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ORIGINAL RESEARCH **INTENSIVE CARE**

Noninvasive hemoglobin monitoring by spectrophotometry in blunt abdominal trauma patients for conservative management

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ABSTRACT

Background & Aim: Nonoperative management is considered the treatment of choice in patients with blunt abdominal trauma, serial clinical assessment and hemoglobin (Hb) measurements is the cornerstone for their evaluation. While automated laboratory analysis is the reference method for measuring Hb, spectrophotometry may be better by allowing non-invasive instant readings. This study aimed to evaluate the accuracy of spectrophotometric non-invasive Hb monitoring (SpHb) and whether it's possible to rely upon in making the decision for operative management or not.

Methodology: a cross-sectional observational study at which 39 patients admitted to our surgical intensive care unit (ICU) following blunt abdominal trauma were subjected to serial measurements of SpHb using an oximeter probe (Radical-7™; Masimo Corp., Irvine, CA), and simultaneous blood samples analyzed using Coulter LH 750 Cell Counter, measurements were done every 8 hours till discharge or admission to operation room, the accuracy and precision of SpHb were evaluated.

Results: The limits of agreement between conventional and noninvasive Hb assays were clinically unacceptable and ranging from -6.45 g/dl (95% CI = -7.54 to -5.37 g/dl) to 4.82 g/dl (95% CI = 3.74 to 5.91 g/dl). The mean difference (bias) was -0.82 g/dl (95% CI = -1.45 to -0.19), the correlation between SpHb and laboratory values was statistically insignificant (r = 0.19, 95% CI = -0.03 to 0.39, P = 0.095, R2 = 0.03).

Conclusion: Spectrophotometric noninvasive hemoglobin measurement didn't offer enough accuracy nor precision and shouldn't be relied upon in deciding operative management of blunt abdominal trauma patients admitted to ICU under observation.

Abbreviations: CBC - Complete Blood Count; ICU - Intensive Care Unit; PI - Perfusion index; SpHb - spectrophotometric non-invasive hemoglobin monitoring

Key words: Blunt abdominal trauma; Masimo; Radical-7™; Hemoglobin; Non-invasive; Perfusion index.

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1. INTRODUCTION

Abdominal injury presents a great challenge, equally faced by the emergency physician, the anesthetist, the intensivist and the surgeons.[1] It may affect up to one-third of the patients with severe trauma.[2]

When feasible, non-operative management of abdominal trauma should always be prioritized. That's why careful clinical assessment, anatomical grading of an abdominal injury, and concomitant injuries are mandatory, together with laboratory and radiological evaluation. Close observation and Hb evaluation should be done every 4–6 h for at least 24 h.[3]

While laboratory-based Hb measurement is considered the reference method,[4,5] it has some limitations like time consumption and the need for a blood sample.[6] Masimo Corporation has developed a spectrophotometric method to estimate Hb concentration.[7] Many studies have been performed to validate the Masimo Radical-7™ in operating rooms, emergency departments, and in the Intensive Care Unit (ICU).[8-10] Continuous measurement of Hb either in the ICU setting or in the operating room was the main concern in many published data,[8] but few studies have evaluated the non-invasive spectrophotometric hemoglobin monitoring (SpHb) in trauma patients.[11,12]

We evaluated the accuracy of SpHb in trauma patients admitted to our ICU for conservative management, to find out whether it's possible to rely upon its measurements in making the decision for operative management or not.

2. METHODOLOGY

This cross-sectional, observational study was performed in the ICU of Ain Shams University Hospital from November 22, 2021 to May 01, 2022 after approval from our institutional ethics committee (No. FMASU R 177 / 2021) and getting registered with www.clinicaltrials.gov database (No. NCT05171296). Written informed consent from all participants or their legal guardians was obtained.

We included patients with American Society of Anesthesiologists (ASA) physical status I to III, subjects of both sexes, 18−80 y of age, non-intubated, who were admitted to surgical ICU, after suffering blunt abdominal trauma and planned for conservative management by trauma surgeons. Patients with fever, hypothermia, and hemodynamic instability necessitating vasopressors were excluded.

Patients were explained the steps of the research. On admission to ICU, standard monitors, e.g., ECG, pulse oximeter, and noninvasive arterial blood pressure (NIBP) monitor were applied, and baseline readings were recorded. The oximeter probe (R1 25 sensor; Rev E) connected to Radical-7™ pulse co-oximeter (Radical-7™; Masimo Corp., Irvine, CA) was attached to the index fingertip of the hand contralateral to the site of blood pressure monitoring and was covered by light shield to decrease heat loss and interference by ambient light. The patients were kept warm with warm fluids at an infusion rate according to our ICU protocol with close follow up by trauma surgeons for possible conversion to surgical management once indicated.

Perfusion index (PI), oxygen saturation (SpO_2), and SpHb were measured by the noninvasive hemoglobin test device. Testing for Hb was done while patients were quiet and sitting upright, then the venous blood sample was obtained by venipuncture of the median cubital vein of the nondominant arm with a disposable syringe and then transferred to a blood testing tube. Venous blood samples were transported at ambient temperature and analyzed for Hb as a part of Complete Blood Count (CBC). Samples were assayed on Coulter LH 750 Cell Counter (Beckman Coulter Corporation, Florida, USA), using reagents supplied by the company.

The following variables were measured and recorded:

1. Demographic characteristics (age, sex, BMI).
2. SpHb every 8 h together with CBC. Till patient was declared safe to be discharged (maximum 48 h) or till decision was made to shift to operating room.
3. PI value associated with each SpHb reading.

The primary outcome was the accuracy of SpHb compared with the values provided by Coulter LH 750 Cell Counter. Secondary outcome was the correlation between the PI readings and the accuracy of SpHb.

By using PASS 11 program (NCSS, LLC, Kaysville, Utah, USA; https://www.ncss.com/) for sample size calculation, and assuming bias of −0.1 ± 1.1 gm/dl between SpHb and laboratory analyzer,[7] a sample size of at least thirty readings produces a 99% confidence interval (two-sided) with a distance from the mean to limits equal to 0.96 when the estimated SD is 1.

Statistical analysis

Data were analyzed using the MedCalc© statistical software version 20 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2021). Continuous numerical variables were presented as mean and standard deviation and categorical variables as counts. Bland-Altman analysis was done for agreement between conventional and SpHb assay. Correlations between continuous variables were examined using the Pearson correlation. Accuracy of SpHb assay was examined

using linear regression and calculation of the standard error of estimate. P < 0.05 was considered statistically significant.

3. RESULTS

The study included 50 patients. In 7 patients the Radical-7™ pulse co-oximeter failed to give SpHb, in 4 patients no laboratory results were obtained, hence 39 patients were left; 13 (33.3%) females and 26 (67.7%) males, with a mean age of 40 ± 16 y (range, 18−75 y), on whom 82 paired measurements of Hb level were taken.

The conventional, and non-invasive Hb assays, as well as the PI, SpO_2, and mean arterial pressure measurements at three time-points of interest were recorded and are shown in Table 1.

Bland-Altman analysis showed limits of agreement ranging from −6.45 g/dl (95% CI = −7.54 to −5.37 g/dl) to 4.82 g/dl (95% CI = 3.74 to 5.91 g/dl). The mean difference (bias) was −0.82 g/dl (95% CI = −1.45 to −0.19) (Figure 1).

To determine the accuracy of the noninvasive Hb assay, we regressed the true (conventional) values on the noninvasive values using linear regression analysis. The correlation between both variables was very weak and statistically insignificant (r = 0.19, 95% CI = −0.03 to 0.39, P = 0.095, R2 = 0.03). The standard error of the estimate (residuals SD) was 2.02 g/dl which is too large. The relation is quantified with the following regression equation: *Conventional Hb assay (g/dl) = 8.31 + 0.16 * Noninvasive Hb assay (g/dl)* (Table 2 & Figure 2).

The correlation between the residuals (errors) and the true (conventional) values was near-perfect (P < 0.0001) denoting breach of the assumption of the constancy of the residuals variance and poor performance of the model (Figure 3).

Table 1: Demographic characteristics of the study population

Variable		Value
Sex (F/M)		13/26
Age (y)		40 ± 16 (18−75)
Weight (kg)		80.4 ± 16.1 (52−130)
Conventional Hb assay (g/dl)	*Time 1*	10.0 ± 2.3 (3.0−14.0)
	Time 2	9.8 ± 1.7 (6.0−13.2)
	Time 3	10.3 ± 1.8 (7.5−13.0)
Non-invasive Hb assay (g/dl)	*Time 1*	10.6 ± 2.4 (6.0−16.0)
	Time 2	11.0 ± 2.3 (6.2−16.0)
	Time 3	11 ± 3 (7−16)
PI	*Time 1*	2.23 ± 1.51 (0.29−6.80)
	Time 2	1.88 ± 1.13 (.29−4.50)
	Time 3	1.86 ± 1.22 (0.63−4.40)
SpO_2 (%)	*Time 1*	96 ± 3 (88−100)
	Time 2	96 ± 3 (89−100)
	Time 3	96 ± 2 (92−100)
MAP (mmHg)	*Time 1*	75 ± 17 (45−111)
	Time 2	77 ± 17 (45−111)
	Time 3	80 ± 20 (56−111)

Data are ratio or mean ± SD (minimum−maximum); MAP = mean arterial pressure, PI = perfusion index, SpO_2 = noninvasive oxygen saturation, Time 1 = baseline, Time 2 = 6 h, Time 3 = 12 h

Table 2: Linear regression for accuracy of noninvasive Hb assay; (n = 82); Coefficient of determination (R2) = 0.03

Regression Equation: Conventional Hb assay (g/dl) = 8.31 + 0.16 * Noninvasive Hb assay (g/dl)

Parameter	Coefficient	SE	95% CI	t	P-value
Intercept	8.31	1.02	6.29−10.34	8.169	<0.0001
Slope	0.16	0.09	-0.03−0.34	1.692	0.095
Analysis of Variance					
Source	DF	Sum of Squares	Mean Square	F-ratio	P-value
Regression	1	11.66	11.66	2.863	0.095
Residual	80	325.98	4.07		
Residuals statistics					
Residual standard deviation	2.02				
D'Agostino-Pearson test for normality of residuals	P-value = 0.747 (accept normality)				

95% CI = 95% confidence interval, DF = degree of freedom, SE = standard error, t = t-statistic

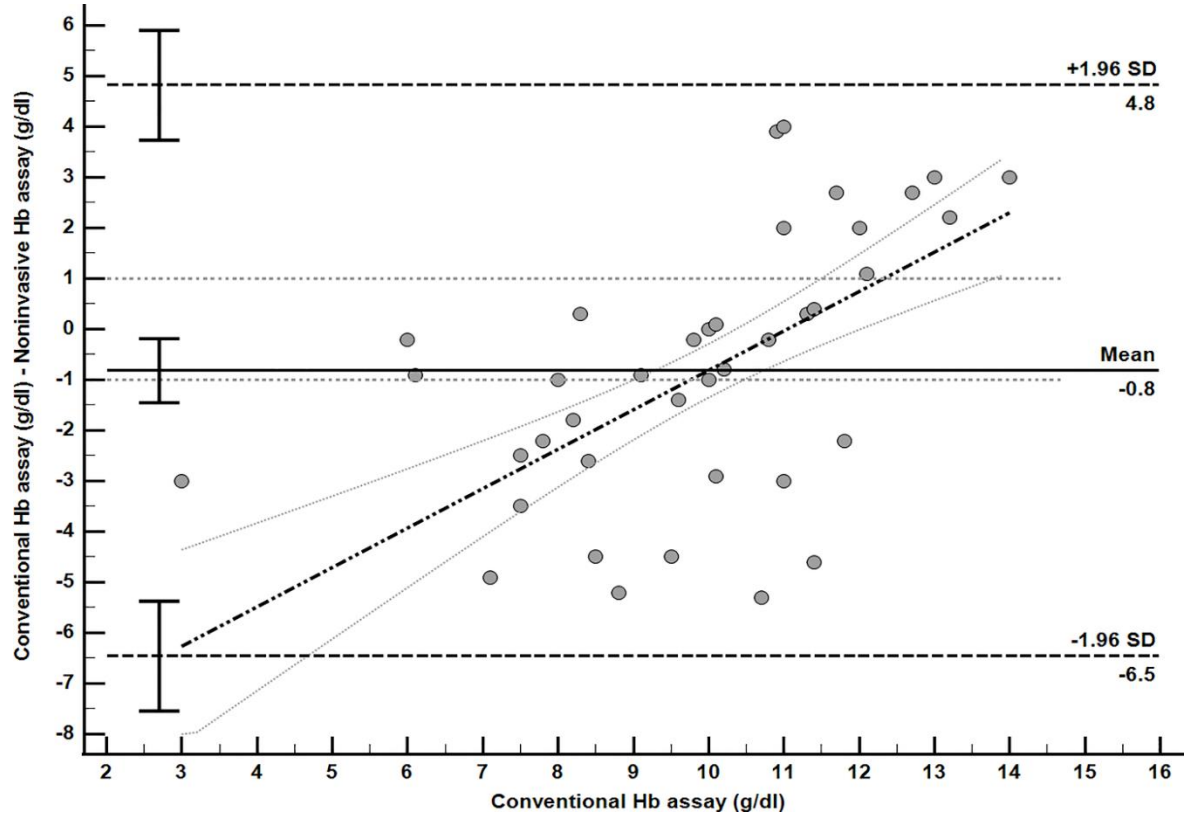

Figure 1: Bland-Altman plot showing difference between conventional and noninvasive Hb assay.

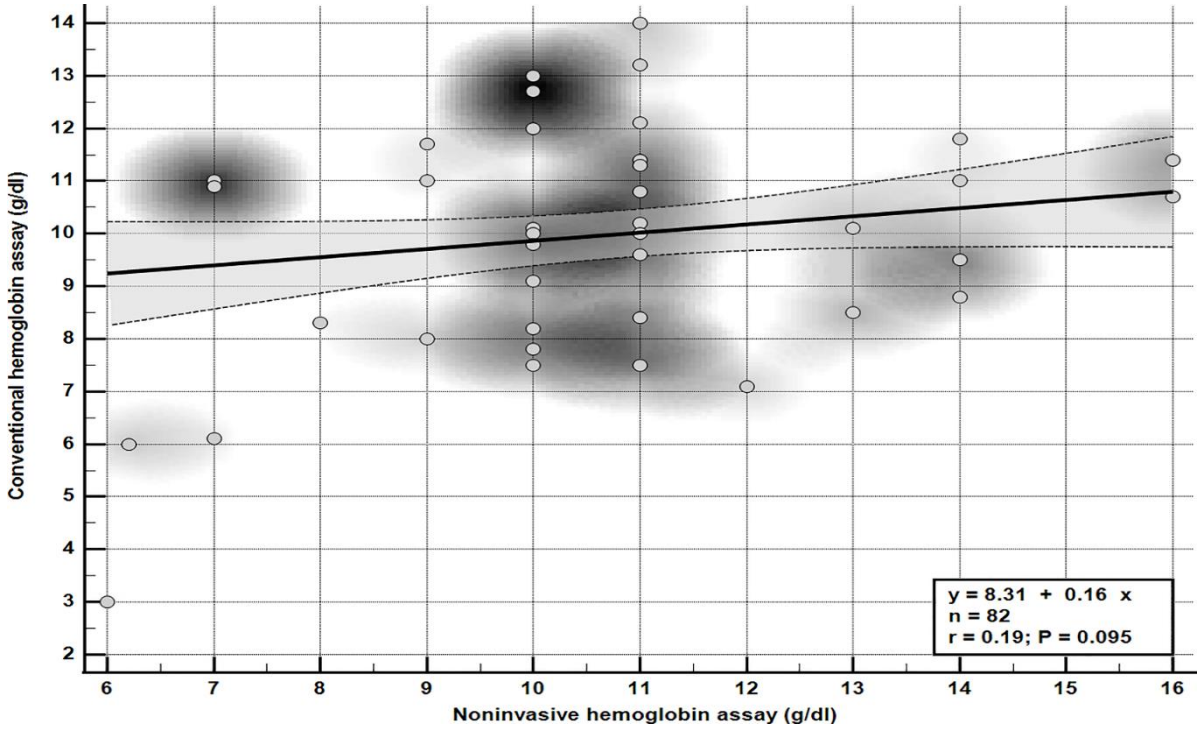

Figure 2: Scatter plot showing the correlation between the true (conventional) and noninvasive values of Hb assay.

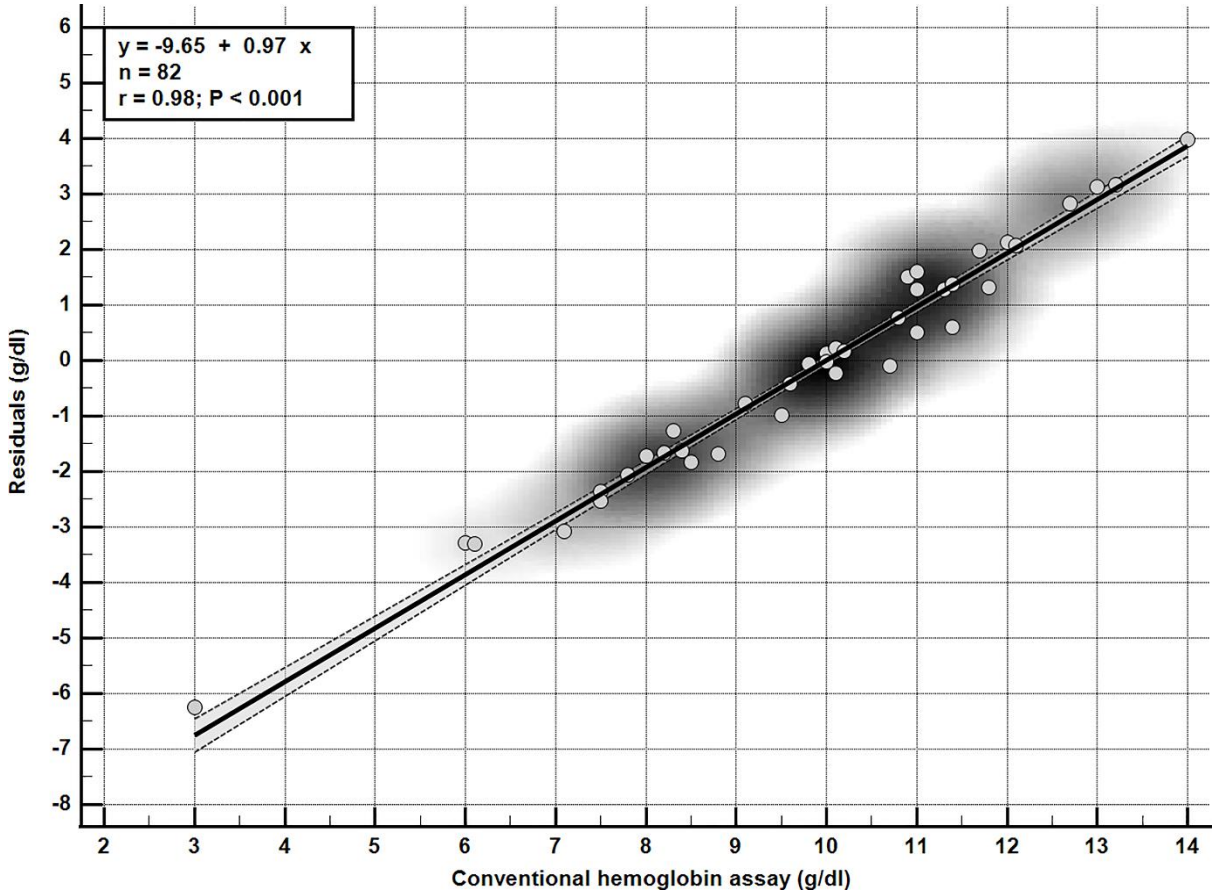

Figure 3: Scatter plot for the correlation between the residuals (errors) and the true (conventional) values.

Table 3: Linear regression model for relation between the difference between conventional and noninvasive Hb assay and the true value of Hb; Sample size = **82;** Coefficient of determination (R^2) = **0.30**

Regression Equation: Difference between conventional and noninvasive Hb assay (g/dl) = 8.59 + 0.78 * Noninvasive Hb assay (g/dl)					
Parameter	**Coefficient**	**SE**	**95% CI**	**t**	**P-value**
Intercept	-8.59	1.34	-11.25−-5.92	-6.41	<0.0001
Slope	0.78	0.13	0.52−1.04	5.92	<0.0001
Analysis of Variance					
Source	**DF**	**Sum of Squares**	**Mean Square**	**F-ratio**	**P-value**
Regression	1	204.200	204.200	35.024	
Residual	80	466.423	5.830	P < 0.0001	
Residuals statistics					
Residual standard deviation	2.41				
D'Agostino-Pearson test for normality of residuals	P = 0.411 (accept normality)				
95% CI = 95% confidence interval, DF = degree of freedom, SE = standard error, t = t-statistic					

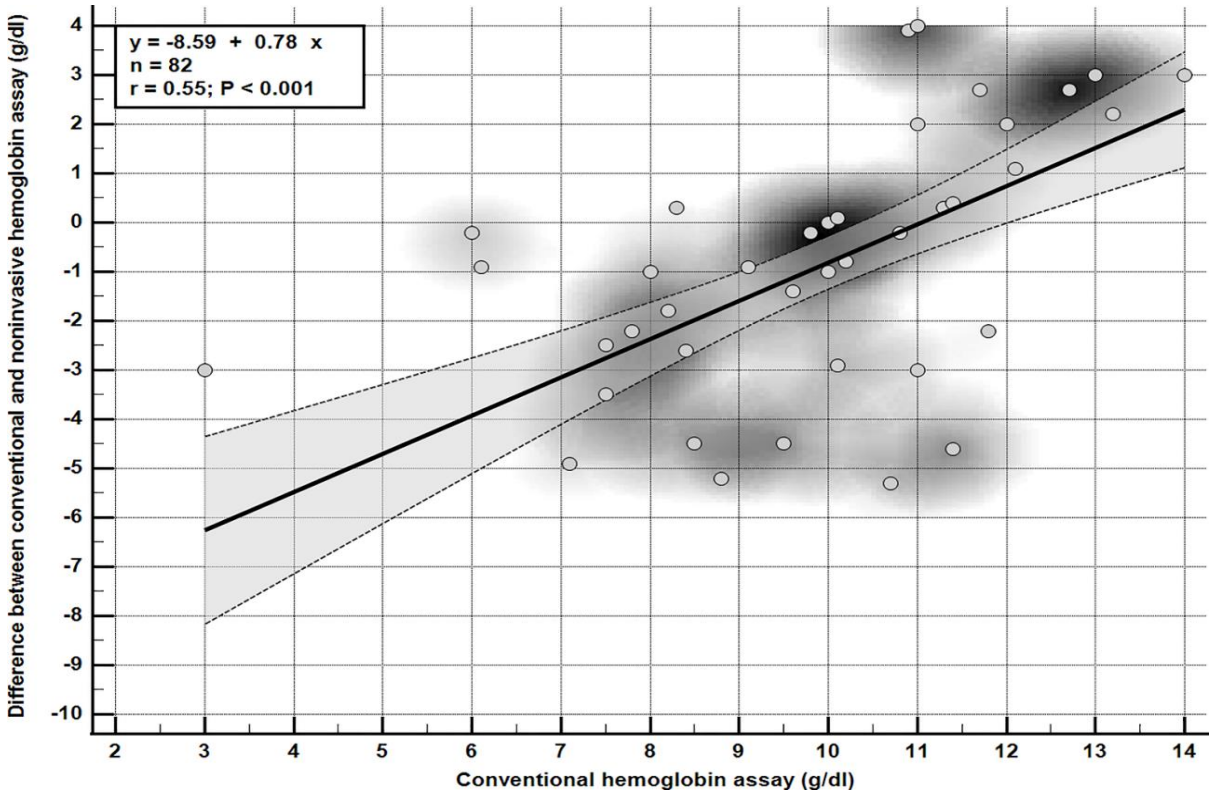

Figure 4: Scatter plot showing correlation between the true (conventional) value of Hb and the difference between the two methods.

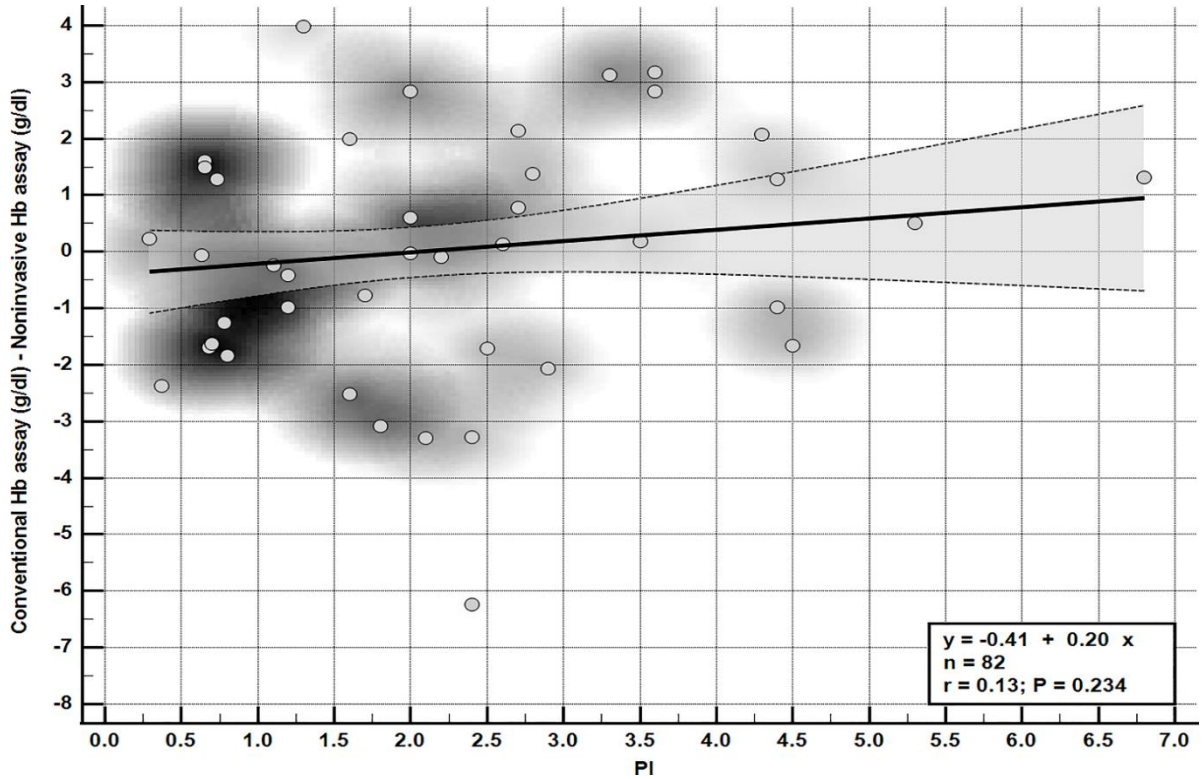

Figure 5: Scatter plot for the correlation between the residuals (errors) and the PI.

There was a moderate positive correlation between the true (conventional) value of Hb and the difference between the two methods. (P < 0.0001). (Table 3 & Figure 4).

We examined the effect of PI on the accuracy of noninvasive Hb assay by examination of the scatter plots of PI versus the residuals (errors). The correlation between the PI and residuals was very weak and statistically insignificant (P = 0.234) (Figure 5).

4. DISCUSSION

The expert nonoperative management of abdominal injuries has significantly reduced the number of laparotomies.[13] Serial Hb measurements together with frequent clinical assessment by trauma surgery team and

24-h available CT-scan, angiography and operating room readiness are considered crucial in these patients.[14]

Data about SpHb are conflicting, many studies had evaluated SpHb either in the perioperative settings or in critical care settings, some studies supported its use based on accepted accuracy and precision while other studies questioned its role.

In our study, we aimed to evaluate the accuracy of SpHb measurements in abdominal trauma patients admitted to ICU under observation to determine whether it's possible or not to rely upon its' readings in making decision for operative management. If proven to be accurate; SpHb would offer a safe, immediate, and a cost-effective alternative to invasive laboratory measurements.

We found that Radical-7™ had a poor and clinically unacceptable agreement with conventional assay, the limits of agreement ranged from −6.45 g/dl to 4.82 g/dl. The mean difference (bias) was -0.82 g/dl (95% CI = −1.45 to −0.19). Also, the correlation between SpHb and laboratory values was very weak and statistically

insignificant (P = 0.095). The standard error of the estimate (residuals SD) was 2.02 g/dl which is too large indicating poor accuracy.

Agreeing with our study, Gayat and colleagues who compared the results of Masimo Radical-7™ with results

obtained by the Siemens ADVIA 2120 analyzer in 300 patients admitted to the emergency department. The results reported were systematically biased and too unreliable to guide transfusion decisions. It is worth mentioning that the study was carried out by an old and obsolete sensor version of Radical-7™ (version 7.4.09 with rev B reusable sensor).[15]

Masimo Radical-7™ wasn't also precise enough to serve as a sole trigger for blood transfusion as concluded by Bridges and Hatzfeld, who found wide limits of agreement between SpHb and Coulter (−2.4, 3.4 g/dL) in 23 combat casualties.[11]

Another study by Tsuei et al. evaluating Radical-7™ device in trauma patients at risk of bleeding showed poor accuracy of SpHb and a bias of 1.49 g/dL with wide limits of agreement of (−2.2 g/dL to 5.0 g/dl) and concluded limited predictability of Radical-7™ for acute hemorrhage.[16]

On the other hand, some studies supported the use of SpHb, like the one by Cheng et al.,[17] who compared Masimo Radical-7™ SpHb readings with laboratory results in 50 patients undergoing spine surgery and showed that mean bias at PI ≥ 1 was −0.21 g/dl and at PI < 1 was −0.04 g/dL, they concluded that Masimo Radical-7™ offers an acceptable accuracy even at low PI. However, it's noted that Cheng and his colleagues' excluded patients with Hb < 7 g/dL and the range of Hb results in their study was between 9.3 and 16.6 g/dL. In our study the range of measurements was wider (between 3 and 14 g/dL). This was intended to strengthen the relevancy for evaluating SpHb monitoring during hemorrhage.

Disagreeing with our results, another study by Lamhaut et al.,[18] who compared measurements from SpHb, HemoCue®, and the laboratory samples obtained from 44 patients undergoing hemorrhagic surgeries and results showed nonsignificant bias in SpHb measurement of (−0.02 ± 1.39 g/ dl) compared with automated analysis in the laboratory. However, the study results showed better performance of HemoCue® as indicated by higher correlation between its' readings and laboratory readings than SpHb.

clinically acceptable accuracy was also reported by Berkow and his colleagues, who compared SpHb with laboratory co-oximetry in 29 subjects undergoing spine surgery.[8] they concluded that continuous monitoring might provide more timely and complete information than the standard measurement methods. SpHb showed a clinically accepted accuracy with a bias and precision of (−0.1 ± 1.0 g/dl).

Interestingly, we found a moderate positive correlation between the laboratory value and the difference between the two methods, denoting that the difference between the two methods increases linearly with the true value of Hb. We quantified this relation using linear regression (Table 3 & Figure 4), which showed that the difference between both methods could be represented with the following equation: *Difference between conventional*

*and non-invasive assay (g/dl) = -8.59 + 0.78 * conventional assay (g/dl).*

To determine the reliable SpHb readings by the Radical-7™ Berkow et al. used signal quality indicator (SIQ) to separate pairs of readings,[8] when they analyzed readings excluding those with low SIQ the precision remained the same and the bias improved slightly. Miller et al. used PI to categorize data into two groups; PI < 1.4 and PI ≥1.4 groups. They found no significant difference between both groups.[19] However, they demonstrated that the accuracy of SpHb is significantly higher when PI is > 2, this high PI was obtained after they performed digital nerve block.[20] Third group of studies. didn't include readings with low perfusion values in analysis.[21,22] In our study there was no significant correlation between the accuracy of SpHb and local tissue perfusion evaluated by PI (P = 0.234) (Figure 5), the same finding was reported before in a study by Lamhaut and his colleagues who showed no significant correlation between the difference (SpHb – laboratory Hb) and PI (R=0.09, NS).[18]

5. LIMITATIONS

Sample size was small. We excluded patients with unstable hemodynamics necessitating vasopressors, so we were unable to assess accuracy in such group. Next, we didn't collect data about comorbid diseases in enrolled subjects, thus we weren't able to evaluate the correlation between the accuracy of SpHb and such variables, future studies are warranted for such an idea. We adapted a spot measurement technique rather than continuous reading, we think that a trend of values especially if rapidly declining in patients at risk of bleeding may give a better insight about the proper timing for invasive Hb measurement.

6. CONCLUSION

Despite the proposed advantages of using spectrometric non-invasive Hb monitoring (SpHb) with Masimo Radical-7™ Pulse CO-Oximeter compared to laboratory Hb tests, we found that the readings are not accurate enough and that the device offers limited value in deciding operative against conservative management of blunt abdominal trauma patients admitted to ICU under observation.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Acknowledgement

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9. Conflict of interest

None declared by the authors, and no external or industry funding was involved.

10. Authors' contribution

AFH: Concept; Methodology; Original draft preparation

IAI: Data curation; Software

RH: Supervision; Software

WAI: Visualization; Validation of the draft; Editing; Data search

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