ICU MANAGEMENT & PRACTICE

New Study Assesses Utility of 1st Generation Masimo Pronto® Pulse CO-Oximeter® with SpHb® Spot

Masimo has announced that in a new study using the 1st Generation Masimo Pronto® Pulse CO-Oximeter®, which noninvasively measures total hemoglobin (SpHb®), researchers found that noninvasive and invasive measurements correlated well and that "[g]iven the rapid availability of results and the lack of requirement of venipuncture, noninvasive hemoglobin monitoring may be a valuable adjunct in the initial evaluation and monitoring of pediatric trauma patients."[1]

Pronto features rainbow SET™ technology, allowing for the noninvasive spot checking of SpHb, oxygen saturation (SpO2), pulse rate (PR), and perfusion index (PI).

In the study, published online in the *Journal of Trauma and Acute Care Surgery* and conducted at the University of Tennessee Health Science Center, Le Bonheur Children's Hospital, Dr. Mark Ryan and colleagues evaluated noninvasive SpHb measurement accuracy relative to current invasive and point-of-care testing in pediatric trauma patients. They performed a prospective observational trial involving 114 patients under age 17, measuring hemoglobin levels with a point-of-care device (i-STAT) and a lab analyzer (Sysmex XN Series). Noninvasive hemoglobin measurement, using 1st Generation Pronto, was performed within 15 minutes of phlebotomy.

Of the 114 patients, SpHb was successfully measured 89% of the time. Mean lab hemoglobin was 12.6 ± 1.9 and mean SpHb was 12.3 ± 1.6 (mean point-of-care hemoglobin was 12.2 ± 2.0). Bland-Altman analysis showed the limits of agreement between lab hemoglobin and non-invasive SpHb to be -2.9 and 1.9, with a mean difference of -0.49.

The researchers concluded that they were able to demonstrate "low bias and strong correlation between hemoglobin measurements using a noninvasive monitor, a point-of-care testing device, and laboratory co-oximeter in pediatric trauma patients." They noted that noninvasive SpHb testing "may be most effective in determining when invasive testing of hemoglobin is warranted."

Key limitations to the study include: the majority of the hemoglobin values measured were within normal limits; limited data on injury severity, morbidity, and mortality to understand their effects on device accuracy and precision; data is based on a convenience sample depending on availability of certified personnel; and no assessment on the effects of pre-hospital administration of intravenous fluids.

The researchers noted that "[f]urther study is required to determine the clinical utility of the [Pronto] device during the initial assessment and its accuracy in evaluating hemoglobin levels in hemodynamically unstable patients." They stated that SpHb measurements should not be relied upon alone to determine active hemorrhage or the need for transfusion, and suggested the following reasons a noninvasive measurement could not be taken in 11% of the study's participants: severe anemia; patients who were normotensive but tachycardic; patients unreadable due to the presence of nail polish; and cold extremities or low signal IQ without hemodynamic instability or anemia.

The University of Tennessee Health Science Center received equipment from Masimo to support the data collection for this study.

References

1. Ryan, Maxwell, Manning, Jacobs, Bachier-Rodriguez, Felizm, and Williams. "Noninvasive hemoglobin measurement in pediatric trauma patients." *Journal of Trauma and Acute Care Surgery*. DOI: 10.1097/TA.0000000000001160. E-published ahead of print.

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