Evaluation of the accuracy of the masimo pronto compared to laboratory spectrophotometric method of intraoperative haemoglobin measurement

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Abstract

Background: Transfusion decisions intra-operatively are generally guided by accurate blood loss estimation and intermittent invasive haemoglobin measurement. We investigated the accuracy of non- invasive intraoperative haemoglobin measurement using the Masimo Pronto (SpHb) as compared to laboratory spectrophotometry (tHb).

Methods and Materials This was a cross sectional study of 110 adult patients undergoing surgery with a potential for blood loss of 500 ml and over under general anaesthesia. Haemoglobin level was determined simultaneously post-induction, pre-transfusion and postoperatively using (SpHb) readings from Masimo Pronto® Pulse CO-Oximeter (Rainbow® SET® Technology Masimo Corporation, Irvine, CA) and haemoglobin analyzer with laboratory spectrophotometry (tHb).

Results A total of 244 sample pairs were analysed; 110 post-induction, 24 pre-transfusion and 110 post-operatively. There was a significant difference in mean haemoglobin between SpHb and tHb during the study at all time periods, $p<0.0001$. The overall mean haemoglobin was SpHb 12.02 ±1.86 g/dl, and tHb10.49 ±1.92 g/dl, $p<0.0001$, bias (1.5 ±1.76 g/dl), and limits of agreement-1.9 to 5.0 g/dl. There was moderate Pearson correlation (0.57) between SpHb and tHb measurements. The mean pre-transfusion haemoglobin was SpHb 10.25 ±1.96 g/dl, and tHb 8.26 ±1.27 g/dl, $p<0.0001$, bias, 2.0 ±1.89 g/dl and limits of agreement, -1.7 to 5.7 g/dl.

Conclusion It is concluded that SpHb overestimated haemoglobin measurement as compared with tHb. Hence the Masimo Pronto was found to be inaccurate as compared with laboratory spectrophotometry in intraoperative haemoglobin measurement. The bias was too large and limits of agreement too wide between SpHb and tHb to make appropriate transfusion decisions.

Keywords: Haemoglobin, invasive, non-invasive, transfusion, intraoperative

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Introduction

Anaesthetists are responsible for over 50% of blood transfusions,[1] and over 70% of all blood transfusion occur in the perioperative period.[2] Rapid changes in intravascular fluid volume and haemoglobin (Hb) could occur intra-operatively which would necessitate frequent and rapid evaluation of the patient's haemoglobin status. Delayed transfusions can result in patient death,[3] as haemoglobin serves the critical function of oxygen transport from the lungs to the peripheral tissues in the human body. It has previously been reported that only 61.8% of blood transfusion was appropriate using estimated blood loss and physiological variables.[4] Hence anaesthetists need tools to monitor Hb quickly and accurately in order to avoid inappropriate blood transfusion. The gold standard for the measurement of the Hb concentration, as recommended by the International Committee for Standardization in Haematology, is the laboratory-based hemiglobin cyanide (HiCN) method.[5] However it is impractical for clinical use, hence haematology analysers are considered the next best method.[6] Recently, non-invasive devices for Hb measurement have been introduced.[7] Masimo Rainbow technology uses multiple (7+) wavelengths of light and adaptive filters to isolate arterial signals using parallel processing engine technology. This study evaluated the accuracy of haemoglobin measurement by the Masimo Pronto compared with laboratory spectrophotometry.

Materials and Methods

This was a cross sectional study from December 2014 to April 2015, which compared intraoperative Hb estimation using a Masimo Pronto non-invasive device with the invasive laboratory spectrophotometry. The sample size was determined a priori by power analysis (β = 95%, a = 0.05, using difference in mean for

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haemoglobin = 0.56 for t–test).[8] A sample size of 55 per group was considered appropriate. Institutional approval and written informed consent were obtained. Patients undergoing general anaesthesia with American Society of Anesthesiologists (ASA) physical status score of I and II and modified John Hopkins Surgical Risk (SRC) Criteria 2 and 3; at risk of blood loss ≥ 500ml were included.[9] Patients excluded were those less than 18 years of age, with finger deformity which would have prevented the proper placement of the SpHb sensor, those with peripheral arterial disease, hypoperfusion, coagulopathy or on anticoagulants. The primary outcome compared the agreeability of intraoperative haemoglobin measurement using the Masimo Pronto to laboratory spectrophotometry. It also determined the limits of agreement between haemoglobin values obtained using the Masimo Pronto to those obtained by laboratory spectrophotometry.

Routine preoperative anaesthetic review was performed before surgery. Baseline investigations such as Hb, electrolytes, urea and creatinine were conducted. Premedication and fasting guidelines were prescribed as needed. Basic monitoring was initiated in the operating room using a multiparameter patient monitor [Datex Ohmeda Cardiocap5, manufactured by General Electric (GE) Healthcare, Helskinki Finland]. The electrocardiogram (ECG), heart rate (HR), SPO_2 and end-tidal carbon-dioxide concentration ($ETCO_2$) were continuously monitored, along with non-invasive blood pressure (NIBP) measurements every 5 minutes.

Induction and maintenance of general anaesthesia was at the discretion of the attending anaesthetist according to the patients need. After induction of anaesthesia, a SpHb sensor connected to a Masimo Pronto CO-Oximeter was placed on the middle finger of the left hand, covered by an opaque material, and a SpHb reading obtained. The attending anaesthetist was blinded to the SpHb readings by another opaque cover over the device display. The opaque cover was lifted only long enough for the SpHb and Perfusion Index (PI) readings as displayed on the device's screen to be recorded by the research assistant, out of the view of the attending anaesthetist. A PI of > 1 was desired; however SpHb readings at PI < 1 were also recorded. Simultaneously, 2 ml of blood was obtained by venepuncture on the other hand and put into an EDTA bottle by the research anaesthetist. Another venous blood sample and SpHb reading were taken simultaneously at the end of surgery. In any patient that required blood transfusion, a venous blood sample was taken after decision for transfusion had been reached, as well as a concurrent SpHb reading. The vital signs (HR, NIBP, SpO_2 $ETCO_2$) at the time of SpHb reading and blood sampling were also recorded by the research assistant. The blood loss prior to commencement of transfusion and at the end of surgery as visually estimated by the attending anaesthetist from swabs, suction bottles and draping was noted. The blood samples were sent to the laboratory immediately. Samples which could not be immediately analysed were kept in a refrigerator for analysis within a maximum of 24 hours. The type and amount of intravascular fluids or blood products given by the attending anaesthetist was also recorded. At the end of surgery, anaesthesia was discontinued and the patient transferred to the post anaesthetic care unit. The blood samples taken to the laboratory were analysed using a MINDRAY haematology autoanalyser BC3200, which utilises a cyanide-free method of Hb measurement and has a precision of 1.5 (CV%). The haematology analyser was calibrated and subjected to daily quality control testing according to the manufacturer's specifications.

Data Analysis

The data was analysed using the Statistical Package for Social Sciences (SPSS) (Chicago, IL) version 22.0. Numerical data were expressed as mean ±SD and categorical data as frequencies. Comparison of means was done using the paired samples t-test and two-way ANOVA. A p value < 0.05 was considered statistically significant. The accuracy of SpHb as compared with the laboratory spectrophotometry were conducted with Pearson correlation coefficient, Bland–Altman plot showing bias and limits of agreement for multiple observations per patient during conditions where the true value varies and Precision - 1 SD of bias.

Results

A total of 244 sample pairs were analysed; 110 post-induction, 24 pre-transfusion and 110 post-operatively. Table 1 detailed the demographic data.

Table 1. Demographic data

Variable	Mean ± SD (n=110)	Range
Age (years)	42.0 ± 11.4	18 - 64
Height (m)	1.6 ± 0.1	1.5 - 1.8
BMI	26.9 ± 4.8	16.7 - 43.0
Duration of surgery (hours)	3.1 ± 1.64	1 - 11
Volume of IVF (L)	2.5 ± 1.2	0.5 - 7.5
EBL post-op (ml)	895.5 ± 841.3	100 - 5000

Overall intraoperatively, there was a significant difference between the mean SpHb (12.02 ± 1.86 g/dl) and tHb (10.49 ± 1.92 g/dl), p < 0.001. At post-induction; there was a significant difference between the

mean SpHb (12.37 ± 1.73 g/dl) and tHb (10.83 ± 1.91 g/dl), p < 0.001. At pre-transfusion; there was a significant difference between the mean SpHb (10.25 ± 1.96 g/dl) and tHb (8.26 ± 1.27 g/dl), p < 0.001.At post-operatively; there was a significant difference between the mean SpHb (12.06 ± 1.76 g/dl) and tHb (10.65 ± 1.74 g/dl), p< 0.001. (Table II).

Table 2 Comparison between haemoglobin means (SpHb vs tHb)

	SpHb (Mean ± SD)	tHb (Mean ± SD)	p value
Overall	12.02 ± 1.86	10.49 ± 1.92	P < 0.0001*
Postinduction	12.37 ± 1.73	10.83 ± 1.91	P < 0.0001*
Pretransfusion	10.25 ± 1.96	8.26 ± 1.27	P < 0.0001*
Postoperative	12.06 ± 1.76	10.65 ± 1.74	P < 0.0001*

Values are mean ± SD
*Indicates significant difference between mean SpHb and mean tHb

In 244 paired measurements an acceptable simple difference between the SpHb and tHb of ≥ 1 g/dl was observed in 32.4%, (> 1d/dl and ,≥2g/dl) in 28.7% and >2g/dl in 38.9%.

Bland-Altman analysis

Figure 1 illustrates the overall agreement between SpHb and tHb in 244 sample pairs, the mean SpHb (12.02 ± 1.86 g/dl) versus tHb (10.49 ± 1.92 g/dl), p< 0.0001. The bias and precision was 1.5 ± 1.76 g/dl, and the limits of agreement -1.9 to 5.0 g/dl.

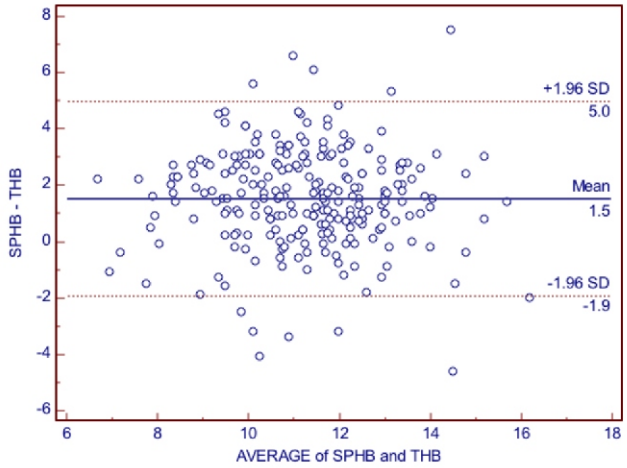

Figure 1. Overall Multiple measures Bland-Altman plot of 244 paired samples.

Figure 1 shows a Bland and Altman plot depicting the bias (mean difference) and 95% limits of agreement. The solid line represents the bias, dashed lines represent the mean difference ± 2SD (95% limits of agreement). Bias was 1.5 g/dl, and the 95% limits of agreement was -1.9 to 5.0 g/dl.

Figure 2 illustrates the agreement between SpHb and tHb in 110 sample pairs at post-induction, the mean SpHb (12.37 ± 1.73) versus tHb (10.83 ± 1.91), p< 0.0001. The bias and precision was 1.6 ± 1.63 g/dl, and the limits of agreement 1.6 to 4.7 g/dl.

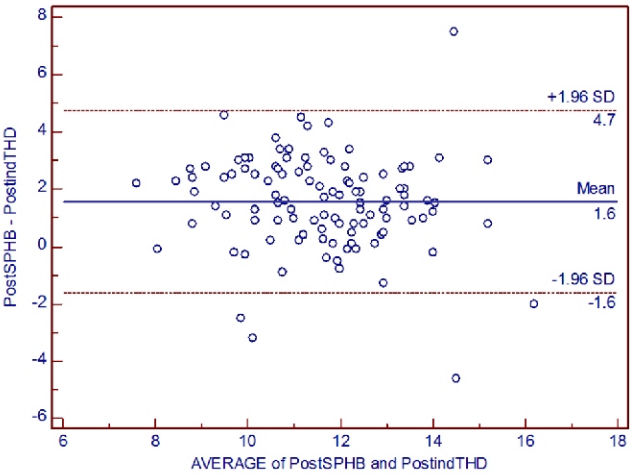

Figure 2. Bland-Altman plot of 110 paired measurements obtained post-induction.

Figure 2 shows a Bland and Altman plot depicting the bias (mean difference) and 95% limits of agreement. The solid line represents the bias, dashed lines represent the mean difference ± 2SD (95% limits of agreement). Bias was 1.6 g/dl, and the 95% limits of agreement was -1.6 to 4.7 g/dl.

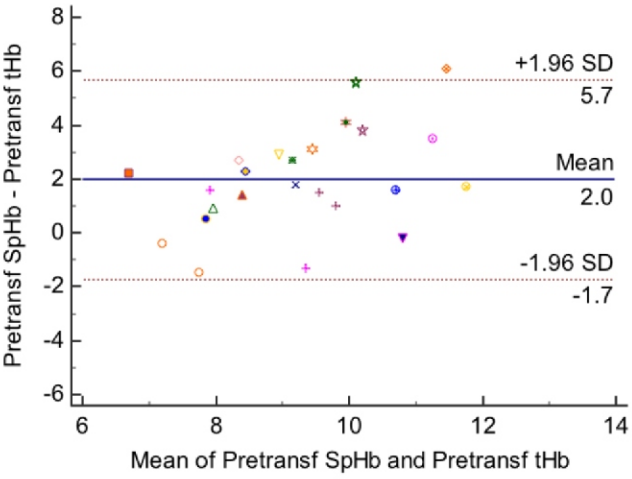

Figure 3. Bland-Altman plot of 24 paired measurements obtained pre-transfusion.

Figure 3 illustrates the overall agreement between SpHb and tHb in 24 sample pairs at pre-transfusion, the mean SpHb (10.25 ±1.96 versus tHb (8.26 ± 1.27), p< 0.0001. The bias and precision was 2.0 ± 1.89 g/dl, and the limits of agreement 1.7 to 5.7 g/dl, which is wide.

Figure 3 shows a Bland and Altman plot depicting the bias (mean difference) and 95% limits of agreement. The solid line represents the bias, dashed lines represent the mean difference ± 2SD (95% limits of agreement). Bias was 2.0 g/dl, and the 95% limits of agreement was -1.7 to 5.7 g/dl.

Figure 4 illustrates the overall agreement between SpHb and tHb in 24 sample pairs at post-operation, the mean SpHb (12.06 ± 1.76 versus tHb (10.65 ± 1.74p< 0.0001. The bias and precision was 1.4 ± 1.84 g/dl, and the limits of agreement -2.2 to 5.0 g/dl, which is wide.

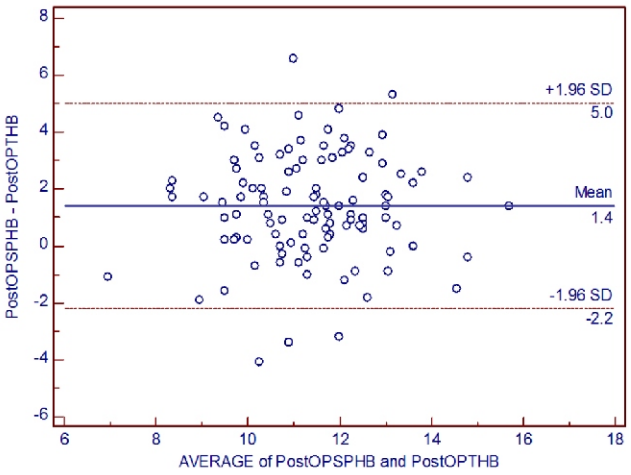

Figure 4. Bland-Altman plot of 110 paired measurements obtained post-op.

Figure 4 shows a Bland and Altman plot depicting the bias (mean difference) and 95% limits of agreement. The solid line represents the bias, dashed lines represent the mean difference ± 2SD (95% limits of agreement). Bias was 1.4 g/dl, and the 95% limits of agreement was -2.2 to 5.0 g/dl.

Discussion

The finding in this study was that mean haemoglobin values obtained with the Masimo Pronto (SpHb) were significantly higher than that obtained from the laboratory (tHb) overall, pre-induction, pre-transfusion and post-operatively. This is in agreement with a previous study conducted among out-patients and volunteers, which observed that the mean SpHb was higher than tHb among individuals with darker skin pigmentation.[10] The authors reported a resultant positive mean difference of 0.34 ± 1.1 g/dl in dark individuals, unlike a mean negative difference of -0.23 ± 1.1 g/dl in lighter skin individuals.[10] As 86.12% of Nigerians have been reported to have dark skin pigmentation,[11] this may account for the higher SpHb observed in our study. Other factors known to affect accuracy of SpHb includes intravascular dyes like indocyanine green or methylene blue, externally applied colouring (such as nail polish), motion artefact, low arterial oxygen saturation levels, peripheral vascular disease, high intensity extreme lights (including pulsating lights and direct sunlight) and haemoglobinopathy.[7,12] However, such confounding factors were controlled in our study.

We observed that SpHb was within 1g/dl of tHb in only 32.4% of the sample sets. Other scholars, however, have suggested that non-invasive devices used to measure Hb concentration should be accurate within 1g/dl of standard laboratory measurement.[13] Our observation with SpHb may suggest that decisions for transfusion in clinical practice cannot be made with the Masimo Pronto as observed. Our observation is contrary to the expectation that during surgical procedures with expected considerable blood loss such as SRC 2 and higher, which may require blood transfusion, the use of a non-invasive Hb technology such as the Masimo Pronto, in the operating room would assist clinicians to make an objective decision to transfuse.[13]

In our study, the bias was large and the limit of agreement (LOA) wide between the overall SpHb and tHb (1.5 ± 1.76 g/ dl, -1.9 to 5.0 g/dl). The wide LOA suggests that the SpHb and tHb are not comparable; hence it could infer that the device may not give an accurate haemoglobin concentration intra-operatively when compared with laboratory method. This is because in individuals with significant blood loss there may be associated reduced capillary refill and vasoconstriction, which has been shown to influence the accuracy of SpHb readings.[12]

Pulse Co-oximetry (SpHb) measures the light absorption of blood in both the microvascular and macrovascular network of the fingertip.[13] During acute haemorrhage, microvascular Hb remains high to maintain tissue oxygenation, while macrovascular Hb measured in a blood sample decreases. The microvascular Hb therefore contributes more to the SpHb estimation during conditions of acute blood loss, increasing the discrepancy between SpHb and invasive Hb (tHb) values, as observed in our study.

Other factor which may contribute to the large bias and wide LOA in our study include the administration of crystalloid, which has been shown to significantly increase the bias of SpHb by 7%.[14] This observation has been attributed to the faster disappearance of crystalloids than colloids from the bloodstream which promotes

tissue oedema, and could diminish the relative strength of the pulsatile part of the signal by affecting the background noise.[13]

In other studies with EBL between 500mls to ≥1000mls, the authors similarly reported a wide LOA.[13,15-16]The interval it takes for the Masimo Pronto to display an Hb value has been shown to influence the bias and LOA.[17] As blood sample for tHb measurement is usually collected over few seconds, compared with SpHb measured over an averaging time of approximately 3 minutes,[7] there may be a time-lag which could account for reduced accuracy of SpHb especially during rapidly-changing Hb. This can also account for the wide LOA obtained by us and other authors.[15,16,18]

Frasca et al. [19] however, reported a smaller bias and narrower LOA (0 ± 1.0 g/dl, -1.0 to 0.9 g/dl) between SpHb and tHb in a group of critically ill patients. There was no active major bleeding in the group of patients in their study, and measurement of Hb occurred over a prolonged interval of 1 to 15 days. While in our study, there was significant blood loss (895.5 ± 841.3 ml) within a shorter interval of 1 to 11 hours, which might not have been adequate for equilibration of plasma and red blood cells, leading to a lower tHb value.

On the contrary, Berkow et al.[20] in their study among patients undergoing complex spine surgery in which patients were also at high risk of "significant" blood loss found a smaller bias and narrower LOA between SpHb and tHb (0.8 ± 0.6 g/dl, -2.0 to 1.8 g/dl) as compared to our study. They however did not include cases in which intraoperative haemoglobin readings were very low as the transfusion protocol of their institution recommends a transfusion trigger of 10 mg/dl for spine surgery. This might have contributed to the increased accuracy of SpHb in their study. Since the accuracy of SpHb had been noted to increase at increased tHb value.[5] This is demonstrated in our study where the bias for tHb values ≥ 10 g/dl (0.9 ± 1.68 g/dl) was lower than that for tHb values < 10 g/dl (2.4 ± 1.5 g/dl).

Similarly, a smaller bias and narrower LOA was reported among volunteers and blood donors.[10] The difference in the result obtained from our study when compared to the latter may be because volunteers and blood donors are not subject to changing peripheral circulatory physiology that may be induced by surgery and anaesthesia.[18]

The device used in this present study, the Masimo Pronto displays an operating range of PI 0.02 to 20; the manufacturer recommends a PI > 1 for obtaining SpHb values.[7] The mean PI observed in this present study (2.69 ± 2.11) was appropriate for obtaining accurate SpHb readings, hence might not be responsible for the large bias and LOA in this study, as shown by the result of the multiple regression analysis.

The following limitations were encountered during the execution of this study: A haematology analyser was used as the reference device instead of the international standard method for determining haemoglobin, the HiCN assay, as the HiCN assay is cumbersome.

From this study, it was concluded that the mean haemoglobin measurement intraoperatively using the Masimo Pronto (SpHb) was significantly higher than that measured using the laboratory reference method. The large bias and wide LOA between SpHb and tHb infer that the device is not accurate for measuring Hb during periods of rapid blood loss as encountered intraoperatively. Therefore it cannot be a substitute for invasive laboratory measurement to make transfusion decisions intraoperatively. However it might be useful as a monitor of the trend of changes in haemoglobin concentration intraoperatively.

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