

Original Article

Accuracy of Continuous Monitoring of Haemoglobin Concentration after *In-Vivo* Adjustment

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Abstract

During open aortic aneurysm repair, continuous, non-invasive measurement of Haemoglobin concentration (SpHb), provided by Radical 7 device (Masimo Corp, Irvine, CA, USA) may be advantageous for assessing acute anaemia and improve the ability of the anesthesiologist to decide when to initiate blood transfusion. A strategy to improve the device's accuracy is the *in-vivo* adjustment (AdHb) using a haemoglobin value provided by Blood Gas Analyser (BGA).

In this retrospective analysis, we hypothesised that adjustment using the first haemoglobin value provided by BGA could increase the accuracy of Radical 7 device when compared with the standard value provided by the laboratory (Lab). Data were analysed using Pearson's correlation and Bland-Altman plots and accuracy and precision were calculated. We calculated the percentage of outliers (difference value with Lab greater than ± 1 g/dL) for SpHb, AdHb and BGA. The difference of outliers between SpHb and AdHb were analysed by the chi-squared test. Data were compared and analysed using Student t-test. A p-value <0.05 was considered significant.

Two hundred-eighty-eight haemoglobin values concentration were obtained for every method of measurements in 72 patients scheduled for open abdominal aortic elective surgery. The proposed adjustment method for SpHb, when compared with Lab, reduced the numbers of the outlier (16.0 % for AdHb vs 77.4% for SpHb, p-value <0.001) and reduced the bias (-1.45 g/dL for SpHb to -0.38 g/dL for

AdHb, p-value <0.0001), but it was associated with a deterioration of precision (0.49 g/dL for SpHb to 0.75 g/dL for AdHb) with wide limits of agreement (-2.41 to -0.48 for SpHb and -1.86 to 1.09 g/dL for AdHb).

During an acute bleeding episode, SpHb values should be interpreted with caution and compared with other quickly available methods such as co-oximeter. Further studies are needed.

Keywords: Aortic surgery; Haemoglobin; *In-vivo* adjustment; Non-invasive monitoring

Introduction

During open aortic aneurysm repair, patients can develop anaemia due to hemorrhagic episodes and/or hemodilution. Non-invasive, continuous monitoring of Haemoglobin concentration (SpHb) may be advantageous for assessing acute anaemia and may improve the ability of the anesthesiologist to decide when to initiate blood transfusion.

Radical 7 device (Masimo Corp, Irvine, CA, USA) pulse CO-Oximetry, based on multiwavelength technology, provides continuous, non-invasive measurement of SpHb. SpHb technology has been tested in various clinical scenarios and two meta-analyses concluded with an alert about clinical decision based on these devices [1,2]. A strategy to improve the accuracy of SpHb is the *in-vivo* adjustment using a haemoglobin value provided by invasive methods like a laboratory or CO-oximetric method [3-6]. However, central laboratory measurement requires 30-60 min before the result is available, while a rapid Hb value, obtained within 1-2 minutes, can be provided by CO-oximetric method, the Blood Gas Analyser (BGA), and this value could be used to improve SpHb performance after *in-vivo* adjustment SpHb.

In this retrospective analysis, we hypothesised that adjustment using the Hb value provided by BGA measurement from arterial blood sampled at the first SpHb measurement would increase the accuracy (precision) of the monitor when compared with the value provided by the standard reference laboratory method.

Materials and Methods

For this retrospective analysis, we used data collected from 72 patients scheduled for elective open abdominal (sub-renal) aortic aneurysm repair in a single surgery centre (AORN dei Colli, Monaldi Hospital, Naples). The local ethics committee approved data collection (University of Naples Luigi Vanvitelli, protocol number 544/2017), and every patient signed written informed consent.

Intraoperative standard monitoring consisted of ECG, SpO₂, end-tidal CO₂ (EtCO₂), non-invasive blood pressure and diuresis. In addition, we monitored invasive blood pressure, Bispectral Index (BIS), neuromuscular blockade (Tof Cuff®), skin temperature, Central Venous Pressure (CVP).

For SpHb measurement, we used the Masimo Rainbow SET Radical 7®: the model was VKF-RAD7A, and the sensor was composed

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of Disposable Optical Sensor (DOS-Rainbow R2-25a) and Reusable Optical Sensor (ROS- Rainbow R2-25r). We applied the Masimo platform (with an optical shield to avoid optical interference) to the middle or index finger of the patient's hand, free from venous and arterial lines or monitoring devices, in absence of nail polish or acrylic nails.

All patients, after premedication with intra-muscular Morphine (10 mg), received general anaesthesia. We used Propofol (0.7 mg/kg), Midazolam (0.07 mg/kg), Sufentanil (0.4 mcg/kg) for induction and Rocuronium (0.6 mg/kg) for neuromuscular blockade.

During the maintenance of anaesthesia, we used exhaled Desflurane 3%, keeping BIS value between 40-60%, Remifentanil infusion (0.15 mcg/kg/min), and next Rocuronium administration (0.2 mg/kg) guided by neuromuscular monitoring. We conducted mechanical ventilation (Zeus Drager) in volumetric mode (Tidal Volume 6 mL/kg ideal body weight, PEEP 5cm H₂O, Respiratory Rate 12-16/min to obtain a PCO₂ 35-40 mmHg and FiO₂ 50% by a closed and Auto Flow system).

To avoid changes in the haemoglobinemia value due to hyper or hypohydration, we followed a Goal-Directed Fluid Therapy Protocol (GDFTP). We used EV 1000™ platform (Edwards Lifesciences) as haemodynamic monitoring. We analysed the parameters with pulse-contour monitoring by FloTrac or Volume View. For FloTrac module, we performed the Allen test to evaluate the state of collateral circulation at the level of the hand and then we placed the intra-arterial catheter in the radial artery. For volume view module, the catheter was placed in the brachial artery and, during the surgery, the anaesthesiologist monitored the presence of distal arterial pulse by pulse oximetry probe and the appearance of signs of ischemia at the level of the hand. The target of our GDFTP was the optimisation of the Stroke Volume Index (SVI) [7].

We administered a basic crystalloid infusion of 1-3 ml/kg/h. After induction of general anaesthesia, in stable haemodynamic condition, we calculated maximal SVI following this protocol: we noted the first value of SVI as baseline, we practised a bolus of colloids in 5-10 min (Fluid challenge 3 ml/kg) and marked the new SVI value so that we calculated the variation respect to the baseline value (Δ SVI%). In case of fluid responsiveness status (Δ SVI% >10%), we repeated the fluid challenge after 10-15 minutes, up to a Δ SVI% <10%.

The last SVI value with fluid responsiveness represented the SVI max and the SVI trigger was SVI max -10% SVmax. We provided a fluid challenge only if the SVI was under the SVI trigger. We administered continuous infusion of Fenoldopam (0.1 mcg/kg/min) for renal protection. If the mean arterial pressure was <65 mmHg (e.g. after declamping of the aorta) despite the optimization of SVI, we used noradrenaline bolus iv (0.01-0.02 mg) to maintain adequate organ perfusion [8].

We used the HOTLINE® blood and fluid warmer to keep the temperature of infusions between 37-39°C. We recorded total volumes of crystalloids, colloids and blood products, the percentage of patients receiving blood products and vasopressors drugs. For each patient, we collected three simultaneous Hb measurements: laboratory (Lab, considered as standard reference method) BGA and SpHb.

For invasive methods, BGA with the GEM Premier 4000 Blood Gas Analyzer (Instrumentation Laboratory) and conventional

laboratory analysis with the COULTER® LH 780 (Beckman Coulter, Inc.), we took a sample of 5 mL of blood from the arterial line, after discarding 10 mL of blood. The arterial line was 44 cm in length with a dead volume of about 1 mL. At the same time, we registered the SpHb value.

For each patient, we performed four measurements of Hb concentration at specific times: after the induction of anaesthesia (T₀), pre and post aortic cross-clamping (T₁ and T₂), and at the end of surgery (T₃). T₀ was also the start time of GDFTP. The volume of blood in the suction chambers represented an estimation of total blood loss. We adopted blood salvage. We performed blood transfusion if Hb value was ≤8 gr/dL in patients without comorbidities or ≤9 gr/dL in patients with cardiac disease or with active bleeding.

The anesthesiologist was the same in all interventions, and the value obtained from BGA and not the value of SpHb was the parameter for intraoperative clinical decision. For *in-vivo* adjustment, we used the difference between the T₀ values of SpHb and BGA. We used a formula to calculate adjusted SpHb (AdHb):

$$\text{AdHb} = \text{SpHb} - (\text{T}_0 \text{ SpHb} - \text{T}_0 \text{ BGA}).$$

The values of SpHb and AdHb were compared with Lab values. The objective was to compare Hb value provided by standard referment method (Lab) with, respectively, SpHb, AdHb and BGA. Data were analysed using Pearson's correlation and Bland-Altman plots. Bias and precision were calculated. The sample size was set to a minimum of 150 measurements according to Bland and Altman [9-11] recommendations for precision of 0.3 SD of the 95% CI of the limits of agreement. We calculated the percentage of outliers for SpHb, AdHb and BGA, which were defined as difference value with Lab greater than ± 1 g/dL. We used the chi-squared test to analyse the difference of outliers between SpHb and AdHb. Data were compared and analysed using Student t-test. A p-value <0.05 was considered significant.

Results

We included in the present study seventy-two patients scheduled for open abdominal aortic elective surgery. We presented the main patients characteristics, surgical and intraoperative data in table 1.

We used the Vascular-POSSUM score (V-POSSUM, <http://www.riskprediction.org.uk/vasc-index.php>) and ASA status to provide information on the risk of morbidity and mortality of all patients.

Two hundred-eighty-eight Hb values concentration were obtained for every methods of measurements. The Hb measurements ranged from 8.3 g/dL to 16.0 g/dL for Lab, from 7.5 g/dL to 16.5 g/dL for BGA, from 6.9 g/dL to 15.0 g/dL for SpHb and from 6.6 g/dL to 17.0 g/dL for AdHb. The mean and SD for methods were 12.62±1.59 g/dL for Lab, 12.01±1.61 for BGA, 11.16±1.56 g/dL for SpHb and 12.23±1.78 g/dL for AdHb.

Figures 1 and 2 showed, respectively the scatterplots, linear regression statistics and Bland-Altman bias analysis for SpHb and AdHb versus Lab measurements. Plot for BGA was not reported.

Table 2 shows the percentage of outliers for both SpHb, AdHb and BGA, and a summary of linear regression and Bland-Altman Analysis.

Patient characteristics, surgical and intraoperative data	
Patients	72
Sex (M/F)	65/7 (90.3/9.7%)
Age (years)	68.8 (7.7)
Weight (kg)	75.9 (12.9)
Height (cm)	169.4 (6.8)
Coronarydisease	28 (38.9%)
CABG*/PTCA†	20 (27.8%)
Cardiomyopathy	15 (20.8%)
Hypertension	59 (81.9%)
Diabetes	16 (22.2%)
Chronicrenal failure	11 (15.3%)
COPD‡	32 (44.4%)
TIA§/Ictus	7 (9.7%)
ASA I	0 (0%)
ASA II	4 (5.5%)
ASA III	68 (94.5%)
Duration of surgery (min)	231 (61)
Crystalloids IV (mL)	647.2 (238.8)
Colloids IV (mL)	795.1 (282.5)
Vasopressors use in patients	42 (58.3%)
Patients transfused with PRBCs¶	12 (16.7%)
PRBCs volume transfused (mL)	700 (432.8)
Patients transfused with intraoperative blood salvage	69 (95.8%)
Intraoperative blood salvage transfused (mL)	623.2 (276.2)
Patients transfused with FFP**	3 (4.2%)
FFP volume transfused (mL)	695 (335.9)
Total blood loss (mL)	1103.5 (498.8)
Diuresis (mL)	627.1 (257.4)
Final Fluid Balance (mL)	328.9 (372.8)

Table 1: Patients characteristics, surgical and intraoperative data. Values expressed as number (proportion) and mean (SD).

*Coronary Artery Bypass Graft; †Percutaneous transluminal coronary angioplasty; ‡Chronic obstructive pulmonary disease; § Transient Ischemic Attack; ¶ Packed red blood cells; ** Fresh Frozen Plasma

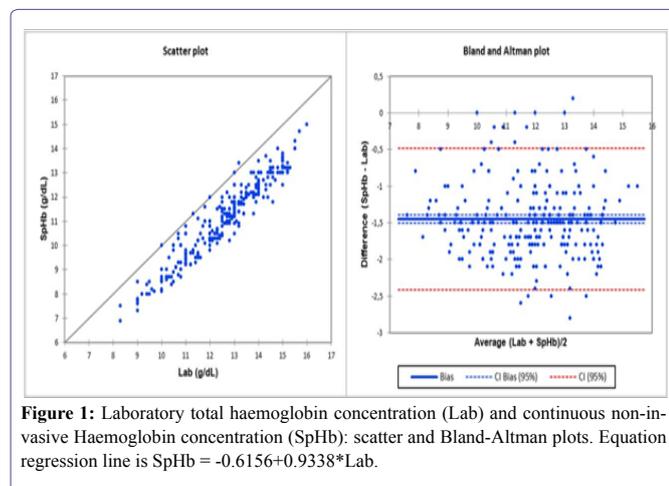


Figure 1: Laboratory total haemoglobin concentration (Lab) and continuous non-invasive Haemoglobin concentration (SpHb): scatter and Bland-Altman plots. Equation regression line is $SpHb = -0.6156 + 0.9338 * Lab$.

The adjustment method was associated with a statistically significant reduction in the percentage of outliers compared to SpHb

(16.0 % vs 77.4%, p-value <0.001) with a small decrease in correlation coefficient, from 0.952 for SpHb to 0.907 for AdHb, while the percentage of outliers for BGA was 6.6%, with a correlation coefficient of 0.979.

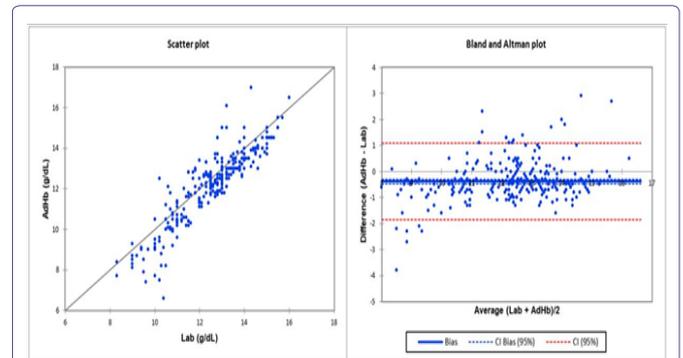


Figure 2: Laboratory total haemoglobin concentration (Lab) and adjusted continuous non-invasive Haemoglobin concentration (AdHb): scatter and Bland-Altman plots. Equation regression line is $AdHb = -0.5426 + 1.0125 * Lab$.

	Outliers	Correlation Coefficient	P-Value	Mean Bias g/dL	Precision g/dL	Limits of agreement g/dL
SpHb	77.4%	0.952	<0.0001	-1.45	0.49	-2.41 to -0.48
AdHb	16.0%*	0.907	<0.0001	-0.38	0.75	-1.86 to 1.09
BGA	6.60%	0.979	<0.0001	-0.61	0.33	-1.26 to 0.04

Table 2: Summary of correlation analysis and Bland-Altman comparison using laboratory total haemoglobin concentration (Lab, n=288), continuous non-invasive total haemoglobin concentration (SpHb, n=288), adjusted SpHb (AdHb, n=288) and BGA (n=288). Values are proportion or number. *P-value <0.001.

When compare with Lab values, adjustment method determined a decrease in bias from -1.45 g/dL for SpHb to -0.38 g/dL for AdHb (p-value <0.0001). The precision worsened from 0.49 g/dL for SpHb to 0.75 g/dL for AdHb, while precision of BGA was 0.33 g/dL. The limits of agreements for SpHb and AdHb were wide, respectively, -2.41 to -0.48 g/dL and -1.86 to 1.09 g/dL. Limits of agreement for BGA were -1.26 to 0.04 g/dL.

Discussion

During acute bleeding, conventional haematological method (Coulter counter) or co-oximetry are the tools for measuring Hb value. However, these methods are time-consuming, costly, invasive, intermittent. Instead of ideal Hb monitoring should be non-invasive, rapid/continuous and easy. Our device for non-invasive intraoperative Hb monitoring was Radical 7 device (Masimo Corp, Irvine, CA, USA) pulse CO-Oximetry. The transcutaneous spectrophotometry-based technology allows continuous Hb determination. Light received by the photodetector, after passing through the measurement site, generates electrical signals that, processed by advanced algorithms, provides an estimation of Hb based on its absorbance characteristics. An optical shield that covers the sensor prevents optical interference by other light sources. In two literature metanalyses [1,2] about accuracy and precision of SpHb, the authors concluded with an alert about clinical decision based on continuous non-invasive haemoglobin devices, with the lowest precision and wider 95% limits of agreement for Masimo. To improve the performance of SpHb, some authors have proposed calibration methods based on *in-vivo* Hb value obtained from other methods [3-6].

In this retrospective analysis, performed on patients scheduled for open abdominal aortic surgery in general anaesthesia, the difference between the initial values for SpHb and BGA was used for the “*in-vivo*” adjustment, and then the values of SpHb and AdHb were compared with Lab values, considered as the gold standard. The proposed adjustment method was associated with a statistically significant reduction in the percentage of outliers compared to SpHb (16.0 % vs 77.4%, p-value <0.001) with a small decrease in correlation coefficient, from 0.952 for SpHb to 0.907 for AdHb. Adjustment method determined a decrease in bias from -1.45 g/dL for SpHb to -0.38 g/dL for AdHb. However, the precision worsened from 0.49 g/dL for SpHb to 0.75 g/dL for AdHb. For SpHb and AdHb, the limits of agreements were wide, respectively, -2.41 to -0.48 for SpHb and -1.86 to 1.09 g/dL for AdHb. Instead, BGA, when compared with laboratory measurement, presented a low rate of outliers (6.60%), with a correlation coefficient of 0.979, a bias of -0.61 g/dL, precision of 0.33 g/dL, with a limit of agreements -1.26 to 0.04 g/dL.

In the literature, authors proposed different *in-vivo* calibration methods to improve performance of SpHb, using different reference methods as laboratory or co-oximeter. Isosu et al., [5] examined the effects of adjustment methods for SpHb based on satellite co-oximeter in 20 Japanese surgical patients, for a total of 92 blood samples collected. Bland-Altman analysis showed a bias of 0.2 ± 1.5 g/dL, with limits of agreement of -2.8 to 3.1 g/dL before *in-vivo* adjustment and -0.7 ± 1.1 g/dL with limits of agreement of -2.8 to 1.4 g/dL after *in vivo* adjustment. Linear regression analysis resulted in a correlation coefficient of 0.76 prior to *in-vivo* adjustment and 0.90 after *in-vivo* adjustment. This study showed that *in-vivo* adjustment improved the agreement of SpHb with satellite co-oximeter, considered as reference methods in these patients. *In vivo* adjustment may represent a significant advance in noninvasive monitoring of haemoglobin as it improved the bias, precision, limit of agreement and correlation coefficient compared to satellite co-oximeter measurements.

Miyashita et al., [3] performed a study to evaluate a simple method for adjusting *in-vivo* SpHb values measured in patients undergoing elective abdominal surgical procedures (19 patients) based on calibrated blood gas analyser. The author used two SpHb sensors: R1-25 and R2-25a. Seventy-three haemoglobin measurements were obtained by R2-25a sensor. When compared to calibrated blood gas analyser, *in-vivo* adjustment method significantly reduced the percentages of outliers in AdHb values (13.6%, 32.8% for SpHb), improved the correlation coefficient (0.93, 0.83 for SpHb), mean bias (0.16 g/dL vs 0.68 g/dL for SpHb), precision (0.77 g/dL vs 1.02 g/dL for SpHb) and limits of agreement (AdHb -1.35 to 1.67 g/dL, SpHb -1.31 to 2.67 g/dL).

Frasca et al., [6] performed a prospective, observational study in patients undergoing elective major surgery with significant blood loss expected (41 patients, 173 haemoglobin measurements) to compare the accuracy of SpHb adjusted *in-vivo* with the mean of three arterial HemoCue measurements and with laboratory values. *In-vivo* adjustment by HemoCue measurements improved precision (1.4 for SpHb, 1.1 for adjusted Hb), without significant impact on SpHb bias, which remained close to 0 g/dL. *In-vivo* adjustment by laboratory values provided the same results.

About the use of laboratory values for *in-vivo* adjustment, Patino et al., [4] performed a prospective observational study in pediatric

population scheduled for major surgical procedures associated with substantial blood loss (76 subjects, 156 SpHb-Hb data pairs). A retrospective analysis of bias and precision of SpHb to Hb obtained from laboratory measurement after *in vivo* adjustment of the SpHb values allowed the user to adjust the SpHb value manually to match an initial laboratory value so that all subsequent SpHb values were offset by the bias entered by the user. Absolute bias \pm precision of SpHb to Hb was 0.4 ± 1.3 g/dL. The retrospective *in-vivo* adjustment resulted in a bias \pm precision of 0.1 ± 1.2 g/dL. Bland-Altman analysis displayed limits of agreement of -2.0 to 3.2 g/dL before and -2.4 to 2.2 g/dL after *in-vivo* adjustment. The study concluded that an adjustment of SpHb values by the first bias to Hb slightly improved the agreement of SpHb with laboratory values, yet one-third of the values can still reach a 2g/dL difference with Hb over time.

In these studies, calibration and reference methods were the same. Instead, we used the first haemoglobin value provided by BGA to calibrate SpHb, and then we compared the results with laboratory values, considered as the reference methods. This aspect could explain the different results obtained in the present study, particularly about precision.

This study presents some limitations. First, this study is a retrospective analysis, so it is not possible to know whether the proposed *in vivo* adjustment method is associated with a change in the clinical decision-making about blood transfusions. Second, we did not evaluate whether this method is related to a change in the trending ability of SpHb. However, in our previous study [12], SpHb showed to be useful to assess the trending of the Hb concentration when compared with laboratory measurement in patients scheduled for elective abdominal aortic surgery. Finally, this study did not evaluate the interaction between Perfusion Index (PI) and SpHb accuracy. The PI is an indirect indicator of peripheral circulation and is obtained by calculating the ratio of the amplitude of the arterial pulse detected by the sensor to the amplitude of non-pulsatile factors such as the veins, bones, or subcutaneous fats [13]. In the present study, two factors could alter the PI and, then, the SpHb accuracy: inhalation anaesthetic agents and noradrenaline bolus. The use of inhalation anaesthetic agents causes arteriolar dilation with alteration in PI value. However, Park et al., [14] demonstrated that the use of sevoflurane for general anaesthesia increased the PI with an improvement in SpHb accuracy. According to our GDFTP, if MAP was < 65 mmHg, despite fluid challenge, anesthesiologist administered noradrenaline bolus (0.01-0.02 mg) to maintain adequate organ perfusion [8]. Saito et al., [15], in a randomised controlled trial, demonstrated that the increase in PI during induction of anaesthesia by maintaining arterial pressure through administration of a vasoconstrictor improved the agreement between laboratory haemoglobin values and SpHb. Based on these evidences, we believe that the aspects mentioned above could minimally interfere with our analysis. However we advocate the need of further studies investigating the interaction between PI, SpHb accuracy and GDFTP application.

Conclusion

In conclusion, the proposed adjustment method for SpHb, when compared with laboratory values, reduced the numbers of the outlier and reduced the bias. However, it was associated with a deterioration of precision with wide limits of agreement. During an acute bleeding episode, the data derived by this device should be interpreted with

caution and compared with other quickly available methods such as co-oximeter. Further well-designed studies are needed.

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None

Author Contributions

Conception and Design, R.C. De Rosa; Data Collection, R.C. De Rosa; Statistical analysis and interpretation, R.C. De Rosa, A. Romanelli; Writing-Original draft preparation, R.C. De Rosa, A. Romanelli; Writing-Review & editing, R.C. De Rosa, A. Corcione; Supervision R.C. De Rosa; Project Administration, R.C. De Rosa.

Conflict of Interest

The authors declare no conflict of interest.

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