Minimally invasive monitoring in patients under general anesthesia

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Accuracy of non-invasive measurement of haemoglobin concentration by pulse co-oximetry during steady state and dynamic conditions in patients undergoing liver surgery

Modified from


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Abstract

Background. The Masimo Radical 7 (Masimo Corp, Irvine, USA) pulse co-oximeter® calculates total hemoglobin concentration (SpHb) non-invasively using transcutaneous spectrophotometry. We compared SpHb with invasive satellite-lab Hb monitoring (Hb$_{satlab}$) during major hepatic resections both under steady state conditions and in a dynamic phase with fluid administration of crystalloid and colloid solution.

Methods. Thirty patients undergoing major hepatic resection were included and randomized to receive a fluid bolus of 15 ml kg$^{-1}$ colloids (n=15) or crystalloids (n=15) in 30 minutes. SpHb was continuously measured on the index finger and venous blood samples were analyzed in both the steady state (from induction till completion of parenchymal transection) and in the dynamic phase (during fluid bolus).

Results. Correlation was significant between SpHb and Hb$_{satlab}$ ($R^2=0.50$, $n=543$). Modified Bland-Altman analysis for repeated measurements showed a bias ± precision of -0.27 ± 1.06 and -0.02 ± 1.07 g dL$^{-1}$ for the steady state and dynamic phase, respectively. SpHb accuracy increased when Hb$_{satlab}$ was < 10 g dL$^{-1}$, with a bias ± precision of 0.41 ± 0.47 versus -0.26 ± 1.12 g dL$^{-1}$ for values > 10 g dL$^{-1}$ but accuracy decreased after colloid administration ($R^2=0.25$).

Conclusions. SpHb correlated moderately with Hb$_{satlab}$, with a slight underestimation in both phases in patients undergoing major hepatic resection. Its accuracy increased for lower Hb$_{satlab}$ values but decreased in presence of colloid solution. Further improvements of the device are necessary to improve its accuracy under these conditions, so that SpHb might become a sensitive screening device for clinically significant anemia.
Introduction

Measurement of hemoglobin (Hb) concentration is one of the most important diagnostic parameters in patients undergoing major surgery and in patients admitted to the critical care unit. Hb monitoring by point-of-care satellite laboratory blood gas analysis (Hb_{satlab}) is considered the clinical standard and provides accurate measurement of Hb concentration. Unfortunately, Hb_{satlab} is relatively expensive, requires invasive blood sampling and is often time consuming, resulting in a “snap shot” impression of the changes in Hb concentration over time. Non-invasive, continuous real-time hemoglobin concentration monitoring would therefore be a major advantage. Recently, with the introduction of the Masimo Radical 7 device (Masimo Corp, Irvine, California, USA), Hb concentration can be monitored continuously in a non-invasive manner, i.e. transcutaneously. This device uses multi-wavelength analysis of hemoglobin absorption spectra to calculate total hemoglobin concentration (SpHb). The ability of SpHb monitoring to measure Hb concentration has been investigated in a few recent studies in patients undergoing surgery and in patients admitted to the critical care unit; however, the results about its accuracy are conflicting. These discrepancies could be explained by differences in the clinical situation in which SpHb monitoring was studied, e.g. stable steady state patients versus actively bleeding non-steady state patients. Also, SpHb monitoring might be influenced by differences in fluid administration or factors such as the presence of high concentrations of oxygen.

An adequate assessment of Hb concentration is important to avoid both unnecessary and redundant blood transfusion. We therefore prospectively monitored SpHb in patients undergoing major hepatic resection to further elucidate the exact factors influencing accuracy of SpHb monitoring. We studied the accuracy of SpHb monitoring under steady state conditions during the hepatic parenchymal transection phase with a continuous standardized fluid administration. In addition, we studied SpHb accuracy under dynamic conditions by administration of bolus fluid administration after completion of parenchymal transection. Patients were randomized to receive either crystalloids or colloids in this phase to investigate the influence of these solutions on SpHb accuracy.

Methods

This observational prospective randomized controlled trial (RCT) was approved by the local ethics committee (Ref: 2009/174, University Medical Centre Groningen, The Netherlands) and was registered at clinicaltrials.gov (NCT01060683). Inclusion of patients was performed using the CONSORT group statement (figure 1). All eligible ASA I-ASA III patients scheduled for major hepatic resection between June 2010 and May 2011 were approached and screened. Patients with an intra-operatively diagnosed irresectable tumor or patients who required extra intravenous fluids in order to maintain hemodynamic stability and thereby violating the study protocol (see further) were excluded. After signing written informed consent, all included patients were randomized shortly before the start of the dynamic phase (see below) by using opaque envelopes allocating patients to either the crystalloid or colloid group.
Assessed for eligibility (n=55)

- Not included (n=15):
  - Not meeting inclusion criteria (n=8)
  - Declined to participate (n=2)
  - Other reasons (n=5)

Included (n=40)

Intra-operative exclusion (n=10):
- Protocol violation (n=4)
- Tumor irresectability (n=6)

Randomised (n=30)

- Allocated to crystalloid group (n=15)
  - Analysed (n=15)
- Allocated to colloid group (n=15)
  - Analysed (n=15)

Figure 1: Consort flow diagram.

Anesthetic management:
A thoracic epidural catheter was inserted at the level of the 7th or 8th thoracic vertebra before induction of general anesthesia. Anesthesia was induced with propofol 2mg kg^-1 and sufentanil 0.3 μg kg^-1. Tracheal intubation was facilitated with rocuronium 0.6 mg kg^-1 and additional rocuronium administration was guided by neuromuscular monitoring during the procedure. Anesthesia was maintained with isoflurane, target bispectral index (Aspect Medical Systems, Norwood, USA) around 50 (range 40 – 60). Sufentanil was administered continuously 20 µg hr^-1 i.v. A central venous line (7F triple lumen) was inserted in the right internal jugular vein for continuous monitoring of central venous pressure (CVP), blood sampling and drug infusion. A radial artery was cannulated (20G catheter) for continuous monitoring of arterial blood pressure and blood gas analysis. If necessary, nor-adrenaline infusion was titrated to obtain a mean arterial pressure (MAP) above 60 mm Hg. Patients’ lungs were ventilated using volume controlled mechanical ventilation (tidal volume: 6-8 ml kg^-1) with a mixture of O₂/air (FiO₂ 0.30-0.35) and isoflurane. The respiratory rate was adjusted to maintain normocapnia.

Fluid administration:
Steady state phase: Was defined as the time period between induction of anesthesia and completion of hepatic parenchymal transection. During this phase, fluid administration was restricted to 6 ml kg^-1 hr^-1 crystalloid solution (NaCl 0.9%, Baxter, Deerfield, USA) to create a low central venous pressure in order to minimize blood loss.\(^9\)\(^{10}\)

Dynamic phase: Was defined as the time period between start of the standardized fluid bolus administration and 30 minutes thereafter. This phase started after hepatic parenchymal transection was completed and was aimed to restore intravascular volume. Patients were randomly assigned to receive a bolus of either 15 ml kg^-1 crystalloid (NaCl 0.9%) or 15 ml kg^-1 colloid (Voluven 6%, Fresenius, Bad Homburg, Germany) in 30 minutes.
Continuous non-invasive SpHb measurement:
SpHb was measured non-invasively and continuously using a Masimo Radical 7 device (Masimo Corp, Irvine, California, USA) running Masimo SET V7.6.0.1 using a finger sensor (R2-25, Rev E). The perfusion index (PI) – the ratio of pulsatile blood versus non-pulsatile blood – can influence SpHb accuracy and is additionally calculated by this device continuously.3
Before induction of anesthesia, the sensor was attached to the index finger, contralateral to the inserted arterial line and connected to the device according to the manufacturer’s instructions.

Invasive hemoglobin concentration measurement:
Hb_satlab was measured by the ABL 800 (Radiometer GmbH, Copenhagen, Denmark) point of care satellite-lab blood gas analyzer, which was located in an adjacent room next to the OR. The ABL 800 device measures hemoglobin concentration by spectrophotometric analysis and is well correlated to central laboratory Hb analysis and has a repeatability error below 2% with a test range between 2.5 and 23 g dL⁻¹. The device is cross-linked to the central laboratory and maintenance, calibration and quality control are performed on a daily basis. After induction of anesthesia but before incision, a baseline blood sample was drawn from the cannulated jugular vein for Hb_satlab analysis, and subsequently every 30 minutes during the steady state phase. In the dynamic phase, Hb_satlab was measured every 5 minutes. Blood samples were drawn into standard 2 ml heparinized collection syringes, after 2 ml blood was extracted and removed in separate collection syringes to ensure valid blood gas analysis. Blood samples were immediately analyzed after collection.

Data registration:
All continuous data, including SpHb, PI and inspired oxygen fraction (FiO₂) were recorded by a medical grade Windows XP based personal computer running RugLoop II software (Demed Engineering, Temse, Belgium).
Data were stored every second and data extraction was performed using Labgrab software (Demed Engineering, Temse, Belgium) and subsequently exported to Microsoft Excel 2010 (Microsoft, Redmond, Washington, USA).

Statistical analysis:
Statistical analysis was performed using Microsoft Excel 2010 and SPSS version 16.0 (SPSS Inc, Chicago, IL, USA). Continuous data were tested for normal distribution using the Kolmogorov – Smirnov test and were expressed as mean (SD) for normally distributed variables and as median (range) for non-normally distributed variables. Patient and surgical characteristics were tested using the Mann-Whitney test or Fisher’s Exact test, when appropriate.
The correlation between simultaneous Hb_satlab and SpHb measurement pairs was depicted in a scatter plot and coefficients of determination (R² values) were calculated which range from 0 to 1. To assess SpHb accuracy in time, consecutive R² values were calculated for all measured intervals in the steady state and dynamic phase.
SpHb accuracy was assessed using a modified Bland-Altman analysis corrected for multiple measurements for comparison of all SpHb and Hb_satlab values in the steady state and dynamic phase.11,12 The bias (mean absolute difference, calculated as SpHb – Hb_satlab) ± precision (1 SD of the bias) and limits of agreement (LOA, ±1.96 SD of the bias) were calculated and corrected for repeated measurements. For the measurement pairs at specific time points (baseline, start and end of dynamic phase), a conventional Bland-Altman analysis was performed.
Differences of SpHb and Hb$_{satlab}$ values (delta values) between consecutive time points were depicted in a scatterplot, aimed to assess whether a directional change of Hb$_{satlab}$ corresponds with a comparable directional change of SpHb. A threshold of 1.0 g dL$^{-1}$ for a delta value was used to compensate for intrinsic SpHb bias. Correlation analysis was performed to assess the influence of Hb$_{satlab}$ concentration, PI and FiO$_2$ on SpHb accuracy. All tests were two-sided and a P-value <0.05 was considered statistically significant.

**Results**

A total of 30 patients were randomized (figure 1). Except for patient height, there were no significant differences in patient characteristics between groups (table 1). More men were randomized to the colloid group and more women were randomized to the crystalloid group but this was not statistically significant.

In total, 543 simultaneous SpHb and Hb$_{satlab}$ data samples were obtained during the investigation. Mean SpHb was 11.5 (1.6) g dL$^{-1}$ (range 7.3 to 15.3 g dL$^{-1}$). Mean Hb$_{satlab}$ was 11.7 (1.6) g dL$^{-1}$ (range 7.4 to 15.3 g dL$^{-1}$). The $R^2$ value between all SpHb and Hb$_{satlab}$ data points was 0.50 (95% confidence interval (CI) 0.45 to 0.55), see figure 2. In the steady state phase (n=335) $R^2$ was 0.45 (CI 0.37 to 0.53) and was 0.42 (CI 0.31 to 0.52) in the dynamic phase (n=208).

<table>
<thead>
<tr>
<th>Patient and surgical characteristics</th>
<th>crystalloid</th>
<th>colloid</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>56 (19-76)</td>
<td>61 (47-72)</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>4/11</td>
<td>10/5</td>
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<tr>
<td>Height (cm)</td>
<td>173 (7)</td>
<td>178 (7)</td>
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<tr>
<td>Weight (kg)</td>
<td>76 (13)</td>
<td>84 (12)</td>
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<tr>
<td>BMI (kg m$^{-2}$)</td>
<td>25.7 (4.6)</td>
<td>26.4 (3.3)</td>
</tr>
<tr>
<td>Pre-operative Hb (g dL$^{-1}$)</td>
<td>13.2 (1.5)</td>
<td>14.0 (1.7)</td>
</tr>
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<td>ASA class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>II</td>
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<td>14</td>
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<tr>
<td>III</td>
<td>0</td>
<td>1</td>
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<td>Blood loss (ml)</td>
<td>433 (150-1500)</td>
<td>466 (50-1300)</td>
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<tr>
<td>Surgery duration (min)</td>
<td>409 (200-722)</td>
<td>440 (247-683)</td>
</tr>
<tr>
<td>Type of resection</td>
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<td></td>
</tr>
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<td>Hemi-hepatectomy</td>
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<tr>
<td>Segmental resection</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>

*Table 1. Values are reported as mean (SD), median (range) or absolute numbers. None of the patients received Red Blood Cell concentrate (RBC) or other blood products. *P<0.05, versus crystalloid group.*
Figure 2: Scatter plot with on the x-axis the Hb \textsubscript{satlab} and on the y-axis the SpHb values. Data are expressed in g dL\textsuperscript{-1} and are shown for data points in the steady state (black circles) and dynamic phase (grey circles).

Modified Bland-Altman analysis for repeated measurements was performed for all data points (not shown) and for the data points during the steady state and dynamic phase (figure 3A and 3B, respectively). The bias ± precision was -0.17 (CI -0.21 to -0.13) ± 1.0, -0.27 (CI -0.32 to -0.21) ± 1.06 and -0.02 (CI -0.09 to 0.05) ± 1.07 g dL\textsuperscript{-1} respectively with concomitant limits of agreement of -2.18 / 1.83, -2.39 / 1.86 and -2.16 / 2.12 g dL\textsuperscript{-1}.

Conventional Bland-Altman analysis for the measurements intervals at baseline and at the start and end of the dynamic phase, showed a bias ± precision of -0.55 (CI -0.75 to -0.35) ± 1.13, -0.47 (CI -0.21 to -0.72) ± 1.44 and 0.18 (CI 0.02 to 0.33) ± 0.89 g dL\textsuperscript{-1} respectively with limits of agreement of -2.81 / 1.70, -3.35 / 2.41 and -1.60 / 1.95 g dL\textsuperscript{-1} (data not shown).
Trend analysis of SpHb accuracy:

Consecutive directional hemoglobin concentration changes of more than 1.0 g dL\(^{-1}\) for both SpHb and Hb\(_{\text{satlab}}\) values were calculated and plotted (figure 4). Of these points (n=60), 72 % (n=43) comes from Hb\(_{\text{satlab}}\) values > 10 g dL\(^{-1}\) (black circles), whereas 28% (n=17) comes from Hb\(_{\text{satlab}}\) values < 10 g dL\(^{-1}\) (grey circles) while 66% of all measurement points came from a Hb\(_{\text{satlab}}\) value above 10 g dL\(^{-1}\) and 34% from a Hb\(_{\text{satlab}}\) value below 10 g dL\(^{-1}\). 

Figure 3 A and B: Corrected Bland-Altman plots for repeated measurements during the steady state phase (A) and during the dynamic phase (B).
Figure 4: Plot of directional changes (delta values) in SpHb (y-axis) and \( \text{Hb}_{\text{satlab}} \) (x-axis) values between consecutive measurement points in the steady state and dynamic phase. Black circles are directional changes for absolute \( \text{Hb}_{\text{satlab}} \) values > 10 g dL\(^{-1}\), grey circles for absolute \( \text{Hb}_{\text{satlab}} \) values < 10 g dL\(^{-1}\). Data points within the box are below the threshold delta value of 1.0 g dL\(^{-1}\).

Influence of dynamic phase and type of fluid on SpHb accuracy:
\( R^2 \) values ranged from 0.36 to 0.56 with a mean of 0.45 (CI 0.37 to 0.53) at the measurement intervals in the steady state phase (data not shown).

At the last measurement interval in the steady state phase, \( R^2 \) was 0.56 (CI 0.34 to 0.78) for all patients and 0.71 (CI 0.49 to 0.93) and 0.55 (CI 0.25 to 0.85) for those patients later allocated to receive crystalloids or colloids, respectively (figure 5). Repetitive \( R^2 \) values and corresponding \( \text{Hb}_{\text{satlab}} \) values at all measurement points in the dynamic phase are shown for the crystalloid and colloid group in figure 5.

At the start of the dynamic phase, \( \text{Hb}_{\text{satlab}} \) was significantly lower in the crystalloid group compared to the colloid group (11.4 (1.1) g dL\(^{-1}\) vs. 12.5 (1.4) g dL\(^{-1}\), p<0.05). The \( R^2 \) value dropped upon start of the dynamic phase from 0.72 (CI: 0.51 to 0.93) to 0.56 (CI: 0.27 to 0.85) for crystalloid patients (n=15) and from 0.41 (CI: 0.08 to 0.74) to 0.13 (CI: -0.14 to 0.41) for colloid patients (n=15). In the crystalloid group, \( R^2 \) gradually increased to 0.81 (CI: 0.66 to 0.96) at the end of the dynamic phase, whereas for colloid patients \( R^2 \) decreased to 0.11 (CI: -0.15 to 0.37) 15 minutes after start of the dynamic phase but eventually recovered to 0.45 (CI: 0.12 to 0.78) at the end of this phase. The \( R^2 \) values of all data points together in the dynamic phase for the crystalloid (n=104) and colloid (n=104) group are 0.72 (CI 0.63 to 0.81) and 0.25 (CI 0.11 to 0.39).
Figure 5: Course of $R^2$ values between corresponding SpHb and Hb_{satlab} values in the dynamic phase for patients receiving crystalloids (black solid line) or colloids (grey solid line). Also, the corresponding Hb_{satlab} values are shown for both groups (dashed lines).

Other influencing factors on SpHb accuracy:
Correlation was significant between the bias (SpHb - Hb_{satlab}) and the Hb_{satlab} concentration ($P < 0.001$) and corresponded with an $R^2$ value of 0.14.
For Hb_{satlab} values below 10 g dL$^{-1}$, corrected Bland-Altman analysis showed a mean bias ± precision of 0.41 ± 0.47 g dL$^{-1}$ with limits of agreement between -0.55 and 1.36 g dL$^{-1}$.
For Hb_{satlab} values above 10 g dL$^{-1}$, a mean bias ± precision was found of -0.26 ± 1.12 g dL$^{-1}$ with wider limits of agreement: -2.50 to 1.84 g dL$^{-1}$.
The bias between SpHb and Hb_{satlab} correlated significantly with the Perfusion Index ($P < 0.001$ with a corresponding $R^2$ value of 0.14), which was not true for the FiO$_2$ (corresponding $R^2 = 0.01$).

Discussion
In this randomized prospective study we evaluated the accuracy of transcutaneous SpHb measurement by the Masimo Radical 7 monitor during both a steady state and dynamic phase in patients undergoing major hepatic resection. We found the SpHb to be moderately correlated with Hb_{satlab} in both phases. The overall correlation between SpHb and Hb_{satlab} remained stable in the dynamic phase although a much lower SpHb accuracy was observed after bolus administration of colloid solution. In addition, we found a superior accuracy of SpHb for Hb_{satlab} values below 10 g dL$^{-1}$.

In the steady state phase between induction of anesthesia and completion of hepatic parenchymal transection, SpHb accuracy was relatively stable while fluid was administered in a continuous matter with 6 ml kg$^{-1}$ hr$^{-1}$ NaCl 0.9%. In general, SpHb accuracy was also relatively stable in the dynamic phase with repetitive $R^2$ values ranging from 0.28 to 0.56 in the dynamic phase when patients receiving crystalloid and colloids are analyzed together.
Bias, precision and limits of agreement were generally comparable in the two phases and showed SpHb to slightly underestimate Hb_{satlab}.

The accuracy of the SpHb measurement has been previously assessed under several clinical circumstances, including patients undergoing surgery.\textsuperscript{2-6, 14, 15} One study in a various population of surgical patients (n=44) found a mean SpHb bias of -0.02 with a precision of 1.39g dL$^{-1}$, limits of agreement of -2.75 / 2.70 g dL$^{-1}$ and a R of 0.77, compared to laboratory Hb measurements.\textsuperscript{6} In another study comparing SpHb with laboratory Hb measurements, a mean bias of 0.26 g dL$^{-1}$ was found
with corresponding limits of agreement of -3.24 and 3.77 g dL\(^{-1}\) in patients undergoing spine surgery (n=20).\(^2\)

Our results are in accordance with these studies, as we found an overall \(R^2\) of 0.50 and a mean bias ± precision of -0.17 ± 1.0 g dL\(^{-1}\) for all data points, but the limits of agreement we found were generally more narrow.\(^3\)\(^-\)\(^6\)\(^,\)\(^14\)

An important finding in this study is the dependency of SpHb accuracy on the level of hemoglobin concentration: For Hb\(_{\text{satlab}}\) values below 10 g dL\(^{-1}\), SpHb accuracy improved dramatically with more precision and narrow limits of agreement compared to values above 10 g dL\(^{-1}\). Interestingly, SpHb tended to overestimate Hb\(_{\text{satlab}}\) in the lower range while it tended to underestimate SpHb in the higher Hb\(_{\text{satlab}}\) range. In a previous study investigating SpHb accuracy in healthy volunteers (n=20) undergoing haemodilution by infusion of crystalloid infusion, a weaker relationship was found between SpHb accuracy and the level of Hb concentration.\(^15\) The dependency we observed of SpHb accuracy on the actual Hb concentration is of major clinical importance because, since a valid decision on whether or not blood transfusion should be administered requires an accurate SpHb measurement in lower Hb concentration ranges.

Patients receiving colloids showed a decrease in SpHb correlation which remained throughout the dynamic phase, although it seemed to be recovering at the end of the dynamic phase. There were more women than men randomized in the in the crystalloid group whereas in the colloid group the converse was true. The observed imbalance was not statistically significant so the selection procedure appears unbiased. Men and women did not have different pre-operative Hb concentrations (14.1 (1.4) g dL\(^{-1}\) vs. 13.2 (1.8) g dL\(^{-1}\), respectively for men vs. women; \(p=0.24\)) but at the start of the dynamic phase a small difference was observed (12.5 (1.0) g dL\(^{-1}\) vs. 11.5 (1.5) g dL\(^{-1}\), respectively for men vs. women; \(p = 0.047\)). The slightly higher Hb concentration in men (about 1.0 g dL\(^{-1}\)) combined with the greater number of men in the colloid group could explain the higher Hb concentrations observed in this group compared to the crystalloid group. This imbalance could also to some extent underlie the decreased accuracy of SpHb in patients receiving colloids since we found SpHb is less accurate for the higher Hb\(_{\text{satlab}}\) values. We did not stratify for sampling between men and women (ensuring equal numbers in each group) but this would probably have, in retrospect, made the results easier to interpret.

The difference between \(R^2\) values for the crystalloid and colloid groups in the dynamic phase suggests that colloid solution influences non-invasive spectrophotometric analysis of total hemoglobin concentration. We speculate that accuracy is decreased immediately after colloid administration; however the temporal resolution of the current study is insufficient to demonstrate this conclusively. There are some reports about the influence of colloid solution on in-vitro hemoglobin measurement, but we found no reports in literature about possible effects of colloid solution on the accuracy of in-vivo, transcutaneous spectrophotometry.\(^16\)\(^,\)\(^17\)

Our data suggest that the accuracy of SpHb is decreased after rapid colloid administration. Colloids are often administered for achieving volume expansion, especially during massive and rapid blood loss. The measured Hb is important for the decision to administer red blood cells. Therefore, the accuracy of the SpHb measurement while rapidly administering colloid solution requires further elucidation to avoid unnecessary blood transfusion or, on the other hand, to withhold necessary blood transfusion as both situations are potentially harmful to the patient.

In addition, we found the accuracy of SpHb to be slightly influenced by the local index of perfusion (PI) of the finger bearing the measurement probe with an overall \(R^2\) of the absolute bias and PI
of 0.14. This finding is not surprising as a diminished tissue perfusion is expected to disrupt spectrophotometric SpHb measurement as reported before.\textsuperscript{2, 3}

A recent pilot-study found that SpHb values changed significantly during pre-oxygenation with a high FiO\textsubscript{2}, suggesting SpHb accuracy to be influenced by the presence of high concentrations of oxygen.\textsuperscript{8} However in our study patients were ventilated with a constant FiO\textsubscript{2} between 0.30 and 0.35 and we can therefore not speculate on the influence of FiO\textsubscript{2} on SpHb in our patients.

According to the manufacturer, SpHb measurement should be accurate within 1.0 g dL\textsuperscript{-1}.\textsuperscript{13} If this threshold for accuracy is applied to our data, 61% of all data points and 58% and 66% of the data points obtained during the static and dynamic phase respectively are within this cut-off value. Also, for the steady state and dynamic data points in our study, precision was slightly above 1.0 g dL\textsuperscript{-1} and thus slightly above this accuracy limit.

Study limitations:
At first, there are multiple technologies and devices available to measure hemoglobin concentration by blood sample analysis. Every device that measures hemoglobin concentration has an intrinsic variability and between devices there is intra-device variability.\textsuperscript{18} Therefore, no gold standard exists for determination of hemoglobin concentration. In this study, SpHb measurements were correlated with Hb measurements by point-of-care satellite laboratory (Hb\textsubscript{satlab}) analysis using the ABL 800. Hb\textsubscript{satlab} blood gas measurement was used because Hb\textsubscript{satlab} measurement is regarded the clinical standard in the operating theatre in our hospital and in many other Western European hospitals to decide if blood transfusion is required. In addition, the satellite laboratory device we used has a very small bias compared to central laboratory analysis, repeatability error below 2% and is superior compared to two other frequently used satellite laboratory devices.\textsuperscript{1} Also, the baseline Hb\textsubscript{satlab} value of the studied patients was highly correlated with the pre-operative Hb concentration as measured by the central laboratory Sysmex XE-2100 (Sysmex, Kobe, Japan) analyzer of our hospital (R\textsuperscript{2} = 0.90).

Nevertheless, one must take into account the inter- and intra-device variation in hemoglobin measurement devices especially when repeated measurement analyses are performed.\textsuperscript{19}

At second, the lowest observed Hb\textsubscript{satlab} value was 7.4 g dL\textsuperscript{-1} and the lowest observed SpHb value was 7.3 g dL\textsuperscript{-1}. Although we observed an increased SpHb accuracy for Hb\textsubscript{satlab} values below 10 g dL\textsuperscript{-1}, we cannot speculate about SpHb accuracy in a Hb range lower than we have observed in our patient population. Further studies should elucidate the exact SpHb accuracy in patients with a low Hb concentration.

At third, spectrophotometric analysis can be influenced by the concentration of serum bilirubin.\textsuperscript{20} However, none of our patients had a pre-operative increase in serum bilirubin and the mean (SD) serum bilirubin was 8 (3) µmol L\textsuperscript{-1}.

In conclusion, in patients undergoing major hepatic resection, non-invasive SpHb measurement by a Masimo Radical 7 pulse co-oximeter correlated moderately with Hb\textsubscript{satlab} and it showed an increased accuracy for lower Hb concentration levels. On the other hand, rapid colloid administration might decrease the accuracy of SpHb monitoring. Further technical improvements of the sensor and software of the device are necessary to improve accuracy of SpHb spectroscopy in order to be less influenced by the Hb concentration and possibly by the use of colloid solutions. Non-invasive SpHb monitoring might become a sensitive screening device for clinically significant anemia.
References


