Agreement of Noninvasive Hemoglobin Monitoring by Pulse CO-Oximetry (SpHb) with Invasive Laboratory Measurements

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Rationale
During surgery, anesthesiologists often need to deal with bleeding events when hemoglobin changes rapidly. A continuous, noninvasive method to measure hemoglobin noninvasively using spectrophotometry called Pulse CO-Oximetry (SpHb) is available. In this study, we compared absolute and trending agreement of SpHb and a Blood Gas Analyzer (BGA) with a hematology analyzer measurement reference (HbXE).

Materials and Methods
After approval by the local Ethics Committee, and informed consent, adult patients undergoing surgery with the possibility of major blood loss, were enrolled. All patients were monitored with Radical-7® Pulse CO-Oximeters (Revision K, Masimo SET 7.8.0.1, Portable R7.7.4.8, D-Station (DC) R5.1.4.0. Masimo Corp., Irvine, CA).

Arterial blood samples were collected 15 minutes after the incision, after each bleeding event (loss of at least 400 ml of blood in 40 minutes), and the end of the surgery and analyzed with a hematology analyzer (XE-2100, Sysmex Corporation, Kobe Japan) as reference method and a COBAS® B221 (Roche Diagnostics, Indianapolis, USA) BGA. Also, SpHb readings at the time of the arterial samples were noted.

Bias (error), precision (standard deviation) and Bland Altman limits of agreement for SpHb and BGA test methods measurements compared to the HbXE reference were calculated. The percentage of outliers (difference of ≥1 g.dL-1) was calculated. Wilcoxon test analysis was performed to determine significant differences between the test methods. To evaluate trending accuracy (sample to sample changes in the reference measurements compared to those of the test methods) sensitivity of each test method to detect correct directional trending was determined.

Results
In total, 138 blood samples (69 for HbXE and 69 for BGA analysis) and 69 simultaneous SpHb values were collected from 33 patients. The reference HbXE hemoglobin measures ranges from 7.8 to 15.4 g/dL. Performance analysis of the 2 test methods is shown in the table below. There was no statistically significant difference between 2 test methods (p=0.08) for absolute accuracy or for trending accuracy (p=0.6).

Discussion
Analysis of absolute accuracy showed a smaller bias but slightly larger standard deviation for SpHb than the Blood Gas analyzer when compared to the hematology analyzer reference. SpHb measurements had less outliers than BGA and similar sensitivity to follow the correct directional sample to sample trend as determined by the reference. Further studies to increase sample size will be required to confirm these results and show potential differences between the test methods.

References
<table>
<thead>
<tr>
<th></th>
<th>Bias (g/dL)</th>
<th>95% CI of Bias</th>
<th>Standard Deviation</th>
<th>Limits of Agreement</th>
<th>Outlier (%)</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>BGA</td>
<td>-1.4</td>
<td>-1.7 to -1.1</td>
<td>1.2</td>
<td>-3.7 to 0.9</td>
<td>40 (69%)</td>
<td>18/20 (90%)</td>
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<tr>
<td>SpHb</td>
<td>-0.8</td>
<td>-1.1 to -0.5</td>
<td>1.3</td>
<td>-3.4 to 1.8</td>
<td>25 (43%)</td>
<td>17/20 (85%)</td>
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