

Study Evaluates Performance of Masimo SpHb® in Trauma Patients with Low Hemoglobin Levels



[Masimo](#) has announced the findings of a recently published study in which researchers at Cairo University in Egypt evaluated the performance of Masimo SpHb®, noninvasive, continuous hemoglobin measurement, in trauma patients with low hemoglobin levels.¹

In the prospective, observational study, Dr. Gamal and colleagues sought to evaluate SpHb measurements on trauma patients with low hemoglobin levels (below 8 g/dL) because trauma patients are “vulnerable to frequent blood transfusion.” They enrolled 70 adult patients with hemoglobin levels lower than 8 g/dL who were admitted to the emergency department (ED) of Cairo University Hospital and scheduled for surgical intervention. While in the ED, the patients' SpHb was continuously monitored using a Masimo Radical-7® Pulse CO-Oximeter®, with initial baseline measurement recorded as well as measurement after each unit of blood was administered. The researchers simultaneously obtained 2 mL venous blood samples, which were analyzed using a Coulter LH 750 Beckman analyzer (LabHb).

A total of 184 samples with corresponding SpHb values were collected for final analysis. The distribution of LabHb values was 20 (11%) below 6 g/dL, 97 (53%) between 6-7 g/dL, and 67 (36%) between 7-8 g/dL. The accuracy of SpHb in comparison to LabHb was assessed using Bland-Altman analysis. The level of agreement between SpHb and LabHb showed a bias of 0.12 g/dL and limits of agreement of -0.56 g/dL and 0.79 g/dL.

To determine the accuracy of SpHb as a trend measurement, the researchers also observed the change in hemoglobin (DeltaHb) before and after each unit of blood was transfused, for both methods. The level of agreement between DeltaSpHb and DeltaLabHb showed a bias of -0.05 g/dL and limits of agreement of -0.62 g/dL and 0.51 g/dL.

The researchers concluded that “SpHb showed accurate precision in both absolute values and trend values compared to LabHb measurement in trauma patients with low hemoglobin levels.” They also suggested several possible uses for SpHb, including as “a trend monitor that would alert the physician to any sudden bleeding mishaps,” and as a “good supplementary measure” to LabHb that can “save time and effort.”

The researchers acknowledged that this study is not sufficient to alone answer the question, “Can we transfuse blood relying solely on SpHb or not?” However, they noted that their findings add to the body of evidence in favor of SpHb and suggest the need for additional research regarding the role of Masimo technology in blood transfusion decisions.

SpHb monitoring is not intended to replace laboratory blood testing. Blood samples should be analyzed by laboratory instruments prior to clinical decision making.

The accuracy specification of SpHb is 1 g/dL ARMS* in the range of 8-17 g/dL. SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation against an invasive laboratory device. SpHb accuracy has not been validated in conditions of motion or low perfusion.

*ARMS accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within \pm ARMS of the reference measurements in a controlled study.

Reference

1. Gamal M, Abdelhamid B, Zakaria D, Abd El Dayem O, Ashraf R, Fawzy M, and Hasanin A. Evaluation of noninvasive hemoglobin monitoring in trauma patients with low hemoglobin levels. *Shock*. July 2017. DOI: 10.1097/SHK. 0000000000000949.

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