Is Continuous Noninvasive Hemoglobin Monitoring Estimates Timing for Detection of Anemia During Operation better than Clinicians

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Abstract Background

Blood loss is a common surgical complication, but patient complications and healthcare costs can be exacerbated by needless blood transfusions. Non-invasive and continuous monitoring of hemoglobin concentrations is possible with the Radical-7 Pulse CO-Oximeter. These determined values are identical to those obtained by blood sampling for hemoglobin concentrations, and the technique enables continuous monitoring over time of changes in Hemoglobin levels. **Aims of Study:** to investigate whether noninvasive, continuous, and real-time monitoring of Hemoglobin could estimate the timing for further Hemoglobin measurements more accurately than clinicians' discretion during surgery. **Patients and Methods:** 54 Patients eligible for the study were underwent different surgeries with planned invasive venous blood gas sampling for blood Hemoglobin for hemoglobin measurement while Radical-7 Pulse CO-Oximeter continuously reading Hemoglobin noninvasively during each surgery. Blood samples were obtained 5 min after induction of anesthesia (other samples was taken multiple time during operations according to time of operation). The Conventional venous blood gas measurements were compared with radical 7 co-oximeter obtained at the time of the blood sampling. **Results:** In our study There was no statistically significant differences ($p>0.05$) in mean hemoglobin level, whether measured by SpHb or by conventional laboratory. in addition, Bland–Altman plot was utilized and show no marked difference between invasive and noninvasive method. All these factors signify a good compatibility between the two methods. **Conclusions:** The radical 7 satisfactorily follows hemoglobin shifts and more reliably predicts the required timing for early Hemoglobin management decisions throughout surgery.

Keywords: *Anemia,Hemoglobin, Surgery, real-time monitoring, spectrophotometry, Pulse CO-oximetry*

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Introduction

Anemia is a global health problem, considering that around 25% of the population is affected, with varying degrees of severity [1-3]. The main factors that cause anemia are iron deficiency, infectious diseases, or genetic factors. Red blood cells and hemoglobin (Hb) concentration levels decrease with anemia, and this leads to a reduction in the function of the blood to transport oxygen to the peripheral tissues. In severe cases, blood transfusion is necessary basing on the Hb measured also daily, normally in the laboratory using a blood sample. Unequivocal several symptoms appear when the compensatory processes activated by the human body are no more sufficient to guarantee the right quantitative of circulating oxygen.

The symptomatology varies according to the severity and type of anemia, but typical symptoms common to all types of anemia include pallor, asthenia, tachycardia, fainting, loss of appetite, nausea, exertional dyspnea[4-6].

Anemia can be detected with invasive and non-invasive techniques. Invasive techniques require blood samples; therefore, they can cause discomfort to patients, can be infection-prone, or require laboratory analysis. Non-invasive techniques are fundamental to patients who frequently take blood tests or suffer blood loss; these techniques generally exploit the pallor of some body parts to determine whether a patient is anemic or not [7–9]. Patients who need recurrent blood sampling can benefit greatly from these techniques and then these approaches are of some importance [10,11].

A great effort has been done in recent years to improve non-invasive tool accuracy. Non- invasive devices can be made portable, cheap, and easy-to-use and offer great advantages in rapid pre-diagnosis and self-monitoring, As is already the case in other medical disciplines that can benefit from the extensive use, as an example, of the image analysis, sound or signal analysis and artificial intelligence techniques [12,13]. In the current clinical pathway for anemia detection during intraoperative blood loss, an invasive Hb measurement is performed at the clinicians' discretion.

Requiring clinicians to determine anemia is energy-consuming and often inaccurate. Attention must be paid not only to the patient's vital signs, blood volume in the surgical field, cotton pads, and cell savers but also ongoing hemostasis procedures. The discretion of the clinician is totally subjective and is largely dependent on their clinical experience [14]. Moreover, Hb measurements are often omitted during intraoperative blood loss. Traditional Hb measurements such as the auto analysis of blood cells and CO-oximetry analysis require blood samples, the collection of which is invasive, time-consuming and intermittent.

Considering the absence of anesthesia nurses in most hospitals in China, anesthesiologists must send the blood sample in person, which often results in delays or is omitted in favor of completing more important work. Consequently, transfusion is often performed without any objective indications, which may result in unnecessary blood transfusions in patients lacking the necessary indications or delayed blood transfusions in bleeding patients [15].

In particularly in the emergency room, perioperative and critical care settings, rapid and on-going assessment of total hemoglobin is crucial, to quantify blood loss and/or the need for transfusion [16].

In addition to the above, trauma related hemorrhagic anaemia is rarely diagnosed by physical examination alone but typically includes measurement of blood haemoglobin, one of the most frequently ordered laboratory tests [17, 18]. The need for resuscitation to achieve adequate tissue perfusion is established by the patient's history, on-going bleeding, and clinical signs of hypovolemia. Hemoglobin and hematocrit measurements, the conventional means to confirm hypovolemia, are not always immediately available at the point-of-care and hemodynamic monitoring may not detect relevant blood loss. If treatment is delayed pending laboratory results or diagnostic studies, patient outcome can be affected [19–21]. For example, the rapid determination of blood haemoglobin levels is essential, for the triage of patients in emergency departments [22], and tracking of changes in haemoglobin, to detect occult bleeding, has the potential to be lifesaving during critical care.Therefore, in the hospital setting, there is growing interest in rapid and continuous techniques for measuring haemoglobin and changes in haemoglobin.

Recently, noninvasive technologies have been developed that allow haemoglobin to be measured immediately without the need for intravenous access or having to take venous, arterial, or capillary blood. Moreover, with these technologies' haemoglobin can be continuously measured in patients with active bleeding, to guide the start and stop of blood transfusions and to detect occult bleeding.

Among other benefits, the reduction of the costs borne by the national health systems and powering the medical and healthcare services can also be considered important.

Noninvasive rainbow SET technology

Advanced rainbow SET sensors utilize multiple wavelengths of light to measure total hemoglobin (SpHb), Pleth Variability Index (PVi), oxygen content (SpOC). carboxyhemoglobin (SpCO) and methemoglobin (SpMet) noninvasively and continuously.

Pulse CO-Oximetry (Radical 7, Masimo, Irvine, CA, USA) is a multi wavelength spectrophotometric technique providing continuous, noninvasive monitoring of total Hb (SpHb). The method is based on measurement of the differential optical density of seven different wavelengths of light passing through the finger and has received Food and Drug Administration 510(k) clearance.

SpHb may be able to inform physicians of decreases in hemoglobin concentrations in a timely and accurate manner, preventing unnecessary diagnostic blood draws and offering detailed clinical evidence for transfusion decisions during surgery [23].

The aim of this study:

To investigate continuous noninvasive hemoglobin monitoring estimates timing for detection of anemia during operation better than clinicians.

Patients and Methods

A prospective cross-sectional study, conducted at Baghdad Teaching Hospital/ Medical City and kadhimiya teaching hospital from 15 of October 2019 to the first of October 2020.

54 patients were included in the study. From each patient written informed consent was obtained.

The purpose and procedures were explained to all participants, and they were given the right to participate or not, verbal and written consent was taken with reassurance that interpret gained will be kept confidentially.

Participants

patients underwent operation such as laparotomy, vascular surgery, gynecological surgery, surgeries were more likely to be associated with a sufficiently large blood loss volume to trigger anemia.

The inclusion criteria

1. ASA l _ ll.

2. patients aged from 16 to 80 years who were scheduled for such surgeries mentioned above.

3. for whom the estimated blood loss was more than 250 ml of their total blood volume.

The exclusion criteria

1. Peripheral vascular disease.

2. An inability to use their upper extremities for SpHb monitoring.

3. preoperative anemia (Hb < 10 g/dl).

4. coagulation disorders (INR > 1.5 times the normal value).

Interventions:

In the SpHb monitoring, an adhesive sensor (R2-25a), connected to the Radical-7® Pulse CO-Oximeter (software version V7740, Masimo Corp., Irvine, CA), was placed on the proximal third of the nail bed of the second, third, or fourth finger of the hand on the side opposite to the cuff of NIBP monitoring before the induction of general anesthesia. If the perfusion index which is an indicator of localized perfusion was < 1%, then the sensor position was recalibrated by switching the monitor off and on. After the SpHb was stable for at least 5 min after anesthesia induction, the baseline SpHb was registered. A blood sample was drawn via VBG to achieve a time matched invasive Hb concentration. As an alarm threshold, a SpHb level of 1 g/dl lower than the baseline was set. After 2hr from the end of operations hemoglobin also monitored noninvasively (radical-7) and routinely laboratory test.

Statistical Analysis

The collected data was handled and analyzed by IBM© SPSS© (Statistical Package for the Social Sciences) Statistics Version 23. Independent samples T- test and was used for numerical and normally distributed data. Pearson correlation was done comparing between the two methods of hemoglobin measurement and Bland–Altman plot-was used to investigate the agreement between the methods. All analyses were done with 95% confidence intervals (CI). P-values less than 0.05 were considered statistically significant throughout this study.

Results

The mean age of the study sample was 47.13± 17.2 years, with 23(42.6%) males and 31(57.4%) females.

Table (1): Basic characteristics of the study sample

Variables	Mean	SD
Age	47.13	17.2
Gender	**Number**	**%**
Male	23	42.6
Female	31	57.4
Surgery field		%
Obstetrics and gynecology	17	31.5
Orthopedics	16	29.6
Abdominal	15	27.8
ENT	5	9.3
Urology	1	1.9
Total	54	100.0

There were no statistically significant differences in mean hemoglobin level, whether measured by Sphb or by conventional laboratory, at baseline the Sphb results were lower by only -0.10 g/dl, other readings showed slightly higher values of Sphb, and maximum mean difference recorded postoperatively by 0.12 g/dl.

Table (2): Distribution of hemoglobin levels according to method of measurement

Variables	Sphb	Lab	Difference	P-value
	Mean± SD	Mean± SD	Mean	
Baseline	11.75±1.2	11.85±1.1	-0.10	.659
15 min	11.55±1.2	11.54±1.3	0.01	.975
30 min	11.46±1.3	11.39±1.2	0.08	.746
Postoperative	11.91±1.1	11.79±1	0.12	.572
Total	11.67±1.2	11.64±1.1	0.03	.817

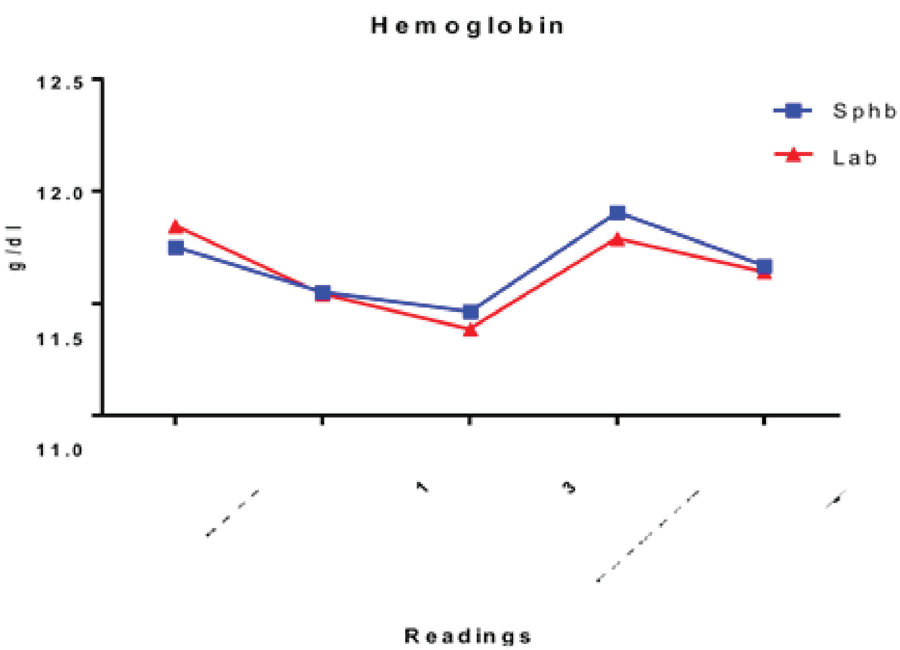

Figure (1): Line graph illustrating the hemoglobin level follow-up and differences between Sphb and Lab

There were statistically significant correlations between the two methods at each investigation interval, lowest postoperatively (r= 0.690), and highest at 15 minutes (r= 0.848). Total correlation was 0.784 with a p-value <.001. As shown in Table (2) and figure (2).

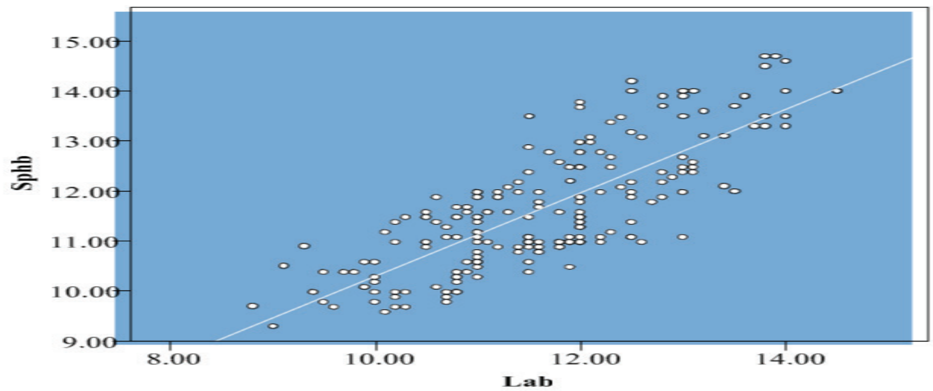

Figure (2): Scatter plot illustrating positive correlation between total Sphb and laboratory values.

To further compare between the two measurements, Bland–Altman plot was utilized, and figure (3) illustrates that the bias was only -0.03 g/dl, there are no points outside the ±1.96 standard deviation, and in addition the distribution of points was almost equal both above and below the mean bias. A very strong agreement between the two measures favors both variables.

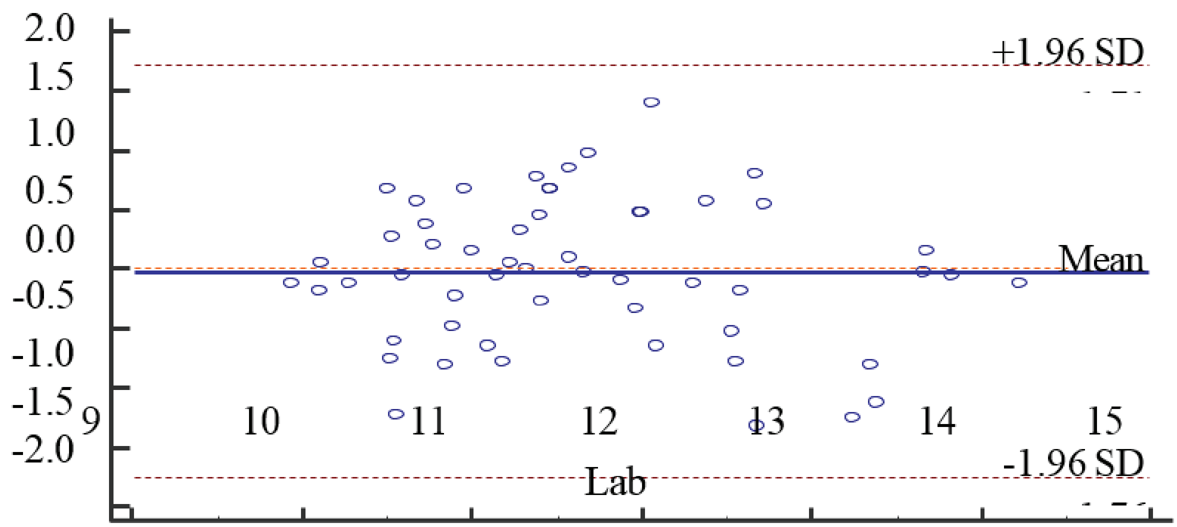

Figure (3): Bland–Altman plot of the relation between the hemoglobin levels measured by Sphb and by laboratory.

Discussion

This study was performed to evaluate efficacy of noninvasive hemoglobin monitoring in decision of initiation and cessation of blood transfusion in real time in patient undergoing surgeries. Continuous noninvasive Hb monitoring can obtain real-time change of Hb. The accuracy of noninvasive Hb monitoring has been reported in several surgeries presenting significant intraoperative bleeding [24-25], the accuracy of noninvasive Hb monitoring has been documented. Therefore, frequent laboratory evaluation is required to detect the decrease of Hb level during an operation, which is not only time-consuming but also may lead to a delay discission about Hb management. In the results, there was no statistically significant differences in mean hemoglobin level, whether measured by Sphb or by conventional laboratory, at baseline the Sphb results were lower by only -0.10 g/dl, other readings showed slightly higher values of Sphb, and maximum mean difference recorded postoperatively by 0.12 g/dl.

Our result supported by Macknet et al. [26] (compared noninvasive CO- oximeter recording {Masimo Inc. Irvine CA} with invasive Hb testing) It is compatible with our result by good correlation between the Hb values obtained during times of rapidly changing Hb concentrations related to surgical blood loss and transfusion.

In his study (Pulse CO-Oximetry based SpHb measurement is accurate within

1.1 g/dL {1 SD} compared to laboratory CO-Oximeter tHb measurement in subjects undergoing hemodilution), Mark R Macknet et al. [27] concluded that this study, on the other hand, applied Hb >= 12 g/dL to healthy subjects.

Causey et al. in His study agree with our result [28] and concluded that noninvasive Hb monitoring is a new technology that correlated with laboratory values in intensive care unit (ICU) patients and in general surgery patients undergoing elective surgeries.

ALSO, our result supported by Berkow et al. study [29] concluded that Continuous non-invasive Hb measurement through pulse CO-oximetry showed clinically appropriate accuracy of Hb measurement within 1.5 g/dL when used during complex spine surgery compared to a standard laboratory reference instrument.

Butwick A Evaluating the use of the Masimo Rainbow SET Radical-7 Pulse CO-Oximeter in pregnant patients undergoing elective cesarean section (CS), Hb levels appeared to be 1.22 g/dL higher than pre-CS laboratory Hb levels and 0.89 g/dL higher after 24 h post-CS. From these findings they concluded that modifications are needed in the calibration of the device to improve accuracy and precision in obstetric patients [30].

Our findings did not agree with the Miller RD study (A review of three hemoglobin monitoring methods in patients undergoing spine surgery) in its study concluded that SpHb in certain patients is not as reliable as clinically required, and they showed that SpHb underestimates true Hb and should not be used to assess the need for blood transfusion[31].

Gayat et al. [32] incompatible with our result, he concluded that (the pulse CO-oximeter underestimated the Hb level and found that it was ‘‘too unreliable’’ to guide transfusion decisions), because he noticed in his result 13% error in terms of transfusion decision.

Conclusion

- SpHb could detect a decrease in Hb in dynamic situations and indicate the appropriate timing for further Hb measurements.

- This technology may provide more timely information on hemoglobin status than intermittent blood sample analysis and thus has the potential to improve blood management during surgery, allowing earlier cessation of RBC transfusion as well as earlier consideration of initiation of RBC transfusion.

Conflict of Interest: None

Source of Findings: None

Ethical Clearance: None

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