
Background
Knowledge of hemoglobin status is an imperative during most surgery procedures. The standard procedure to measure hemoglobin is through intermittent, invasive methods. A new noninvasive, continuous method of hemoglobin determination (SpHb), as part of Pulse CO-Oximetry (Masimo Rainbow SET platform), has been recently introduced but limited clinical validation is available. The objective of this study was to validate the accuracy of SpHb compared to invasive hemoglobin measurement during surgery.

Methods
After local ethics committee approval, written informed consent was obtained from 27 patients scheduled for surgery under general anesthesia in which an intra-arterial cannula was required. Patients were excluded if blood samples could not be obtained from the lower extremities. Following arterial cannulation, an adult adhesive sensor (Rainbow R1-25) connected to a Pulse CO-Oximeter (Masimo Radical-7) was placed on the hand opposite to cannula placement. An ambient shield was placed over the sensor to prevent light interference. Blood samples were drawn approximately every 15 minutes during each surgical procedure. Blood samples were sent to the central laboratory for standard analysis of hemoglobin. SpHb data (one data point every 2 seconds) was downloaded to a laptop computer. The laboratory value of the first blood sample was used to retrospectively calibrate the first SpHb value and was used as a constant to adjust all subsequent SpHb measurements. SpHb results were not included when the Perfusion Index (PI, noninvasive index of peripheral perfusion and vasomotor tone) values were less than 0.5. The calibrated SpHb measurements were compared to subsequent laboratory values to create a Bland Altman plot and calculate bias, confidence interval, Passing and Bablock regression, and concordance correlation coefficient.

Results
437 measurements were obtained from 27 patients with an average of 16.2 +/- 4.5 measurements per patient. 27 measurements were excluded due to low PI. The Bland Altman graph is shown in Figure 1. The bias is 0.04 and the 95% confidence interval was -1.22 to +1.31. The Passing and Bablock analysis (Figure 2) shows a perfect correlation (y = 0 + 1x; intercept A=0.0 (95% CI: -0.2 to 0.4), slope B=1 (95% CI: 0.9 to 1). Concordance correlation coefficient was 0.93 (95% CI: 0.91 to 0.94) with precision of 0.93 and accuracy of 0.99.

Conclusions
After calibration of SpHb to the first invasive lab value, most subsequent SpHb values varied from laboratory hemoglobin measurements by <1.0 g/dL. Given the known variation in laboratory measurements, calibrated SpHb values demonstrated clinically-acceptable accuracy and precision in this group of surgical patients.