

## Multicenter Study Evaluates Trend Accuracy of Three Hb Monitoring Methods, including Masimo SpHb



Masimo announced today that in a multicenter study recently published in the Journal of Clinical Monitoring and Computing, researchers at three institutions – Loma Linda University in California (LLU), the University of California at Irvine (UCI), and Mayo Clinic in Jacksonville, Florida (MCF) – evaluated the trend accuracy of three hemoglobin (Hb) monitoring methods, including noninvasive, continuous Masimo [SpHb®](#).<sup>1</sup>

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Dr. Applegate and colleagues prefaced their investigation by noting that Hb measurement “informs patient-specific perioperative transfusion decisions within the context of symptoms, comorbid conditions, surgical procedure, observed bleeding and hemodynamic performance.” They also noted, however, that “the time needed for blood sampling and analysis can cause Hb measurement to lag clinical situations. In surgical settings in which blood loss may not be apparent or be difficult to estimate, continuous rather than intermittent Hb monitoring could provide earlier warning of decreasing Hb.” Thus, they sought to determine whether noninvasive, continuous hemoglobin monitoring using Pulse CO-Oximetry (SpHb) might provide useful real-time information about changes in Hb.

The researchers compared noninvasive SpHb measurement and two invasive methods of determining intraoperative Hb changes – arterial blood gas CO-oximetry (ABGHb) and point-of-care hemoglobin using arterial blood (aHQHb) – to laboratory determined hemoglobin changes (tHb) for trend accuracy. SpHb was measured using Masimo [Radical-7® Pulse CO-Oximeters®](#) with [rainbow®](#) fingertip sensors at all sites. Based on the institution, ABGHb was measured using either a Radiometer ABL800, Nova Biomedical CCX or PhOX, or Siemens RAPIDLab 1265; aHQHb was measured with a HemoCue HB 301; and tHb was measured using either a Sysmex XE5000 or Coulter AcT-diff or LH 750, also depending on the institution.

The researchers independently enrolled 135 adult patients undergoing non-cardiac surgery in which arterial catheterization was planned and repeated intraoperative blood gas analysis was expected (51 at LLU, 26 at UCI, and 58 at MFC). During surgery, whenever arterial blood analysis was performed, SpHb (as displayed at the time blood was drawn) was recorded, and samples were analyzed within ten minutes using ABGHb, aHQHb, and tHb. On average, patients had 4 samples obtained (ranging from 2 to 13), with a total of 551 blood gas samples analyzed, providing 416 sequential changes in Hb for trend assessment.

Using modified Bland-Altman analysis, the researchers assessed trend accuracy for the three methods compared to laboratory analysis, calculating mean bias (95% limits of agreement) of 0.10 (-1.14 to 1.35) for SpHb, -0.02 (-1.06 to 1.02) for ABGHb, and 0.003 (-0.95 to 0.95) for aHQHb. Defining a change in SpHb, ABGHb, or aHQHb as  $\pm 0.5$  g/dL and a change in tHb as  $\pm 0.25$  g/dL, the researchers found that changes in direction agreed with tHb changes in direction as follows: in 94.2% (88.9 – 97.0%) of SpHb changes, in 98.9% (96.1 – 99.7%) of ABGHb changes, and in 99.0% (96.4 – 99.7%) of aHQHb changes.

The researchers concluded, “We found that SpHb, ABGHb and aHQHb changes more than  $\pm 0.5$  g/dL have similar correlation to the direction but not necessarily the magnitude of tHb change during surgery. The similar agreement in trend direction suggests that clinicians can choose which to use based on availability or preference, although continuous SpHb monitoring may provide useful ongoing Hb trend information. Continuous noninvasive SpHb decreases exceeding  $-0.5$  g/dL may prompt a decision to obtain a confirmatory tHb measurement if low tHb is clinically suspected, but not replace blood Hb measurement in guiding transfusion decision making.”

Comparing their results to two previous single-center studies involving changes in SpHb compared to changes in tHb,<sup>2-3</sup> the researchers noted that their multicenter study produced “similar” results in both cases: one study (of volunteers) found 95.4% SpHb change agreement in 22 samples with tHb  $< 10.0$  g/dL,<sup>2</sup> while the other study (of 70 trauma patients) reported bias of -0.05, with limits of agreement of -0.62 to 0.51.<sup>3</sup>

SpHb is not intended to replace laboratory blood testing. Clinical decisions regarding red blood cell transfusions should be based on the clinician’s judgment considering, among other factors, patient condition and laboratory diagnostic tests using blood samples.

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