Accuracy of Continuous and Noninvasive Hemoglobin Monitoring in the Presence of CO_2 Insufflation: An Observational Pilot Study

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Laparoscopic surgery has several benefits, but it requires prolonged carbon dioxide (CO_2) insufflation. Several factors affect the accuracy of continuous and noninvasive hemoglobin (SpHb) monitoring, but the effects of CO_2 insufflation are undetermined. This study investigated the effect of CO_2 insufflation on SpHb monitoring in laparoscopic surgery.

Material/Methods: Twenty patients undergoing laparoscopic gastrectomy were enrolled. Anesthesia was maintained using sevoflurane and remifentanil within an end-tidal CO_2 of 30-45 mmHg. The CO_2 insufflation was maintained at 12 mmHg using CO_2. SpHb was monitored with a Radical-7 Pulse CO-Oximeter, and laboratory hemoglobin (tHb) was analyzed using a satellite blood analyzer.

Results: Forty paired measurements were analyzed. The mean perfusion index, SpHb, and tHb were 3.10±1.77%, 10.92±1.48 g/dL, and 11.51±0.88 g/dL, respectively. SpHb underestimated tHb with a bias (precision) of -0.59 (1.28 g/dL), and the 95% limit of agreement was wide (-3.11 to 1.92 g/dL). SpHb was moderately correlated with tHb ($r=0.50$, 95% CI: 0.23 to 0.70). The concordance rate was 67%. ΔSpHb was not correlated with ΔtHb ($r=0.29$, 95% CI: -0.18 to -0.65). A similar bias, wider limits of agreement, a higher |SpHb-tHb|, but more significant correlation between SpHb and tHb were observed for the "$PaCO_2$ <40 mmHg" range compared with the "40 mmHg ≤$PaCO_2$" range.

Conclusions: SpHb may have an acceptable accuracy but has a weak trending ability in the presence of CO_2 insufflation, and it can be affected by $PaCO_2$. Further research on the effects of CO_2 insufflation on SpHb is needed.

Keywords: Hemoglobins • Laparoscopy • Monitoring, Intraoperative • Pneumoperitoneum

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Background

Minimally invasive surgeries, such as laparoscopic and robotic surgeries, have become increasingly common due to their advantages, including less intraoperative bleeding, faster recovery, shorter hospitalization, and improved quality of life compared to open surgery [1]. However, it requires prolonged carbon dioxide (CO$_2$) insufflation, which causes physiologic changes related to hypercarbia and respiratory acidosis [2].

Continuous and noninvasive hemoglobin (SpHb) monitoring using a Radical-7 Pulse CO-Oximeter displays the blood hemoglobin (Hb) concentrations on a monitor using a spectrophotometric Hb sensor. SpHb monitoring is based on the measurement of the differential optical density of light at multiple wavelengths that pass through the tissue. SpHb allows clinicians to rapidly detect occult bleeding and effectively perform transfusion without blood loss due to repeated blood draws [3]. Its usefulness perioperatively [3] and in traumatized patients with low Hb levels has been documented [4]. A meta-analysis reported an acceptable accuracy of SpHb based on 28 studies conducted only in the operating room [5]; subgroup analysis was performed for age, continent, method (venous or arterial), funding, and measurements (single or multiple), but no subgroup was based on CO$_2$ insufflation.

In a previous study, the altered arterial CO$_2$ pressure (PaCO$_2$) levels reduced the agreement between arterial oxygen saturation measured by pulse oximetry and arterial oxygen pressure (PaO$_2$) as calculated from arterial blood gas co-oximetry [6]. Moreover, increased end-tidal CO$_2$ tension (EtCO$_2$) enhances regional cerebral oxygen saturation in obese patients during laparoscopic surgery [7]. Although there have been no experimental studies regarding the effect of PaCO$_2$ on oximetry, an increased carbaminohemoglobin level and changes in red blood cell morphology was proposed as a mechanism [6].

SpHb is affected by several factors, such as laboratory hemoglobin concentration (tHb), perfusion index (PI), hemodilution during fluid loading, dark skin, and indigo carmine [8-12]; however, it has not yet been determined whether the elevated PaCO$_2$ in the presence of CO$_2$ insufflation affects the agreement between SpHb and invasive tHb. Therefore, this observational pilot study aimed to investigate the accuracy of SpHb in the presence of CO$_2$ insufflation in patients undergoing laparoscopic surgery.

Material and Methods

Patient Recruitment

This prospective observational pilot study involved patients undergoing laparoscopic gastrectomy between November 2017 and December 2017 at Ajou Hospital, Suwon, Republic of Korea. The study protocol was approved by the Ajou University Hospital Institutional Review Board (IRB number: AJIRB-MED-OBS-17-216) and registered with ClinicalTrials.gov (identified: NCT 03957460). Written informed consent was obtained from all the participating patients. A total of 31 patients aged 19-85 years who underwent elective laparoscopic gastrectomy under general anesthesia were enrolled. The exclusion criteria were the presence of psychiatric problems, cardiorespiratory dysfunction, renal failure, chronic use of opioids, hyperbilirubinemia, anemia, hemoglobinopathy, infection, peripheral neuropathy, or possible intraoperative conversion to open surgery.

Anesthesia

On arrival in the operating room, standard monitoring including pulse oximetry, electrocardiography, bispectral index, and noninvasive blood pressure measurements were performed. General anesthesia was induced with intravenous propofol (2.0 mg/kg) and remifentanil (3.0-4.0 ng/mL as target concentrations) using target-controlled infusion. Rocuronium bromide (1 mg/kg) was used to facilitate orotracheal intubation. A 20-G radial arterial catheter was inserted for continuous monitoring of hemodynamics and blood sampling. Mechanical ventilation was used to maintain EtCO$_2$ between 30 and 45 mmHg with 50% inspired oxygen with air. Anesthesia was maintained with continuous infusion of remifentanil (0-5.0 ng/mL) and sevoflurane at 2 vol% to achieve a bispectral index value of 40-60 and a mean arterial pressure (MAP) within 20% of the baseline. Rocuronium (0.2-0.4 mg/kg/h) was also continuously infused. Lactate Ringer's solution with 6% hydroxyethyl starch solution (Volulyte, Fresenius Kabi, Bad Homberg, Germany) was infused at a constant rate of 6 mL/kg/h. In the case of MAP of <60 mmHg, an intravenous bolus of ephedrine (4 mg) was administered. At the end of the surgery, the neuromuscular block was reversed using sugammadex (2 mg/kg), and tracheal extubation was performed.

All procedures were performed by 3 skilled surgeons using the same method. The reverse Trendelenburg positioning was performed at 30° until the removal of endoscopy. The abdominal insufflation was formed using CO$_2$, and the abdominal gas pressure was set at 12 mmHg in all patients.

SpHb and tHb Measurements

Before the induction of anesthesia, an adult disposable spectrophotometric Hb sensor (Rainbow R1 25, Rev E; Masimo, Irvine, CA, USA) was applied to the fourth finger of the patient and was covered with an impermeable black shield to prevent optical interference (by N.Y.K). SpHb levels were continuously monitored using a Radical-7 Pulse CO-Oximeter (software version 1451; Masimo Corporation, Irvine, CA, USA).

For tHb, the blood sample was taken from the arterial catheter, and then sample was analyzed immediately after collection with an operation room satellite blood analyzer (Stat Profile pHOx Ultra; Nova Biomedical, Waltham, MA, USA). Blood sampling were performed at 2 time points: 60 min after the CO$_2$ insufflation and 10 min before the end of surgery (by H.Y.K. and N.Y.K.). Simultaneously, SpHb values were recorded within 10 s after blood sampling. In vivo adjustment (calibration) was not performed.

The blood gas was calculated for pH, PaCO$_2$, PaO$_2$, tHb, and bicarbonate. Data on the monitor including EtCO$_2$ and hemodynamics (heart rate and MAP) also were recorded simultaneously with the SpHb recording. PI, a measure of peripheral circulation calculated by the Pulse CO-Oximeter, was also recorded at the time of the blood draw. All PI values <1.0 were included.

Statistical Analysis

The values are reported as mean±standard deviation (SD), median (interquartile range), or number (%). The normality of the distribution was assessed using the Shapiro-Wilk test. All paired data (SpHb-tHb) and changes in SpHb (ΔSpHb) and tHb (ΔtHb) between the 2 consecutive measurements were analyzed. The statistical analyses were performed using SPSS for Windows (version 25.0; IBM Corp., Armonk, NY, USA) and SAS (version 9.4; SAS Inc., Cary, NC, USA).

The Bland-Altman analysis accounting for repeated measurements from the same subject was used to evaluate the agreement and precision between the SpHb and tHb. The bias was derived as SpHb-tHb. The precision was defined as 1 SD of the bias. The 95% limit of agreement (LOA) was calculated as the interval defined by the bias±1.96 SD.

Error grid analysis was used to graphically demonstrate the clinical implications of the differences between SpHb and tHb using an Hb cutoff of 9 g/dL [13]. The value of ±10% was chosen because this deviation represents 1 g/dL Hb at the upper range of transfusion consideration (10 g/dL). The error grid had 3 zones based on the difference between SpHb and tHb (Zones A, B, and C). Zone A had 3 sections according to the Hb value: an isthmus section representing a 10% error for Hb values between 6 g/dL and 10 g/dL, where a transfusion decision may occur, the lowermost section of <6 g/dL where a transfusion will likely occur, and the uppermost section of >10 g/dL where a transfusion is unlikely. Zone B reflects a potential therapeutic error that is not as significant as that of zone C. Zone C represents the potential for a major therapeutic error in the administration of blood. In this analysis, the coefficients of determination (r values) were also calculated.
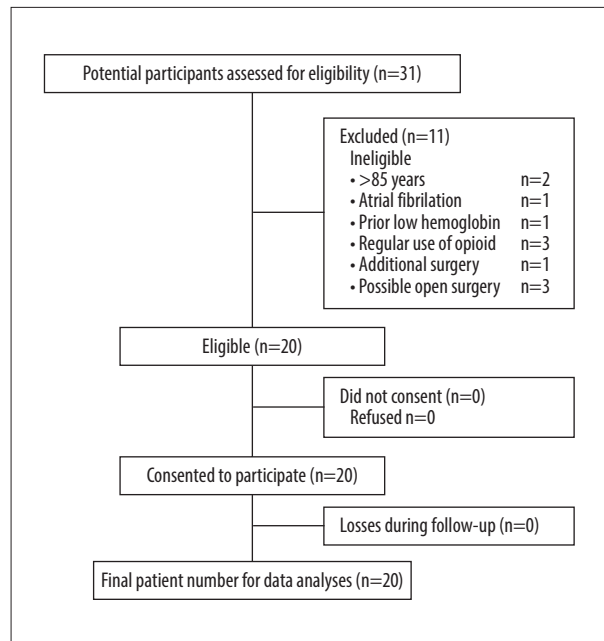

Figure 1. Flow diagram for patient enrollment.

A 4-quadrant plot was used to demonstrate the trending ability over time with differences in ΔSpHb and ΔtHb [14]. A central exclusion zone of 1 g/dL, approximately 10% of the measured data, was applied to prevent larger random errors. The concordance rate was defined as the percentage of the data points that fell into the quadrants agreement (upper right and lower left), indicating agreement in the direction of change. This was considered a reliable trending ability of more than 90%.

Lastly, for the comparison of groups based on PaCO$_2$, the accuracy-related variables, including bias, LOA, correlation, and the absolute difference between SpHb and tHb, were analyzed with a mixed-effects model for the various PaCO$_2$ ranges (PaCO$_2$ <40 mmHg and PaCO$_2$ ≥40 mmHg).

Results

Of the 31 patients, 11 were excluded, and 20 patients were included, as shown in **Figure 1**. The patient characteristics and operational data are summarized in **Table 1**. None of the patients received transfusion during surgery.

Heart rate and MAP were adequately maintained during surgery (**Table 2**). In arterial blood gas analysis, pH and bicarbonate levels were within the normal range, and PaO$_2$ was maintained at approximately 200 mmHg. The mean PaCO$_2$ values during surgery were 41.58±3.24 (range, 28-47) mmHg.

In total, 40 paired measurements of SpHb and tHb from 20 patients were analyzed. Among them, 4 SpHb measurements

Table 1. Patient's characteristics and operational data.

	n=20
Age (years)	54 (49-70)
Height (cm)	161.8±9.6
Weight (kg)	69.6±14.7
Gender (Male/Female)	12/8
ASA physical status (1/2/3)	8/8/4
Diabetes	6 (30%)
Crystalloid (mL)	1100 (600-1525)
Colloid (mL)	500 (450-500)
Packed RBC (unit)	0 (0-0)
Urine (mL)	160 (115-260)
Bleeding (mL)	100 (50-100)
Total dose of remifentanil (ug)	900 (660-1200)
Total dose of rocuronium (mg)	110 (85-150)
Operation time (min)	160 (133-213)
Anesthesia time (min)	218.8±62.5
Pneumoperitoneum time (min)	100 (145-185)

Values are presented as mean±standard deviation, median (interquartile range) or number (%). ASA – American Society of Anesthesiologists; RBC – red blood cell.

were measured with a PI value of <1.0. The mean PI value for the 40 SpHb measurements was 3.10±1.77% (range, 0.5-6.8%). The mean SpHb was 10.92±1.48 g/dL, and the mean tHb was 11.51±0.88 g/dL. Fifteen instances (38%) of all the pairs showed an absolute difference of ≤1.0 g/dL between SpHb and tHb, and 26 instances (65%) showed an absolute difference of ≤1.5 g/dL (**Table 3**).

An error grid analysis for the data points of all the SpHb and tHb pairs is shown in **Figure 2**. For all the pairs, 90% (36 of 40) were in zone A and 10% (4 of 40) were in zone B. There were no cases in zone C. In addition, there was a moderate positive correlation between SpHb and tHb: the correlation coefficient (*r*) values were 0.50 (*P*=0.001, 95% confidence interval [CI]: 0.23 to 0.70). The Bland-Altman plot for 40 paired measurements is shown in **Figure 3**. The bias (precision) values were -0.59 (1.28) g/dL, and the 95% LOA was -3.11 to 1.92 g/dL. The 4-quadrant plot of ΔSpHb and ΔtHb is shown in **Figure 4**. The concordance rate was 67% (4 out of 6), and the correlation coefficient for the paired measurements of ΔSpHb and ΔtHb was 0.29 (*P*=0.226, 95% CI: -0.18 to -0.65).

Table 2. Hemodynamics and arterial blood gas analysis.

	60 min after CO_2 insufflation	10 min before end of surgery
Heart rate (bpm)	64±10	60±8
Mean arterial pressure (mmHg)	80±11	76±9
Arterial blood gas analysis		
pH	7.386±0.030	7.382±0.032
PaO_2 (mmHg)	200.5±46.1	215.1±46.4
$PaCO_2$ (mmHg)	38.9±5.6	39.0±5.3
Bicarbonate (mmol/L)	22.8±1.8	22.8±1.7

Values are presented as mean±standard deviation. CO_2 –carbon dioxide; PaO_2 – arterial oxygen pressure; $PaCO_2$ – arterial carbon dioxide pressure.

Table 3. Groups based on magnitude of differences between Radical-7 Pulse CO-Oximeter (SpHb) and laboratory CO-Oximeter (tHb) hemoglobin concentration.

|SpHb–tHb| (g/dL)	Number (%)
<0.5	3 (8%)
0.5-1	12 (30%)
1.1-1.5	11 (27%)
1.6-2.0	8 (20%)
>2.0	6 (15%)

Values are presented as number (%).

Bias was similar across the $PaCO_2$ ranges (*P*=0.948), but LOA was wider for the $PaCO_2$ <40 mmHg range than for the $PaCO_2$ ≥40 mmHg range (**Table 4**). In addition, there was a moderate positive correlation between SpHb and tHb for the $PaCO_2$ <40 mmHg range but no correlation for the $PaCO_2$ ≥40 mmHg range (**Table 4**): the correlation coefficient (*r*) values were 0.55 and 0.18 (*P*=0.003 and *P*=0.554, respectively). |SpHb-tHb| was significantly higher for the $PaCO_2$ <40 mmHg range than for the $PaCO_2$ ≥40 mmHg range (*P*=0.033, **Table 4**).

Discussion

In this prospective observational pilot study, we evaluated the accuracy of SpHb during laparoscopic surgery. In the presence of CO_2 insufflation, the average SpHb tended to underestimate the tHb on consideration of -0.59 (1.28 g/dL) of bias (precision) values. In addition, there was a moderate positive correlation between SpHb and tHb, but no correlation between
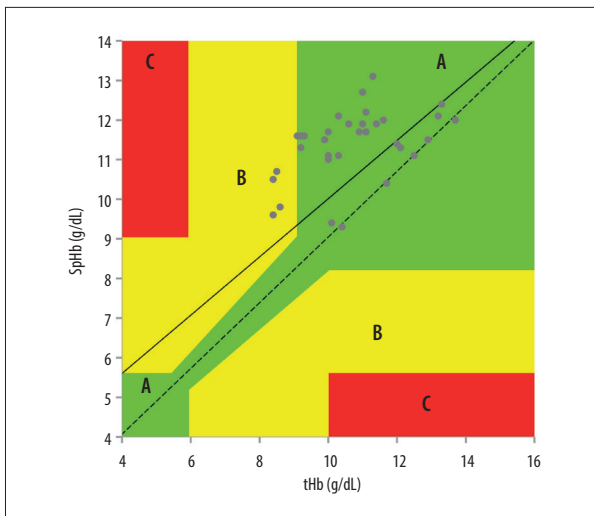
Figure 2. Error grid analysis for the data points of the SpHb and tHb pairs. Zone A represents a clinically acceptable difference (±10%) for hemoglobin from 6 g/dL to 10 g/dL. Zone B represents differences greater than ±10% with a potential for therapeutic error. Zone C represents differences with a major therapeutic error. SpHb – continuous and noninvasive hemoglobin monitoring; tH – laboratory hemoglobin
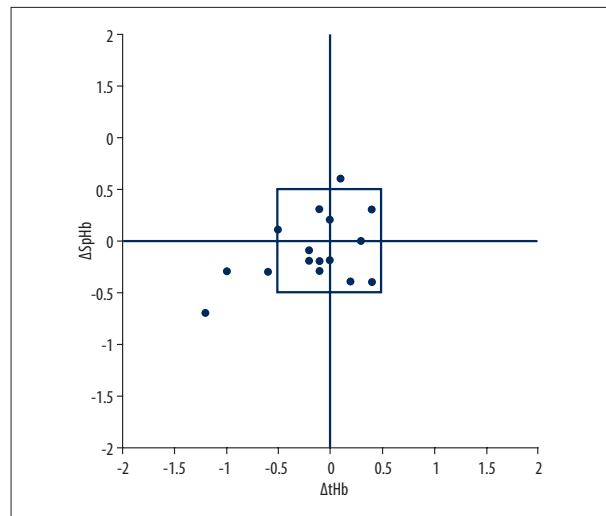

Figure 4. The 4-quadrant plot. It shows the directionality of the trend with a central exclusion zone of 1 g/dL hemoglobin. SpHb – continuous and noninvasive hemoglobin monitoring; tHb – laboratory hemoglobin
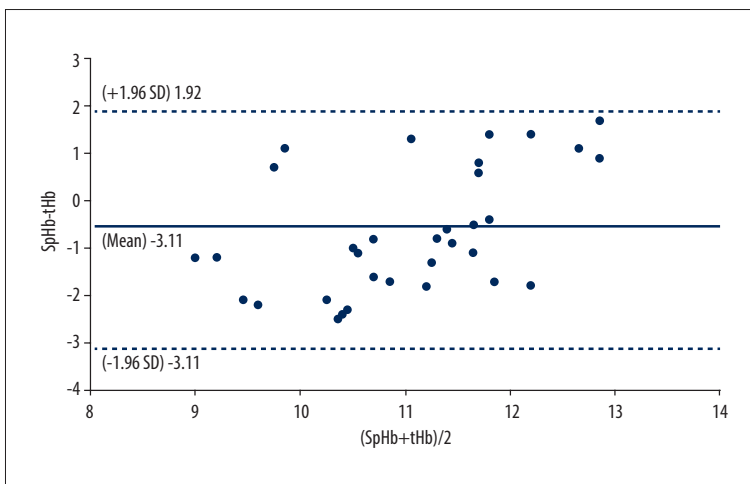

Figure 3. Bland-Altman analysis. The solid line represents the bias (SpHb–tHb), and the dotted line represents the 95% limit of agreement. SpHb – continuous and noninvasive hemoglobin monitoring; tHb – laboratory hemoglobin.

Table 4. Accuracy of SpHb by $PaCO_2$ range.

	PaCO₂ <40 mmHg (n=26)	40 mmHg ≤PaCO₂ (n=14)	P value
Bias (95% CI) (g/dL)	-0.60 (-1.18 to -0.02)	-0.57 (-1.15 to 0)	0.948
95% Limit of agreement (g/dL)	-3.41 to 2.21	-2.52 to 1.38	
Correlation coefficient (95% CI)	0.55 (0.20 to 0.77)	0.18 (-0.39 to 0.65)	0.235
|SpHb–tHb| (g/dL)	1.25±0.59	1±0.51	0.033
≤1.5 g/dL	15 (58%)	11 (79%)	0.299
1.5 g/dL<	11 (42%)	3 (21%)	

Values are presented as number (%). SpHb – continuous and non-invasive hemoglobin monitoring; tHb – laboratory hemoglobin; $PaCO_2$ – arterial carbon dioxide pressure.

ΔSpHb and ΔtHb. The group comparison based on the PaCO$_2$ ranges showed conflicting results of bias, a wider LOA, and a higher value of |SpHb-tHb|, but a more significant correlation between SpHb and tHb in the PaCO$_2$ <40 mmHg range.

In our study, the bias (precision) was -0.59 (1.28 g/dL), and the 95% LOA was -3.11 to 1.92 g/dL in the presence of CO$_2$ insufflation. A meta-analysis by Kim et al included 32 studies, but only 13 studies were performed in the operating room [15]. Despite the minimal bias and SD of 0.39±1.32 g/dL for the SpHb and tHb, 16 studies in the operation room showed a wide LOA of -2.21 to 2.98 g/dL, and they were not homogeneous (I^2=93%). A meta-analysis showed no significant heterogeneity of 28 studies conducted in the operating rooms, but the mean difference between SpHb and tHb was as low as -0.27, and the 95% LOA was wide (-0.44 to -0.1 g/dL) [5]. These tendencies toward a minimal bias and a wide LOA are consistent with our results, which imply the possibility of an increase in bias during laparoscopic surgery compared with conventional surgery. Considering 1 g/dL as the clinical threshold, a bias of -0.59, in the presence of CO$_2$ insufflation, is an acceptable result despite the wide LOA. Bleeding complications and major vascular injuries are common even in minimally invasive laparoscopy, and internal bleeding into the peritoneal cavity or retroperitoneum is difficult to recognize due to the restricted view from the camera tip [16]. Rapid detection of anemia and timely transfusion decisions are vital for dynamic surgical conditions [17]. Therefore, a reliable accuracy of SpHb may help manage patients undergoing laparoscopic surgery in the presence of CO$_2$ insufflation.

The error grid analysis showed that SpHb was significantly correlated with tHb in our study (r=0.50), which supports the above-mentioned reliability of SpHb. Moreover, it was a favorable outcome for the accuracy that 90% of paired measurements existed in zone A in our study. However, all the paired measurements of zone A were for the uppermost section. Red blood cell transfusion is typically recommended for Hb values of <6.0 g/dL and probably is not needed for values of >10.0 g/dL [18]. Thus, no transfusion will occur for the uppermost section, and the patient will likely be transfused for the lowermost section, irrespective of any bias between the 2 measurements. The isthmus section of zone A (6.0 g/dL<Hb<10.0 g/dL) is the clinical decision-making region for blood transfusion [13]. The experimental observations are recommended to be a part of this isthmus when evaluating a new device [13]. Thus, further studies should be directed at laparoscopic procedures with higher degrees of intraoperative blood loss, such as laparoscopic hepatobiliary or thoracic surgeries, for clinical validity. The revised 2015 practice guidelines for perioperative blood management by the American Society of Anesthesiologists recommend a restrictive transfusion strategy, although Hb concentration between 6 and 10 g/dL is determined for transfusion [19]. There

is a need to pay attention to alterations in the recommended Hb level for the error grid analysis.

In the 4-quadrant plot, the concordance had an unacceptable rate of 67%, and ΔSpHb was not correlated with ΔtHb (r=0.29). In addition, the precision of SpHb was 1.28 g/dL (22%) in our study, although a precision of 20% is considered as the upper limit for reliable trending ability [14]. Therefore, the trending ability of SpHb in the presence of CO$_2$ insufflation may be expected to be weak despite the fewer data points. Although there are few studies on trending ability in operation room, SpHb showed a good trending ability in adult patients scheduled for major orthopedic surgery, spine surgery, and high blood loss neurosurgery [20-22]. During liver transplantation, it was also a useful trending monitor, considering that the concordance rate was 79%, but the correlation coefficient for ΔSpHb and ΔtHb was 0.79 [23]. Since Baker et al reported greater benefits of SpHb in indicating an unexpected status change, such as Hb decrease due to actual bleeding or acute hemodilution, the possible low trending ability in the presence of CO$_2$ insufflation should be taken into account when deciding on blood transfusion [3,10,21]. Lastly, most data points in our study existed within the central exclusion zone, which means that Hb did not change appreciably, which may be because blood sampling during laparoscopic gastrectomy may be primarily due to the assessment of the acid-base status or electrolyte rather than a clinical suspicion of bleeding.

The group comparisons based on the PaCO$_2$ ranges showed that PaCO$_2$ can affect the accuracy of SpHb, but the results were inconsistent in our study. In patients with hypercapnia, the PaCO$_2$ status impaired the agreement between PaO$_2$ and arterial oxygen saturation measured by pulse oximetry [6]. In 70 adults undergoing laparoscopic herniorrhaphy, gastric bypass, or cholecystectomy, significant changes in cerebral oxygenation occurred during insufflation during laparoscopy [24]. In laparoscopic bariatric surgery, increased EtCO$_2$ enhances regional cerebral oxygen saturation [7]. As possible mechanism, Munoz et al proposed an increased carbaminohemoglobin level, changes in red blood cell morphology, and venous blood pulsatility [6]. Further experimental studies are needed to determine the effect of PaCO$_2$ on oximetry.

This study has limitations. First, this was a pilot study involving a small sample size, and the statistical power might be too weak to draw definitive conclusions. Second, the baseline values of SpHb and tHb were not measured. Anesthetic drugs can influence the microcirculation and accuracy of SpHb; thus, baseline values obtained after anesthetic induction are needed [25]. Third, a radial arterial catheter was placed on the same side arm as the spectrophotometric Hb sensor. Although radial blood flow decreased immediately and recovered 5 min after cannulation, blood flow reduction at the fingertip may

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have occurred because the diameters of the radial artery or its dorsal branch significantly decreased after cannulation [26,27]. Fourth, SpHb with PI of <1.0 should be excluded from the final analysis because the decrease in PI after phenylephrine administration reduced the changes in the bias values after anesthesia induction [9].

The results of this study were inconsistent. However, our observation may be meaningful, because the importance of a pilot study with a small sample is to provide estimates for sample size calculation and assist in planning and improving the quality of further research and minimizing unnecessary effort from researchers and participants [28].

Conclusions

This observational pilot study suggests that SpHb has an acceptable accuracy but weak trending ability in the presence of CO$_2$ insufflation, and SpHb may be affected by PaCO$_2$ levels. Further research with larger populations or randomized controlled studies are needed to definitively establish the effect of CO$_2$ insufflation on the accuracy of SpHb.

Conflict of Interest

None declared.

Declaration of Figures Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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