Continuous noninvasive monitoring of the hemoglobin during cardiac surgery and comparative analysis with existing technique

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Abstract

Hemoglobin (Hb) concentration monitoring is the most required analysis during surgery and critical care treatment to make proper decision regarding blood transfusion. Blood gas analysis is required invasive intermittent blood sampling. Various non-invasive Hb monitoring techniques are under research for better real time patients' management. Masimo rainbow® Pulse CO-Oximeter® is to monitor continuous and noninvasive hemoglobin (SpHb) whereas blood samples give intermittent results. Recently, disposable SpHb sensor has been updated. We evaluate the SpHb sensor compared with total Hemoglobin(tHb) in patients undergoing cardiac surgery using cardiopulmonary bypass (CPB).

A total of 272 SpHb and tHb paired data samples from 60 patients. To analyze the tHb, the patients' blood samples were drawn intermittently by the radial arterial line and blood gas analyzer ABL 90 (Radiometer corp., Denmark) as per anesthesiologist decision. SpHb sensors (RD rainbow SET-2 Adt sensor, Masimo Corp., USA) were attached to the patients' ring finger connected to Root® with Radical-7®. Reliability and trending ability between the SpHb and tHb were analyzed by the regression analysis, Bland-Altman analysis, four quadrant plots and polar plot. Limits of agreement between SpHb and tHb is calculated to be -2.01 to 2.2 g/dL with a bias of 0.13 g/dL. The correlation coefficient (r) of SpHb and tHb were 0.8036. Concordance ratio of four quadrant and polar plots were 93% and 91%, respectively.

Both Absolute and trend accuracy of SpHb with the latest version are clinically acceptable in patients undergo cardiac surgery using CPB.

1 Introduction

Patient monitoring to evaluate their physiological condition which includes blood pressure, heart rate, respiration rate, hemoglobin oxygen saturation level, anesthetic state and EEG monitoring is basic in the patient diagnosis during anesthetic process. [1–4] Various kinds of sensors were used to analyze different parameter for the successful surgical process.[5–7] Patients undergoing critical cardiac surgery are higher risk of hemorrhage and subsequently indicated by reduction of Hb level.[8–11] To monitor hemorrhage and blood transfusion at optimal timing, continuous monitoring of the blood Hb may improve the precise decision making of anesthesiologist. Currently blood withdrawn from the anesthetized patients followed Hb concentration analysis carried out in laboratory instruments.[12–15] But this kind of traditional method have the disadvantage such as invitro blood sampling and lack in the continuous tracking of the Hb.

Various non-invasive techniques have been investigated based on fluro-photometric techniques.[4, 17–20] Also, continuous monitoring of the hemoglobin is not used widely yet. Statistical validation yet to be confirmed with the current version of Masimo used[21]. Various comparative studies carried to check the near infra-red spectrum based Hb monitoring and they are currently used in the US and other country hospitals briefly.[1, 4, 22] But there are no such published studies carried out with this model of sensor in the Japanese ethnicity peoples. Recently, disposable adhesive SpHb sensor which measure the SpHb by

optical density variation has been updated. Where is validation of the previous devices applied for US and few other ethnic groups had been published. However, the accuracy of the latest version of SpHb sensor in Japanese patients during acute open-heart surgery with current model of the sensor has not yet been evaluated.

In this validation study, we evaluate SpHb compared with ABL 90 (Radiometer corp., Copenhagen, Denmark. (Reference laboratory blood gas analysis) during critical open-heart cardiac surgery using CPB.

2 Materials And Methods

Patients

Sixty patients who underwent cardiac surgery using CPB from October to May 2020 were enrolled in this study. This study was approved by the ethical monitoring committee of Hamamatsu medical university (Ethical committee approval No.19–109)

Anesthesia and monitoring

Standardized inhalation anesthetic and propofol/remifentanil-based anesthetic protocol was carried out in all patients and monitored using Masimo SedLine Patient State Index® (PSi) (Masimo Corp., Irvine, CA) (PSi of the anesthetized patients maintained with in the rage of 25–50). Other monitoring like Non-invasive Blood Pressure (BP), pulse, Invasive Blood Pressure (IBP), Central Venous Pressure (CVP), pulmonary artery pressure, oximetry, electrocardiogram, arterial pressure monitoring was apllied to patients undergoing surgery. Body and blood temperature were also monitored during surgery and cardiopulmonary bypass pump process.

Hemoglobin concentration measurements

Before the start of general anesthesia, arterial catheter was placed on right Radical Artery. SpHb was measured using Root® with Radical-7® (Masimo Corp. Irvine, CA, USA) with disposable adhesive SpHb sensor (RD rainbow SET Adt, Rev.O). The sensor was applied right-hand ring finger covered with opaque shield to protect interference with ambient light. SpHb continuously monitored from anesthetic induction until the surgical process ends. Perfusion Index (Pi), the ratio of pulsatile blood flow to non-pulsatile blood, was measured to check peripheral perfusion with SpHb. These data collected every two second via MICT, data downloading software (Masimo Corp., Irvine, CA, USA) and recorded at same time of blood drawing.

Hemoglobin analysis with the automated ABL-90 analyzer (tHb) was executed with standard clinical practice for critical cardiac surgery. Blood analysis was drawn via arterial catheter and analyzed immediately after collection. The timing of blood drawing is right after completion of anesthesia induction, before and after the CPB and at surgical events based on anesthesiologist requirements.

Blood transfusion

Hemoglobin concentration thresholds for the blood transfusion were recommended commonly by world standard groups were 6–8 g dl^{-1} during surgical process with either autologous blood or heterologous blood depending on the patient's state. Blood transfusion was decided from the laboratory analysis data (tHb) and anesthesiologists' judgements. On the other hand, in this study SpHb values were not used for blood transfusion decision making.

Statistical analysis

Patients' demographic and clinical data were collected and reported in Table 1. Patients' demographic details were expressed as mean value ± standard deviation (SD) and 60-day mortality was found to be nil in this study. The concordance between two methods was examined using linear regression and Bland and Altman analysis, by determining the bias, precision, agreement between tHb and SpHb hemoglobin analysis. Limits of agreement (LoA) were calculated as the mean bias ± 1.96 SD. SpHb values are not able to be evaluated when the low perfusion index happened due to the usage of cardiopulmonary bypass devices.[23] Trending ability was assessed in in addition to regression analysis using the four-quadrant plot and Critchley polar plot to test the change in the directionality of Hb concentration. As per the specification we exclude the zones of 1.0 (g/dL) to minimize the interference of analysis. In terms of Critchley polar plot, concordance rate was defined within ± 30°.[8]

Table 1
Patients demographics

Characteristics	
Average age (years)	69.62 ± 12.58
Gender (Male/Female)	21/39
Average height (cm)	159.64 ± 9.73
Average weight (Kg)	58.57 ± 12.28
BMI	22.90 ± 3.80
Blood loss (mL)	1137.93 ± 860.91
Blood transfusion (mL)	1044.78 ± 528.15
Surgery	15 (with CPB)
Coronary artery bypass grafting (CABG)	4 (without CPB not included in statistics)
Valve replacement surgery	23
CAPBG with Valve replacement surgery	8
Thoracic vascular surgery	11
Anesthesia time(hh:mm)	8:18 ± 2:29
Pump time (hh:mm)	3:28 ± 1:16
Surgery time (hh:mm)	6:36 ± 2:21
60 day mortality	0

Statistical analyses were performed using SPSS v 25 for Macintosh (IBM Corp, Armonk, NY) and R 4.0.1 statistical software (R Foundation for Statistical Computing, Vienna, Austria).

3 Results

A total of 272 SpHb and tHb paired data samples from 60 patients were obtained. 92% of data have the good signal quality and therefore available for the further analysis.

Regression analysis of the 272 data points are displayed in the Fig. 1. Among those points most of them are fallen in and above 10 g/dL and very less in the 6 to 10 g/dL. Also, none of the points are fallen below 6 g/dL. We used correlation coefficient and Cohen`s Kappa statistical validation which is used for the inter-rater reliability. In our case correlation coefficient (r) of SpHb and tHb were 0.8036 and it produces a Cohen’s Kappa value of 0.64 (moderate agreement) with hemoglobin concentration less than 10 g/dl based the blood gas values. Figure 2 shows the Bland Altman analysis with 95% limits of agreement.

Limits of agreement is calculated to be -2.01 to 2.2 g/dL with a bias of 0.13 g/dL for the difference between SpHb and tHb.

Four quadrant analysis and Critchley's polar plots are used to show the trending ability of the SpHb and tHb values. For both plots we excluded the zones under ± 1 g/dL. This zone of exclusion is the zone corresponding to correct directionality. Figure 3 shows trending ability in the four-quadrant analysis plot and concordance factor calculated as 93%. In terms of Critchley polar plot concordance factor calculated as 91% and which is represented in Fig. 4.

4 Discussion

This study, we have revealed the latest SpHb sensor acts as an obsolete and acceptable trend monitor in patients undergoing cardiac surgery. So far, various publications have been published on the trending ability of noninvasive hemoglobin.[2, 4, 24] This is the first study used the latest SpHb sensor in the cardiac surgery patients.

Our examinations were obtained only from the patients underwent cardiac surgery with CPB. Few patients' data we can't be able to measure due to braided nails, damaged skin and thick callus. Also, patients' low perfusion state, anemia, nail deformity, motion artifact may affect the measurement data. In our study, we compare the data with only one single ethnic group and only one reference data has been used. This is the first study based on our knowledge on the patients undergoing cardiac surgery using Rev.O sensors. Also, we applied the trending analysis of Critchley and Quadrant plot to prove the trend ability. We adopt the same error bars as proposed by Critchley method as ± 30° on either side of the plot.[8, 10, 18] Concordance ratio in both 4 quadrant and polar trending ability showed more than 90% or greater which were acceptable trending ability.

4 quadrant plot analysis considers directionality of the change in the SpHb values and tHb analysis. But in terms of polar plots includes both directionality and magnitude change by considering error data. The limits of both 4 quadrant and polar data analysis derived from review of the existing literatures and used to define the trending ability.[8] Angular limits were adopted from Critchley's study. Blood transfusion and threshold (6 g/dL) limits were maintained by the anesthesiologist who followed the guideline of Japanese Society of Anesthesiologist. [16, 25, 26]

When compare with Morey analysis, our data represented more than 93% of it false in the zone A region of Morey graph. However, the correlation data of this experiment resulted in R = 0.80 in Fig. 1. This clearly shows the potential validity, and a few nonlinear points may be due to patient's lower perfusion index. On the other hand, Gaya et al. used sensor in spot check measurements so the data variation and error value may be high for their study.[27, 28]

There are various limits of agreement from previous studies obtained by statistical analysis like Bland Altman. Lot of studies provided the larger limits of agreement for various kind of monitoring condition. Which varied from − 5 to 3 g/dL. Few reported smaller limits of agreement as -2 to 2 g/dL. The variation

of these limits is based on the study population, surgical process and blood loss variations. Patients underwent less blood loss surgery or non-anemic patients have lower limits of agreement. In terms of our study we recorded high blood in most of the case due to cardiac surgery the limits are calculated as -2.0 to 2.2 g/dL which is mere negligible when compared to previous studies.[29–32]

Our trending studies clearly showed the greater number of recorded points presented inside the central exclusion zone. In which change of hemoglobin hasn't changed in dramatic way. This may have been due to earlier sample collection for the analysis and assessment of other intraoperative monitoring and resuscitation than blood loss criterion. However, ABL-90 blood gas machine, has its own error and bias but its widely accepted for the decision making in terms of blood loss and determination of blood transfusion. So, we used the values of ABL-90 as reference values for testing and determine the bias of the SpHb sensor.[3, 15, 23]

Further studies should explore the potential of the devices on the changes in the hemoglobin with surgical and non-surgical patients' populations. As overall conclusion, we propose this device for the continuous trend monitor and absolute measurement of hemoglobin.

Declarations

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Conflicts of Interest

We authors declare that there is no conflict of interests.

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Figures

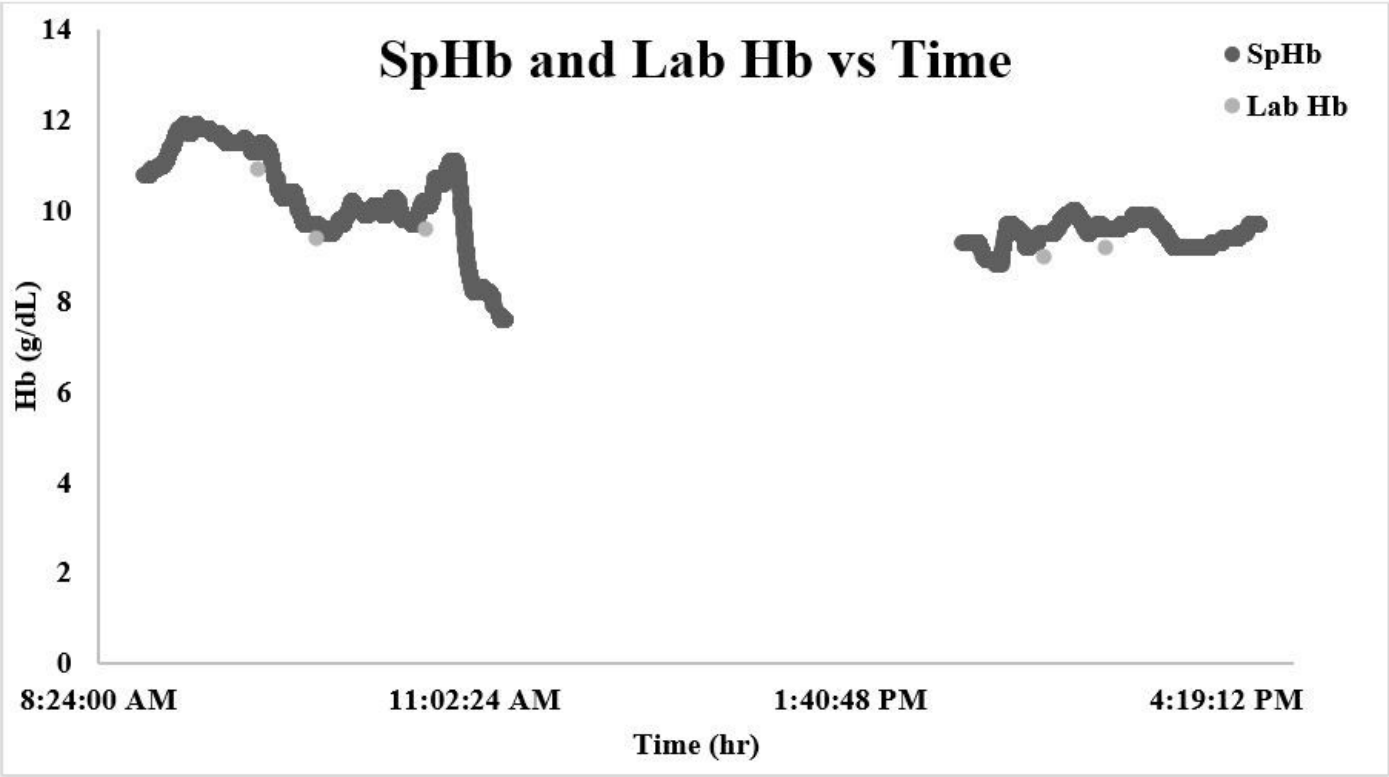

Figure 1

Example of comparison on invasive and noninvasive Hb measurement

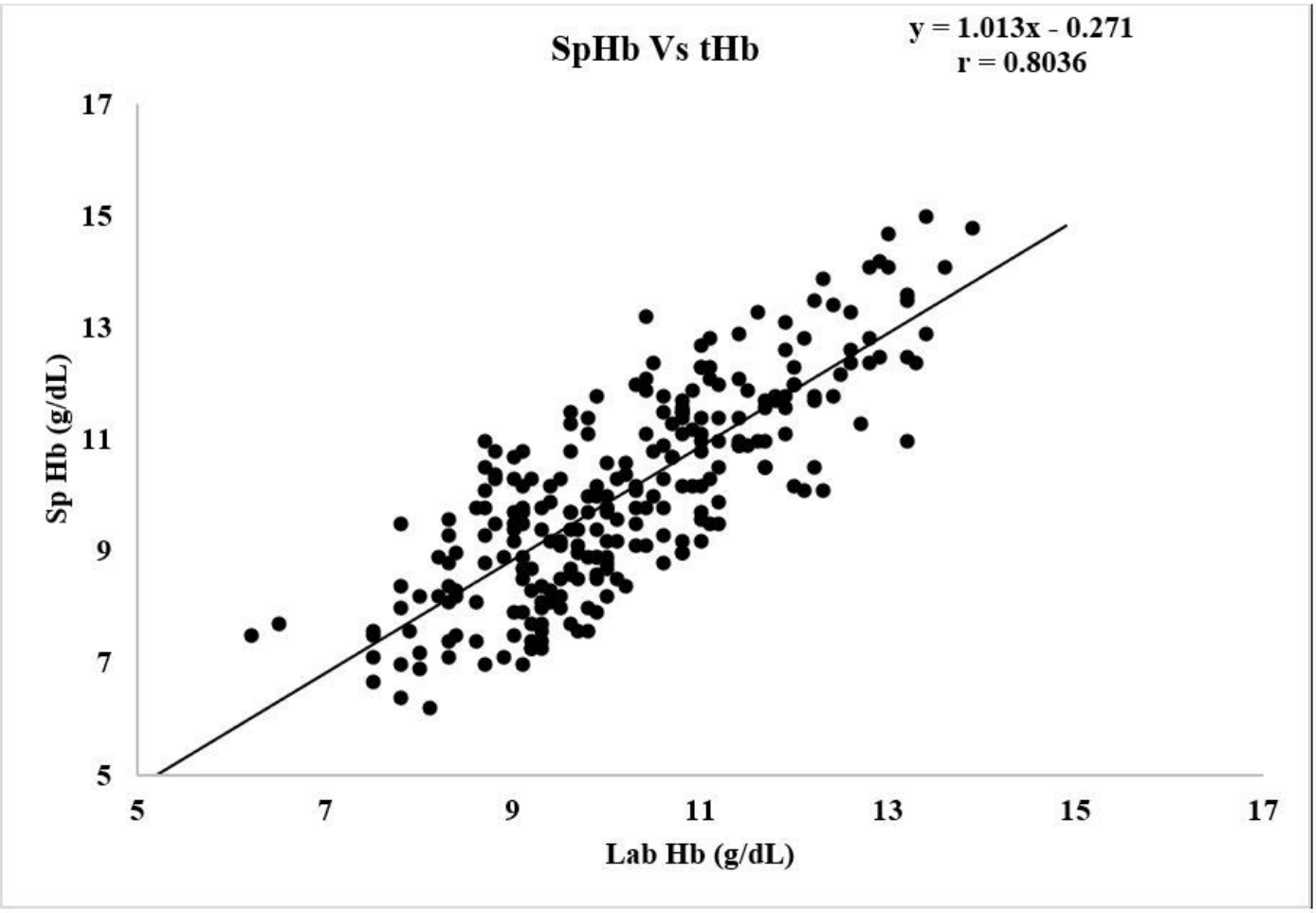

Figure 2

Clinical significance analysis of SpHb and tHb by regression analysis none of the patients' Hb level doesn't went below 6

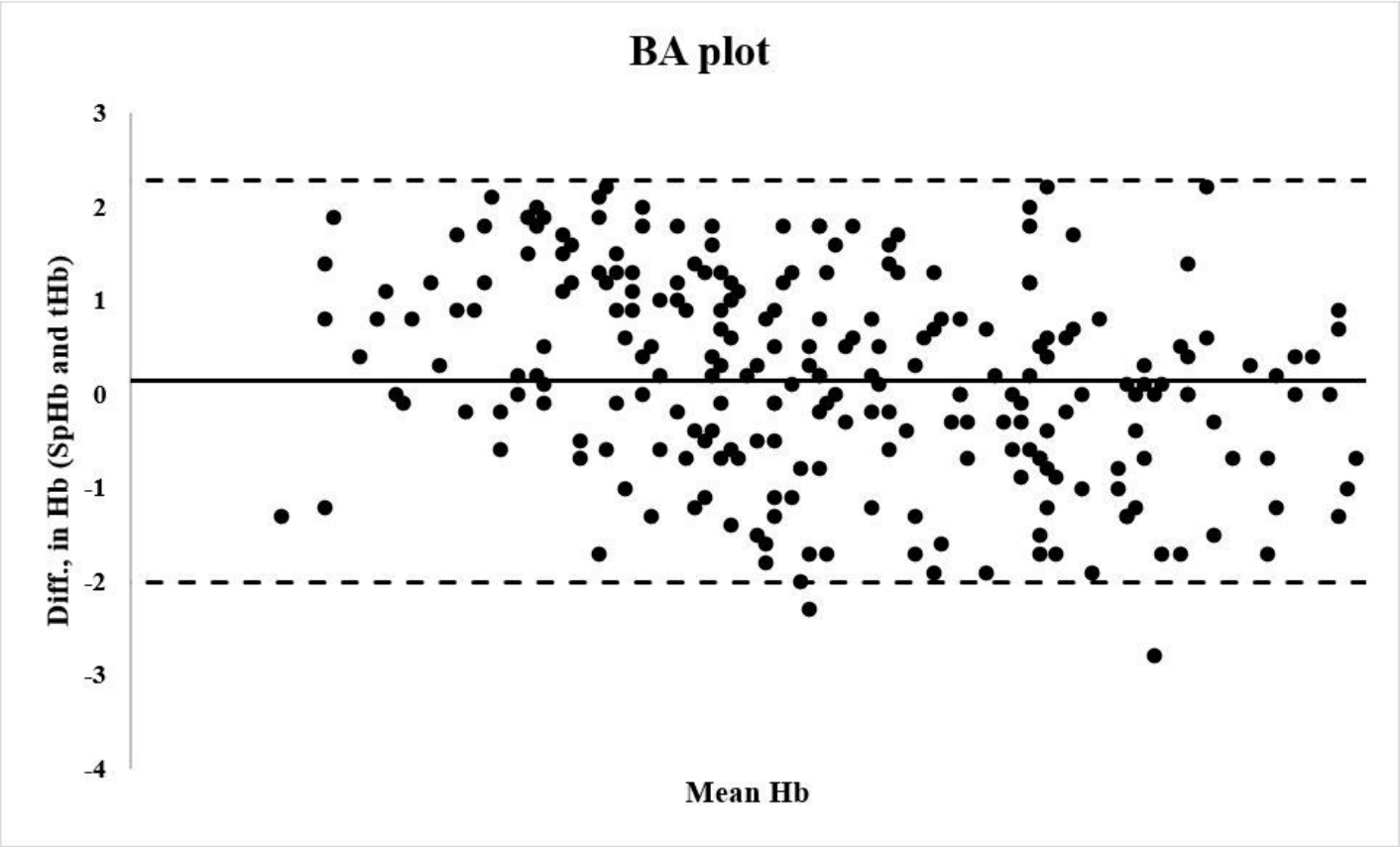

Figure 3

Bland-Altman plot analysis carried out using mean and difference of Hb of both methods. Limits of agreements calculated based on conventional methodology. [23]

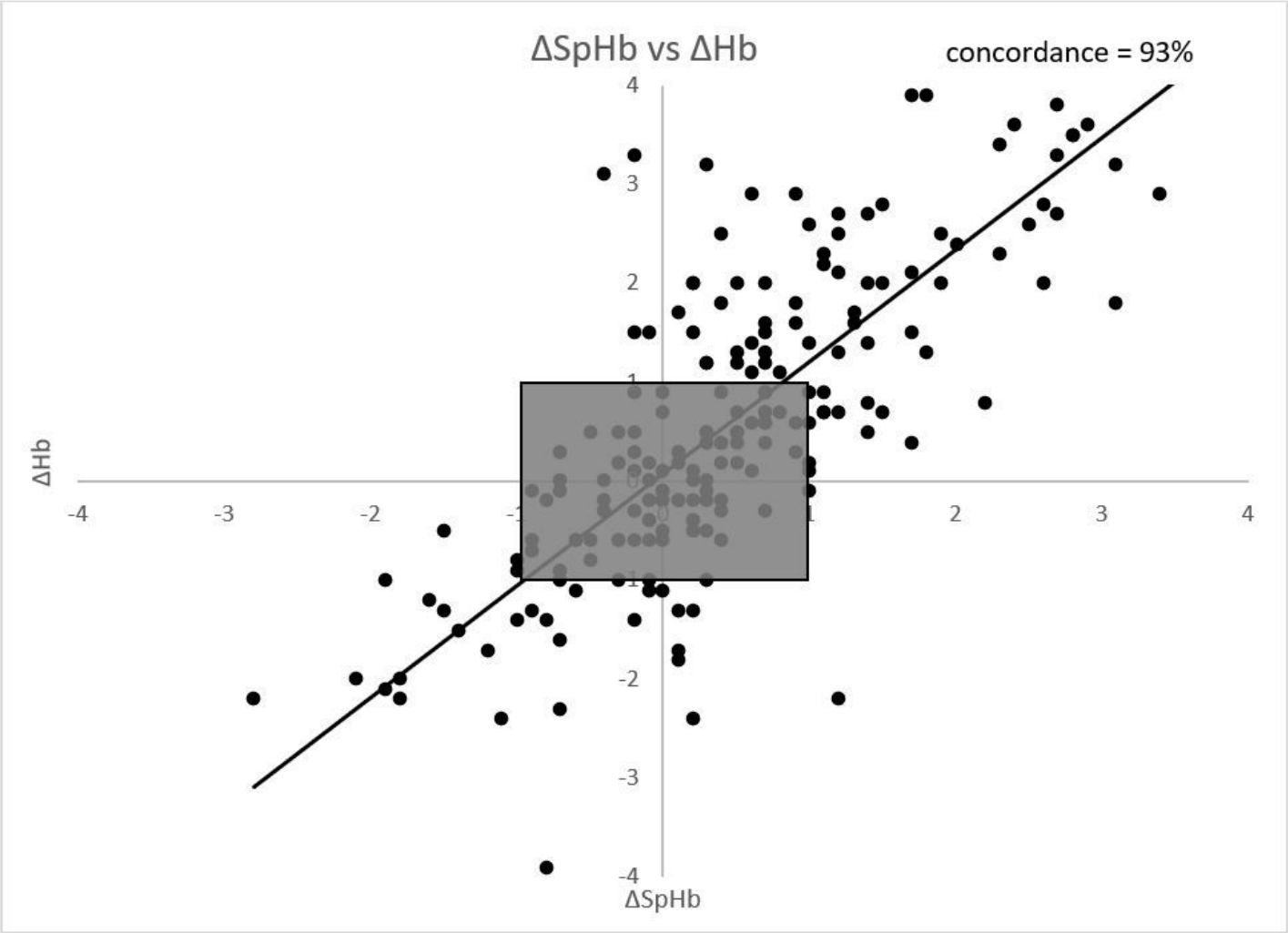

Figure 4

Trending ability analysis of Hb with exclusion of central zone (1 g/dL). Concordance factor shows acceptable directionality trending

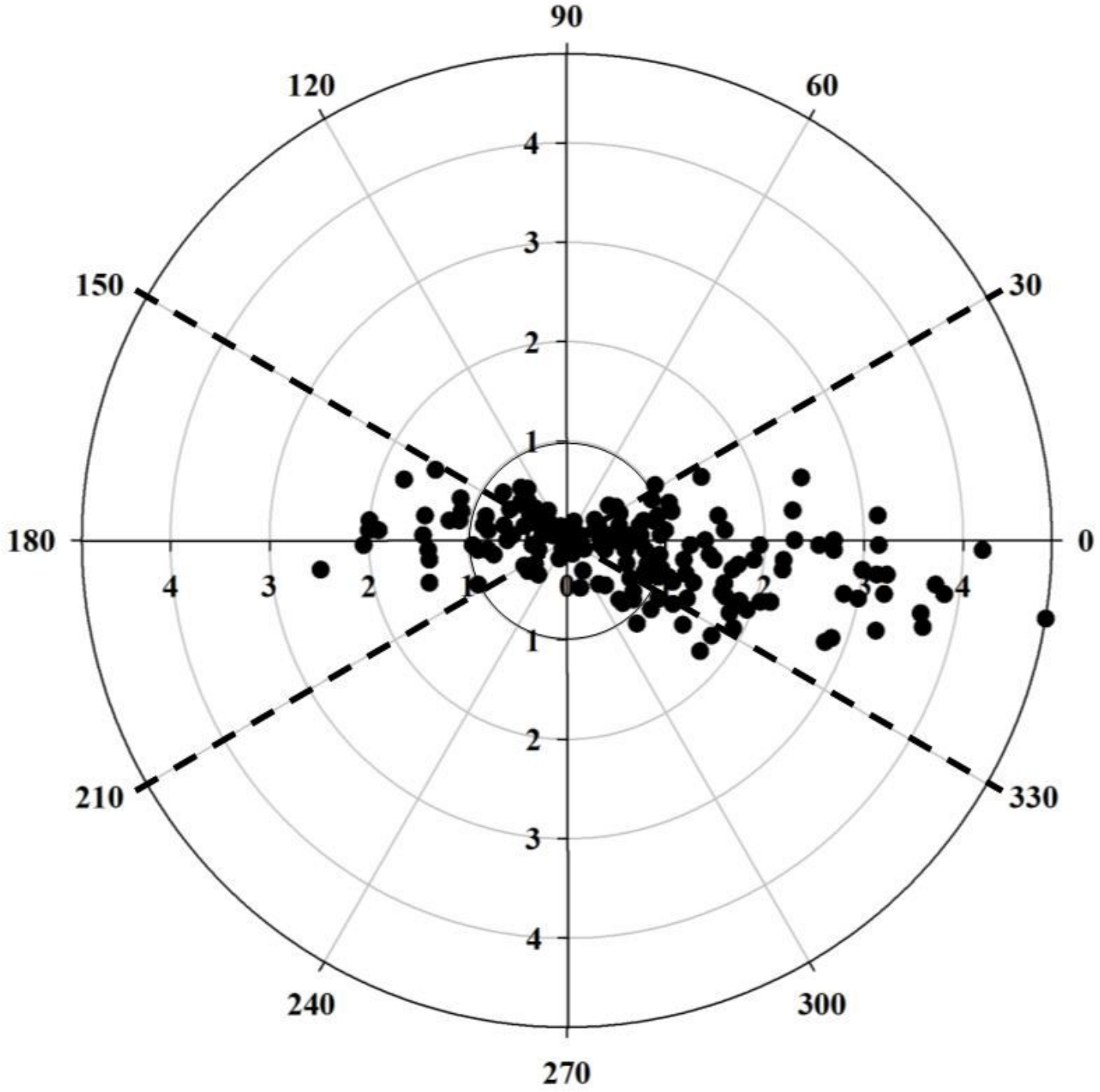

Figure 5

Critchley polar plot analysis of trending ability for directionality and magnitude. Limits were adopted from the Critchley's method. [8]