

Accuracy of Noninvasive and Continuous Hemoglobin Measurement by Pulse CO-Oximetry™: Data Submitted by Masimo as Part of FDA 510(k) Clearance

INTRODUCTION

Studies have shown invasive total hemoglobin (tHb) measurements can vary as much as 0.9 g/dL between different laboratory devices across the normal tHb range, using a reference calibrator.¹ In addition, point-of-care (POC) devices analyzing finger stick capillary blood samples are susceptible to even greater differences from traditional laboratory measurements, with differences up to 1.2 to 1.8 g/dL from reference standards.²⁻⁵

Noninvasive and continuous hemoglobin (SpHb[®]) measurement may be of value in a variety of clinical settings. The purpose of this study was to validate the accuracy of SpHb from Pulse CO-Oximetry compared to invasive laboratory measurement of hemoglobin. These results were submitted as part of the FDA 510(k) clearance process.

METHODS

All data were collected under institutional review board approval and all patients provided written, informed consent. A self-calibrating Pulse CO-Oximeter (Masimo rainbow SET[®], Masimo, Irvine, CA) with a spectrophotometric sensor (rainbow[®] DCI) with multiple wavelengths of light was utilized. The reported accuracy is applicable to all Masimo devices with rainbow[®] MX-series circuit boards, including Radical-7™, Rad-87™, Rad-57™, and Pronto[®]. The Pulse CO-Oximetry method discerns the distinctive light-absorption characteristics of different hemoglobin species and applies proprietary algorithms to determine Hb levels. Study subjects consisted of healthy adults, volunteers undergoing a hemodilution protocol, and surgery patients (liver transplant, caesarean section, or exploratory laparotomy). The hemodilution protocol consisted of replacing one unit of blood with 30 ml/kg of saline. Each SpHb measurement was matched with a corresponding invasive Hb measurement from a laboratory CO-Oximeter (Radiometer model ABL-820). The A_{RMS} values (accuracy in terms of root-mean square) were calculated. The data were also analyzed in terms of bias and precision (for one standard deviation).

RESULTS

Data were collected at three sites, Loma Linda Medical Center (Loma Linda, CA), Mayo Clinic (Jacksonville, FL), and Masimo Corporation (Irvine, CA). A total of 492 data pairs were collected from 59 subjects, 35 (59%) healthy adults, 16 (27%) hemodilution subjects, and 8 (14%) from surgical subjects. A total of 43 subjects (72%) were male and 53 subjects (90%) had light skin pigmentation. Collected invasive hemoglobin (tHb) values had a range of 6 to 17 g/dL, with 220 (45%) tHb measurements <12 g/dL, 145 (29%) <11 g/dL, and 74 (15%) <10 g/dL. Tabular results are shown in Table 1, range accuracy is shown in Table 2, and a scatter plot of tHb and SpHb measurements is shown in Figure 1.

CONCLUSION

Pulse CO-Oximetry SpHb measurement provides clinically acceptable accuracy compared to laboratory CO-Oximeter tHb measurement in the 8 to 17 g/dL range.

Correlation	Bias	Precision (1 SD)	A _{RMS}
0.90	0.08 g/dL	0.95g/dL	0.96 g/dL

Table 1 - Tabular analysis (N=492)



Difference Between SpHb and tHb N (%)			
tHb Range	<1.0 g/dL	<1.5 g/dL	<2.0 g/dL
<10 g/dL	59 (80%)	72 (97%)	74 (100%)
10 - 11.9 g/dL	100 (68%)	140 (96%)	145 (99%)
12 - 17 g/dL	182 (67%)	236 (87%)	257 (94%)
Total	341 (69%)	448 (91%)	476 (97%)

Table 2 - SpHb accuracy by tHb range

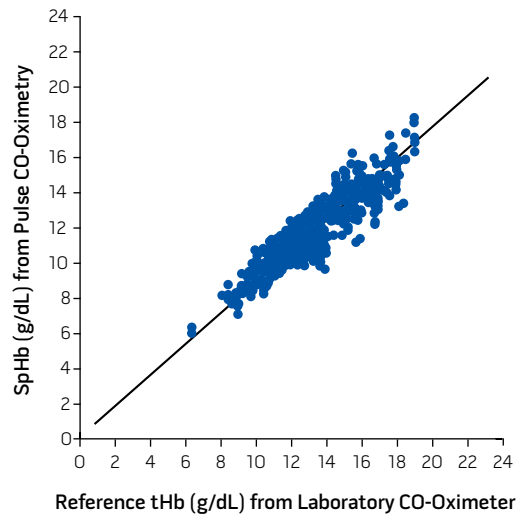


Figure 1 - Scatter plot of SpHb vs. tHb measurements (N=492)

REFERENCES

- ¹ Product of RNA Medical. CVC 223 CO-Oximeter Calibration Verification Controls.
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