Evaluation of Absolute and Trend Accuracy of Revision G Noninvasive and Continuous Hemoglobin Monitoring During Major Surgery

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Introduction

Intraoperative hemoglobin changes are integral to decision-making regarding administering or withholding red blood cell transfusion. Both increases and decreases in hemoglobin may be unapparent to treating clinicians, which may lead to either unnecessary transfusion or late bleeding detection. We previously reported on absolute and trend accuracy of noninvasive and continuous hemoglobin (SpHb) monitoring. Our objective in this study was to investigate the absolute and trend accuracy of a new version of the SpHb adhesive sensor and software.

Methods

IRB approved investigator initiated trial. Following written patient consent, adult patients scheduled for major surgical procedures at high risk for blood loss were enrolled. In addition to standard care ASA monitoring during the perioperative period, patients received arterial catheters, as is our practice for patients undergoing these procedures. Additionally, a SpHb Resposable sensor (R2-25, revision G) connected to a Radical-7 Pulse CO-Oximeter (Masimo, Irvine CA), was placed on a finger of either hand. During each procedure, time-matched SpHb was recorded when arterial hemoglobin samples were obtained for analysis by CO-Oximetry (ABL-800, Radiometer, Copenhagen, Denmark) (ABG Hb). Bias and standard deviation of the bias for SpHb- ABG Hb were calculated. Linear regression analysis with coefficient of determination (R^2), Bland Altman analysis with limits of agreement, and linear regression of paired changes in sequential measurements of SpHb to tHb were performed.

Results

45 patients were studied, with characteristics shown in Table 1. Estimated surgical blood loss ranged from 20 to 5500 ml. 218 paired SpHb-tHb measurements were collected. Compared to what we previously reported for an earlier version of the sensor (revision E) in the same population, bias and standard deviation of the bias showed improved accuracy (-0.10±1.3 g/dL vs Rev E 0.5±1.4g/dl). Additionally, linear regression analysis (Figure 1) showed higher correlation (slope 0.80 R2 of 0.58 vs Rev E slope 0.67; R2 0.48); Bland Altman plot (Figure 2) showed narrower limits of agreement (-2.73 to 2.53 g/dL, vs -2.3 to 3.3 g/dl), and linear regression plot of paired sequential changes in ABG Hb and SpHb (Figure 3) showed higher correlation for trending (R2 of 0.37 vs Rev E 0.31). SpHb increased in only 2 of 29 samples in which the sequential decrease in ABG Hb was >1 g/dl.

Discussion

The revision G SpHb sensor showed improved absolute and trend accuracy compared to the previous revision E sensor in patients undergoing major surgery. Analysis of accuracy in different physiologic and estimated blood loss ranges is ongoing.

Table 1: Demographic and intraoperative characteristics of 45 patients analyzed. Results are show as count or mean ± standard deviation. Median and interquartile ranges are included for ABG and estimated blood loss results.

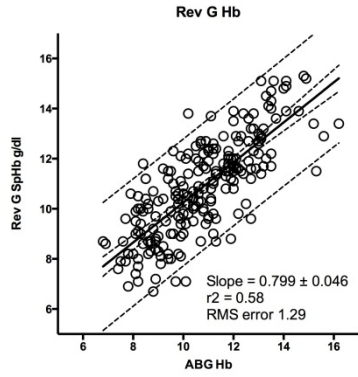|	
Gender # Female; Male	32; 13
Age years	59.8 ± 16.7
Weight kg	81.6 ± 19.6
Body mass index kg/m2	30.3 ± 7.8
Number of ABG samples during surgery	3.5 ± 2.4 Median 3, interquartile range 2 to 5
Estimated blood loss ml	847 ± 1053 Median 500, interquartile range 200 to 1138

Figure 1: linear regression analysis of paired arterial hemoglobin (ABG Hb) and SpHb from Rev G sensors in patients undergoing major surgery.
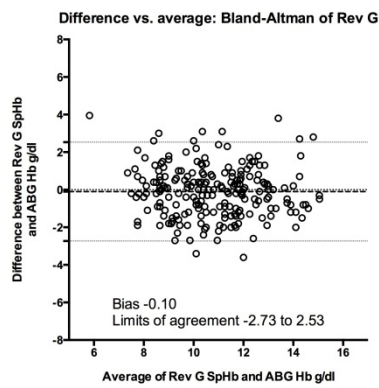

Figure 2: Bland Altman analysis of paired arterial hemoglobin (ABG Hb) and SpHb from Rev G sensors in patients undergoing major surgery.
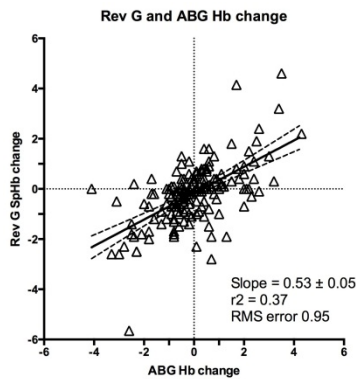

Figure 3: linear regression analysis of paired sequential changes in arterial hemoglobin (ABG Hb) and SpHb from Rev G sensors in patients undergoing major surgery.