the cardiac anesthesiologists. Therefore, time points when arterial blood samples for Hb measurements were obtained differed from patient to patient. The observational character and the limited patient number also precluded identifying factors possibly associated with poor accuracy such as, e.g., the degree of hemodilution, perfusion, temperature, etc.

Second, we have used Point of Care i-STAT CG8+ cartridges as our and many other institutions' intraoperative standard-of-care to assess Hb intraoperatively. iSTAT measures hematocrit and calculates Hb by division with a fixed ratio of the two. iSTAT utilizes electrical conductivity. Although, compared to other references, it is reasonably accurate under stable conditions, its measurement is affected by other components that conduct electricity such as, e.g., electrolytes, hypoproteinemia during hemodilution,⁴³ heparin, leukocytosis, etc.⁴⁴ Under those conditions, iSTAT may underestimate true Hb. Thus, we cannot exclude that the current observations are not influenced by bias or imprecision inherent to the iSTAT method.^{32, 45} On the other hand, noninvasive SpHb measurement by co-oximetry can also be affected by a variety of conditions such as poor perfusion, movement, exogenous light or light reflectors such as lipids or hemolysis. Since Masimo uses a proprietary algorithm, it is unknown if these conditions are corrected for or not.

Third, we did not record any measure of the quality of perfusion to the digit from which SpHb was measured. As a result, the potential influence of low perfusion on the results, especially post-CPB, must be considered.^{17, 31, 37} However, all patients separated from CPB successfully with stable hemodynamics, and all pulse oximetry readings obtained with the device were of good quality. These observations suggest that it is unlikely that low perfusion to the measurement digit was solely responsible for the current results.

Finally, the results may have been altered by a relative increase in microcirculatory Hb concentration during anemia, which is common after CPB.³⁴ Co-oximetry measures absorption due to total hemoglobin which includes macro- and microcirculatory hemoglobin. Conductivity techniques as utilized by iSTAT, on the other hand, have been reported to measure lower Hb during conditions of hemodilution such as after CPB.⁴³ Thus, a differential effect of free Hb may have contributed the increased discrepancy between the two technologies especially post-CPB.

In conclusion, non-invasive SpHb can reflect arterial Hb concentration before, but not after CPB in patients undergoing CABG and/or valve surgery. SpHb may be an unreliable indicator of arterial Hb under these conditions and cannot be used as a sole technology to quantify Hb concentrations or guide decisions about transfusion.

Acknowledgments

Funding: Institutional only. Unrelated research funding to MLR was received from the Department of Veterans Affairs (IK2 BX001278) and the National Institutes of Health (5R01 HL123227).

The authors would like to thank Adele Vogel, Guillermo Hernandez, Thomas J. Ebert, MD, PhD and Darren S. Nabor, MD for their assistance with this study.

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Figure 1.

upper panel: Regression of pooled SpHb vs pooled Hb in a hemoglobin error grid for all *pre*-CPB data (circles). The iSTAT reference method of Hb is plotted along the abscissa (x-axis), the experimental method of non-invasive hemoglobin (SpHb) is plotted along the ordinate (y-axis). The line of regression (solid straight line) with 95% confidence intervals (solid round lines) and the line of identity (dotted diagonal line) are noted. The regression was $\text{SpHb} = 3.85 \pm 2.05 + 0.73 \pm 0.18 \text{ Hb}$, $R^2 = 0.33$, $P < 0.001$. Zones A (green), B (yellow), and C (red) symbolize different significances. Zone A is defined by the area between the following two lines: a lower line stretching from the origin to ordered pairs (x, y) of (6.0, 2.0), (6.0, 5.4), (10.0, 9.0), and (18.0, 9.0) and an upper line stretching from the origin to (2.0, 6.0), (5.4, 6.0), (9.0, 10.0), and (9.0, 18.0). Zone A has a smaller lower section for Hb < 6.0 g/dL, an isthmus, and a larger upper section for Hb > 10.0 g/dL. These values were chosen based on the 2015 ASA practice guidelines for transfusion which recommends red blood cell transfusion for Hb < 6.0 g/dL (lower zone A) whereas transfusion is likely not

necessary for Hb >10.0 g/dL (upper zone A).¹⁰ Thus, in the upper zone A, any measurement bias will not affect the patient as transfusion is unlikely to occur; in contrast, in the lower zone A, the patient will be transfused irrespective of the measurement method. The isthmus of zone A is the clinical decision making section where Hb is a critical element if a patient is transfused. This is the most important section of the Morey grid where the reference and alternative device must closely agree. Upper and lower zones B are defined as the areas between zone A and the upper and lower zones C. The upper zone C is defined by a line with the following ordered pairs: (2.0, 10.0), (6.0, 10.0), and (6.0, 18.0). The lower zone C is defined by a line with the ordered pairs: (10.0, 2.0), (10.0, 6.0), and (18.0, 6.0). Lower panel: Bland-Altman blot of the individual differences of SpHb/Hb value pairs over their individual means (pooled data) with a bias (average of differences in Bland-Altman blot, solid line) of +0.88 and 95% upper and lower limits of agreement (± 1.96 standard deviation of bias, dashed lines) of +4.45 and -2.69, respectively.

Figure 2.

upper panel: Regression of pooled SpHb vs pooled Hb in a hemoglobin error grid for all *post*-CPB data (diamonds). The iSTAT reference method of Hb is plotted along the abscissa (x-axis), the experimental method of non-invasive hemoglobin (SpHb) is plotted along the ordinate (y-axis). The line of regression (solid straight line) with 95% confidence intervals (solid round lines) and the line of identity (dotted diagonal line) are noted. The regression was $\text{SpHb} = 5.78 \pm 2.28 + 0.50 \pm 0.25 \text{ Hb}$, $R^2 = 0.13$, $P = 0.062$. For explanations regarding zones A (green), B (yellow), and C (red) please refer to Figure 1 legend. Lower panel: Bland-Altman blot of the individual differences of SpHb/Hb value pairs over their individual

means (pooled data) with a bias (average of differences in Bland-Altman blot, solid line) of +1.33 and 95% upper and lower limits of agreement (± 1.96 standard deviation of bias, dashed lines) of +4.53 and -1.88 , respectively.

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