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Original

Accuracy and Clinical Utility of Spot-Check Noninvasive Hemoglobin Monitoring: A Preliminary Study

Ichiro Kamiya[1], Chol Kim[1], Makiko Yamamoto[3], Yuki Genda[2,3], Hiroshi Mase[2,3] and Masashi Ishikawa[3]

[1]Department of Anesthesiology, Nippon Medical School Chiba Hokusoh Hospital, Chiba, Japan
[2]Department of Surgical Intensive Care, Nippon Medical School Hospital, Tokyo, Japan
[3]Department of Anesthesiology and Pain Medicine, Graduate School of Medicine, Nippon Medical School, Tokyo, Japan

Introduction: Hemoglobin (Hb) monitoring is essential for perioperative management, particularly for detecting anemia and guiding transfusion decisions. Conventional invasive methods provide accurate results but are limited by delays, intermittent sampling, and iatrogenic blood loss. Noninvasive spot-check Hb (SpHb) monitoring offers rapid assessment, but its accuracy is unclear. This study thus evaluated agreement between SpHb obtained with the Rad-67 and invasive Hb measurements in anesthetized patients.
Methods: This single-center, prospective, observational study enrolled 25 adults who underwent gastrointestinal surgery under general anesthesia between June 2023 and March 2024. After induction and stabilization, SpHb was recorded simultaneously with arterial blood sampling. Reference Hb was measured with an automated hematology analyzer (XN-9100), an arterial blood gas analyzer (LC-661), and a portable spectrophotometric device (HemoCue). Correlation was assessed by Pearson's coefficient, and agreement by Bland−Altman analysis.
Results: The cohort comprised 18 men (72.0%) with a mean (±SD) age of 66.8 ± 13.4 years and body mass index of 22.9 ± 3.2 kg/m^2. Mean Hb was 12.6 ± 1.7 g/dL (SpHb), 11.1 ± 1.8 g/dL (XN-9100), 11.4 ± 1.8 g/dL (LC-661), and 11.4 ± 1.8 g/dL (HemoCue). Strong correlations were observed (r = 0.931, 0.930, 0.841; $p < 0.001$ for all). Bland−Altman analysis showed fixed positive biases of +1.47 g/dL (XN-9100) and +1.19 g/dL (LC-661, HemoCue), without proportional error.
Conclusions: SpHb correlated strongly with invasive Hb but consistently overestimated values by 1−1.5 g/dL. While unsuitable as a direct substitute, SpHb may serve as a bias-aware screening tool that reduces unnecessary phlebotomy.
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Keywords: noninvasive hemoglobin monitoring, pulse CO-oximetry, perioperative blood management, preoperative screening

Introduction

Hemoglobin (Hb) monitoring is a critical component of perioperative patient management and is essential for diagnosing anemia, detecting active bleeding, and guiding red blood cell (RBC) transfusions[1−3]. Preoperative anemia is a determinant of increased perioperative morbidity and mortality[4,5], which underscores the importance of its timely detection and treatment before surgery[6]. Moreover, perioperative hemorrhage is a significant complication that often leads to rapid changes in Hb concentration

Correspondence to Masashi Ishikawa, masashi-i@nms.ac.jp
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and increased morbidity and mortality if not promptly addressed[2]. Traditional methods of Hb assessment, including central laboratory analyzers and various point-of-care devices, rely on invasive blood sampling[7]. These techniques provide valuable information but are intermittent, time-consuming, and subject to delays in the availability of results. These limitations can hinder timely decision-making during dynamic surgical events and may contribute to iatrogenic anemia from repeated blood sampling.

One promising alternative is noninvasive, continuous hemoglobin (SpHb) monitoring using technologies such as pulse CO-oximetry[7–9]. This technology provides real-time Hb estimations, either spot or continuous, potentially facilitating more timely clinical interventions and improving blood management. The Rad-67 (Masimo Corp., Irvine, CA, USA) is a portable, spot-check pulse CO-oximeter capable of measuring SpHb as needed, from the preoperative outpatient setting to intraoperative use. However, recent trials have suggested that although noninvasive Hb monitoring may help maintain Hb within target ranges and reduce unnecessary transfusions, device-specific accuracy is unclear[2,7,10]. As an essential first step in evaluating its applicability for perioperative use, this study compared SpHb values with those measured by established invasive Hb methods in stable surgical patients after anesthesia induction.

Materials and Methods

Study Design and Patient Selection

This single-center, prospective, observational study enrolled adults who underwent gastrointestinal surgery under general anesthesia at Nippon Medical School Hospital between June 2023 and March 2024. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by the Ethics Committee of Nippon Medical School (Tokyo, Japan; approval no. B-2023-662)[11]. Written informed consent was obtained from all patients before enrollment.

The analysis included all adult patients in stable condition after anesthesia induction who required arterial blood sampling as part of routine intraoperative care. Exclusion criteria included severe peripheral circulatory failure, hematological disorders, coagulopathy, finger deformities or skin conditions interfering with SpHb measurement, and any other condition deemed unsuitable for participation by the principal investigator.

Data Collection

Patient demographic information (age, sex, body mass index [BMI]) was recorded. At least 15 minutes following anesthesia induction, after circulatory and respiratory status had stabilized, arterial blood sampling was performed concurrently with SpHb measurement. Blood was collected from an indwelling arterial catheter, with 3 mL drawn into a heparinized blood gas syringe or an EDTA-containing vacuum tube. The SpHb value and perfusion index displayed by the Rad-67 (Masimo Corp.) at the time of blood sampling were recorded. Collected blood samples were properly mixed and immediately sent to the central or satellite laboratory for analysis. For comparative invasive hemoglobin measurements, arterial blood samples were analyzed in the central laboratory of the hospital using the Sysmex XN-9100 automated hematology analyzer (Sysmex Corp., Hyogo, Japan) and the LC-661 blood gas analysis system (Fukuda Denshi Corp., Tokyo, Japan), as well as with the HemoCue portable hemoglobin measuring device (AMCO Corp., Tokyo, Japan) in the operating room.

Statistical Analysis

Data are presented as means and standard deviations (SDs). Categorical data are expressed as numbers and percentages. The correlation and agreement between noninvasive SpHb measurements and the invasive Hb measurement methods were evaluated. Pearson's correlation coefficient was used to assess the direction and strength of the linear relationship between SpHb values and those obtained from invasive Hb measurements. Bland−Altman analysis was used to evaluate agreement between measurement methods and to determine the mean bias and precision. Mean bias was defined as the average difference between SpHb and the reference method, and precision was defined as the SD of this bias. Statistical analyses were performed using GraphPad Prism version 8.4.3 (GraphPad Software, San Diego, CA, USA). A P value of <0.05 was considered to indicate statistical significance. Because this study was a preliminary method-comparison investigation, the sample size was not determined by a priori power calculation but instead considered feasibility and previous reports[12].

Results

A total of 25 patients undergoing surgery were enrolled in this prospective observational study. Baseline demographic and physiological characteristics are summarized as follows: 18 patients (72.0%) were male, mean age was

Table 1 Patient characteristics

Variables	
Age, years	66.8 ± 13.4
Male, n (%)	18 (72.0%)
BMI, kg/m^2	22.9 ± 3.2
SpO_2, %	98.6 ± 1.4
Perfusion index	6.9 ± 3.9

Table 2 SpHb and invasive hemoglobin measurement

	Hemoglobin concentration (g/dL)
SpHb	12.6 ± 1.7
XN-9100	11.1 ± 1.8
LC-661	11.4 ± 1.8
HemoCue	11.4 ± 1.8

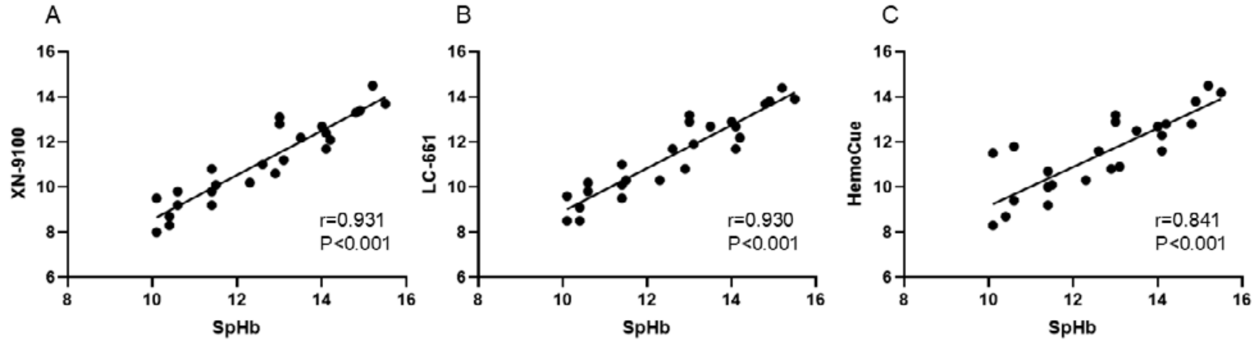

Figure 1 Pearson correlation between SpHb (Rad-67) and invasive hemoglobin measurements
The scatterplots show Pearson correlation between noninvasive hemoglobin monitoring and invasive hemoglobin measurements. Each dot is an individual measurement. The solid lines indicate the linear regression fit, with the correlation coefficient (r) and p-value shown in the panel. A) Rad-67 vs XN-9,100; B) Rad-67 vs LC-661; C) Rad-67 vs HemoCue.

66.8 ± 13.4 years, and BMI was 22.9 ± 3.2 kg/m^2. Mean peripheral oxygen saturation was 98.6 ± 1.4%, mean pulse rate was 65.6 ± 13.6 beats/min, and mean perfusion index was 6.9 ± 3.9, indicating a hemodynamically stable and well-perfused population during anesthetic induction (**Table 1**).

Mean Hb concentration was 12.6 ± 1.7 g/dL for noninvasive SpHb according to the Rad-67 monitor, 11.1 ± 1.8 g/dL for the automated hematology analyzer (XN-9100), 11.4 ± 1.8 g/dL for the arterial blood gas analyzer (LC-661), and 11.4 ± 1.8 g/dL for the portable spectrophotometric device (HemoCue) (**Table 2**). Across the cohort, SpHb consistently yielded higher values than the invasive tests.

Correlation analyses revealed strong linear relationships between SpHb and reference Hb values, namely, r = 0.931 ($p < 0.001$) versus XN-9100, r = 0.930 ($p < 0.001$) versus LC-661, and r = 0.841 ($p < 0.001$) versus HemoCue (**Figure 1**). Bland–Altman analysis was used to characterize method-specific biases. As compared with XN-9100, SpHb exhibited a fixed positive bias of +1.47 g/dL, without evidence of proportional error across the hemoglobin range. Similar findings were observed in comparisons with LC-661 and HemoCue: the bias was +1.19 g/dL in both comparisons (**Figure 2**). The absence of proportional error across all comparisons suggests that the observed discrepancies are a fixed systematic bias rather than variability dependent on anemia severity or absolute Hb concentration.

Discussion

In this prospective evaluation of perioperative Rad-67, a spot-check, noninvasive Hb monitor, SpHb showed strong linear agreement with all comparator methods, including central laboratory hematology (XN-9100), arterial blood gas analysis (LC-661), and a portable photometric device (HemoCue). Bland–Altman analyses showed a fixed bias of +1.47 g/dL versus XN-9100 and +1.19 g/dL versus both LC-661 and HemoCue, without evidence of proportional error across the observed hemoglobin range. These results suggest that while SpHb reliably reflects hemoglobin values, absolute values are systematically higher than reference values by approximately 1–1.5 g/dL. SpHb correlated closely with laboratory Hb but consistently demonstrated a positive bias, suggesting that the values provided are more appropriate for screening than as a direct substitute for invasive measurement. Consequently, unnecessary phlebotomy could be avoided when SpHb values are well above clinically relevant decision thresholds. Because the bias appears independent

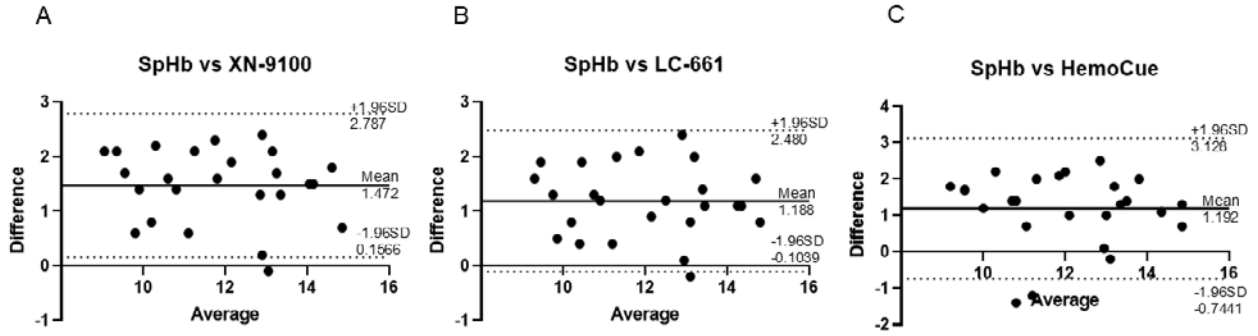

Figure 2 Bland–Altman plot comparing SpHb (Rad-67) with invasive hemoglobin measurements
The Bland–Altman plots show agreement between SpHb (Rad-67) and invasive hemoglobin measurements. The solid lines represent mean bias, while dashed lines indicate the 95% LOA (mean bias ±1.96 SD). Each dot corresponds to a paired measurement. A) Rad-67 vs XN-9,100; B) Rad-67 vs LC-661; C) Rad-67 vs HemoCue.

of Hb level, pragmatic implementation could incorporate a calibrated offset or an adjusted anemia threshold that accounts for the observed fixed error within a given clinical environment and device configuration. Notably, measurements were obtained under stable anesthetic conditions with adequate peripheral perfusion, supporting the interpretation that the observed bias is methodological rather than perfusion-related. This suggests that SpHb may be useful not only perioperatively but also during outpatient visits and routine health examinations.

Although CO-oximeters are generally regarded as highly reliable for assessing Hb levels, numerous studies have reported considerable variability and inherent measurement error between different devices and within the same device type[13]. This inherent imprecision requires cautious interpretation of absolute SpHb values in clinical settings. For instance, studies comparing various CO-oximeters and point-of-care devices with a laboratory reference have reported heterogeneous findings regarding accuracy and precision. In a direct comparison, Lamhaut et al.[8] reported that SpHb yielded lower readings, significantly poorer precision, and a higher proportion of outliers than the HemoCue device (46% vs. 16%), when both were evaluated against automated laboratory Hb measurements in surgical patients. Similarly, Frasca et al.[14] observed varying biases and limits of agreement (LOA) across different invasive and noninvasive methods, as compared with laboratory Hb. The reported biases and LOA across studies further underscore this variability. A meta-analysis reported a pooled random-effects mean difference of 0.10 ± 1.37 g/dL (95% LOA: −2.59 to 2.80 g/dL), with substantial heterogeneity across studies (I^2 = 95.9% for mean difference and 95.0% for SD)[15]. The accuracy of SpHb should thus be evaluated against invasive Hb measurement for each device and version. In this study, no proportional error was observed across the Hb range, although values were consistently higher than the reference by approximately 1–1.5 g/dL. These findings indicate that adjusting the anemia cutoff by 1–1.5 g/dL allows the Rad-67 to be used as a screening tool, although not as an absolute diagnostic measure, suggesting potential clinical utility as a screening adjunct.

Preoperative anemia is highly prevalent, affecting approximately 30–35% of surgical patients globally[5,16,17]. It is widely recognized as a significant independent risk factor for adverse outcomes, including increased 30-day morbidity and mortality[5,16,17], prolonged length of hospital stay[18], and higher rates of postoperative complications such as infection, acute kidney injury, sepsis, and venous thromboembolism[19]. Further, preoperative anemia is the strongest predictor of perioperative RBC transfusion, which itself carries independent risks for adverse outcomes[20]. Addressing this substantial risk necessitates systematic implementation of patient blood management programs, which emphasize early detection and investigation of the causes of preoperative anemia[21]. Hb determination should be performed no later than 28 days before elective surgery, to ensure adequate time for diagnostic evaluation and therapeutic correction of preoperative anemia[22]. Iron deficiency is the most common underlying cause of preoperative anemia worldwide[23]. Targeted preoperative treatment, often involving iron supplementation, successfully increases Hb concentration, reduces perioperative transfusion requirements[16], and can yield downstream financial benefits by decreasing the length of stay and reducing the costs of managing complications[24]. Preoperative screening and treatment of anemia aimed at optimizing hematological status are therefore essential for enhancing patient safety and reducing the overall healthcare burden. In this context, noninvasive Hb assessment using SpHb, which enables repeated measurements without blood sampling, may be particularly valuable in perioperative practice.

This study has several limitations. First, it was a single-center, prospective, non-interventional evaluation of a small cohort of patients who underwent surgery under general anesthesia, which limits statistical precision and external validity. In addition, the required sample size was not determined by a priori power analysis, and inter-operator variability in sensor placement may have influenced measurement consistency. Second, eligibility required the presence of an arterial line and adequate peripheral signal quality, and patients with poor perfusion or nail abnormalities were excluded, resulting in a cohort with relatively stable physiology, thus potentially overestimating performance under more challenging clinical conditions. Third, measurements were obtained at a single time point after induction following a 15-minute rest, without repeated sampling across dynamic states (e.g., hypotension, hypothermia, vasopressor use) or over time. As a result, trending performance and responsiveness to acute perioperative changes could not be assessed. Finally, the study did not evaluate decision thresholds or clinical outcomes (e.g., transfusion), so the impact of adopting adjusted cutoffs remains inferential.

Conclusion

SpHb obtained using the Rad-67 strongly correlated with invasive hemoglobin measurements but consistently overestimated actual Hb values by approximately 1–1.5 g/dL. Therefore, SpHb should be interpreted as a screening tool rather than as a direct alternative to laboratory testing. The main benefit of SpHb is that it enables rapid, noninvasive assessment without blood sampling. Its primary limitation is fixed positive bias that might affect clinical decision-making if unadjusted. To validate optimal bias-corrected thresholds for perioperative use, larger studies are warranted.

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