

Accuracy of Noninvasive and Continuous Hemoglobin Measurement by Pulse CO-Oximetry

INTRODUCTION:

Total hemoglobin (Hb) is one of the most frequently-ordered laboratory measurements in both acute and outpatient settings. Current laboratory methods are invasive, time consuming, and can only provide intermittent Hb measurements. Noninvasive and continuous Hb measurement would offer many advantages in the assessment of both acute and chronic anemia in a variety of clinical settings. The purpose of this study was to evaluate the accuracy of a new noninvasive Hb measurement technology called Pulse CO-Oximetry™ compared to invasive laboratory measurement of Hb.

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 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

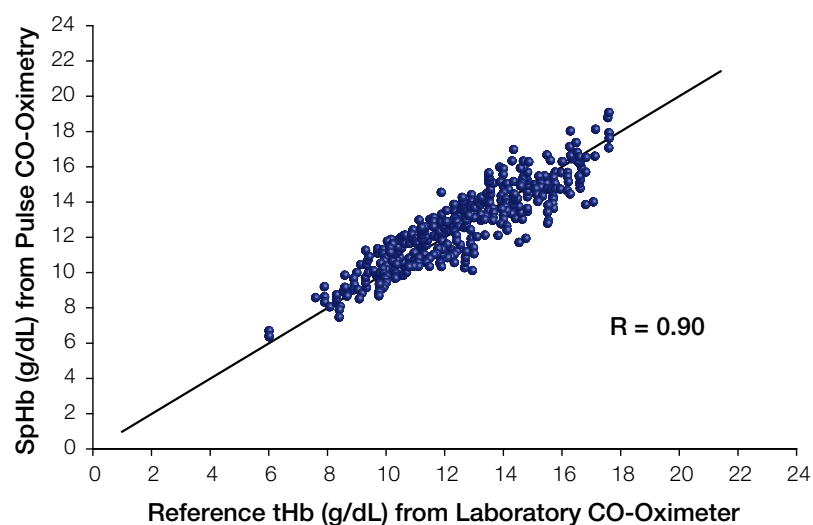


Figure 1 - Scatter plot of SpHb vs. tHb measurements (N=492)