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ORIGINAL ARTICLE

Does a digital regional nerve block improve the accuracy of noninvasive hemoglobin monitoring?

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Abstract
Background Blood hemoglobin (Hb) can be continuously monitored utilizing noninvasive spectrophotometric finger sensors (Masimo SpHb). SpHb is not a consistently accurate guide to transfusion decisions when compared with laboratory Co-Oximetry (tHb). We evaluated whether a finger digital nerve block (DNB) would increase perfusion and, thereby, improve the accuracy of SpHb.
Methods Twenty adult patients undergoing spinal surgery received a DNB with lidocaine to the finger used for the monitoring of SpHb. SpHb–tHb differences were determined immediately following the DNB and approximately every hour thereafter. These differences were compared with those in our previously reported patients ($N = 20$) with no DNB. The SpHb–tHb difference was defined as "very accurate" if <0.5 g/dL and "inaccurate" if >2.0 g/dL. Perfusion index (PI) values at the time of each SpHb–tHb measurement were compared.
Results There were 57 and 78 data points in this and our previous study, respectively. The presence of a DNB resulted in 37 % of measurements having SpHb values in the "very accurate group" versus 12 % in patients without a DNB. When the PI value was >2.0, only 1 of 57 DNB values was in the "inaccurate" group. The PI values were both higher and less variable in the patients who received a DNB.
Conclusions A DNB significantly increased the number of "very accurate" SpHb values and decreased the number of "inaccurate" values. We conclude that a DNB may facilitate the use of SpHb as a guide to transfusion decisions, particularly when the PI is >2.0.

Keywords Anesthesia techniques regional · Blood-flow-peripheral · Blood-hemoglobin · Blood-transfusion · Measurement techniques

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Introduction

A noninvasive, continuous spectrophotometric monitor of blood hemoglobin (SpHb) levels (Masimo Radical 7 Pulse Co-Oximeter with SpHb; Masimo, Irvine, CA, USA) has been available for several years [1]. The accuracy of SpHb monitoring is often, but not always, sufficient for decisions regarding the assessment of acute blood loss or need for transfusion [2–5]. The accuracy of SpHb values has been based on comparison of the SpHb readings with a standard laboratory Co-Oximeter hemoglobin level (tHb) and related to the perfusion of the finger and possibly other variables [2, 6]. As a result, we hypothesized that increasing perfusion to the finger would decrease the variability and

improve the accuracy of SpHb monitoring. Finger perfusion can be increased by warming the finger [7] or by regional anesthesia [8]. We selected the regional anesthetic approach which blocks the digital nerves of the monitored finger with a local anesthetic digital nerve block (DNB). We postulated that finger perfusion and the accuracy of SpHb in predicting tHb should increase.

We, therefore, determined the accuracy of SpHb in patients who had received a DNB to the finger used for the monitoring of SpHb. The accuracy of SpHb for patients with a DNB was compared with SpHb values for patients from our recently published study, using the same study design, who underwent SpHb monitoring but did not receive a DNB [2].

Methods

Patients and data collection

After approval was obtained from the University of California, San Francisco, Human Research Protection Program, 20 patients, 33–84 years of age who were categorized as American Society of Anesthesiology physical status II or III, were studied. These patients' data were compared with our previously reported data from patients without a DNB [2]. The demographics of the patients receiving a DNB in this study were compared with the demographics of our previously studied patients without a DNB [2] (Table 1). All patients were undergoing spinal surgery in the prone position under general anesthesia and had provided informed consent preoperatively. All patients had radial artery catheters inserted as part of their routine anesthetic care.

SpHb was continuously monitored on the third or fourth finger using the Masimo Radical 7 Pulse Co-Oximeter with SpHb™ and Rainbow Adult Adhesive sensors, version RevF [1]. The sensors were covered with an optical shield to prevent optical interference. After application of the SpHb sensor, a DNB was performed using 2 % lidocaine, 0.5 mL, at the base of the medial and lateral side of the finger for a total of 1.0 mL of local anesthetic. In addition to SpHb, tHb levels were also determined from a blood sample analyzed by Co-Oximetry [tHb; Beckman-Coulter (Brea, CA, USA)] at the University of California, San Francisco Clinical Laboratories [2].

The patients had 2–4 pairs of hemoglobin (Hb) data collected. Each pair included a simultaneous recording of both an SpHb value and an arterial blood sample drawn for tHb determination. Arterial blood samples for tHb measurements and SpHb values were obtained prior to surgical incision, but after the patient had been anesthetized, placed in the prone position for the surgery, and received the DNB. Peripheral perfusion of the finger being used for SpHb measurement was assessed by continuous recording of the perfusion index (PI). The PI is an indirect measure of perfusion of the finger determined using plethysmography [1, 2]. Following surgical incision, blood samples were taken on approximately an hourly basis. The data from the SpHb, tHb, and PI were recorded manually. The SpHb–tHb difference was defined as "very accurate" if it was <0.5 g/dL, "acceptably accurate" if it was between 0.5 and 1.5 g/dL, and "inaccurate" if the difference was >2.0 g/dL. To determine the overall pattern of results, we categorized the 57 paired absolute differences into 1 of 5 groups based on the magnitude of the differences between the SpHb and laboratory Co-Oximeter (tHb)-derived Hb concentrations (g/dL) (Table 2). These data were compared with our previously published data from patients without a DNB also using the RevF SpHb sensor [2]. The comparison group of patients underwent the same protocol for evaluating SpHb and tHb, but did not receive a DNB.

Statistical analysis

Accuracy was assessed by comparison of SpHb with tHb values measured at the same time point on the same patient. The primary outcome for analysis was the difference between these measures, defined as SpHb minus tHb

Table 1 The demographics of the patients who did and did not receive a digital nerve block

	Digital block patients	No block (control) patients[a]
Spinal surgery patients studied	20	20
Age (years)	33–84	40–80
American Society of Anesthesiologist's physical classification I–III[b]	II: 11 III: 9	I: 1 II: 10 III: 9
Weight (kg)	49–120	50–120
Pre-operative arterial blood pressure >150/90 mmHg[b, c]	2	6
Diabetes mellitus[b]	2 (type II)	1 (type II)
Coronary artery disease[b]	3	3
Smoking history[b]		
None	10	9
In the past	7	9
Currently	3	2

[a] Data reported from prior study [2]

[b] Number of patients

[c] No patient had an arterial blood pressure >173/103

Table 2 Groups based on magnitude of differences between noninvasive (SpHb) and laboratory Co-Oximeter (tHb) hemoglobin in patients with and without a finger regional anesthetic block

	All perfusion indexes (0.29–8.3)		Perfusion index >2.0	
Groups	**No block[a]**	**Block[b]**	**No block[a]**	**Block[b]**
<0.5 g/dl	9 12 %	21 37 %	5 11 %	13 37 %
0.5–1.0 g/dl	26 33 %	11 19 %	13 29 %	9 26 %
1.1–1.5 g/dl	22 28 %	10 18 %	14 31 %	7 20 %
1.6–2.0 g/dl	11 14 %	10 17 %	5 11 %	5 14 %
>2.0 g/dl	10 13 %	5 9 %	8 18 %	1 3 %
Total	78 100 %	57 100 %	45 100 %	35 100 %

[a] No-block patients were originally described in our previous study [2]

[b] Block patients are reported in this study

(SpHb–tHb). We considered the absolute difference as an estimate of overall error in the measurement of SpHb. We used Bland–Altman plots to display the differences versus their average values [9]. For the primary analyses we took the absolute value of the differences and divided them into categories: <0.5, 0.5–1.0, 1.0–1.5, 1.5–2.0, and >2.0 g/dL. We used multinomial logistic regression to compare the distribution across the accuracy categories and used robust standard errors to accommodate the repeated measures on the same patients [10]. The multinomial logistic regression was conducted both with and without adjustment for before versus after surgical incision and PI. Analyses were repeated for various cutoffs of PI. Exact binomial confidence intervals were used to quantify the probabilities of exceeding an absolute difference of 2.0 g/dL for use/nonuse of a DNB.

To assess the association between the differences and PI, we used a restricted cubic spline to flexibly model the relationship in a generalized estimating equations analysis. We used this model to plot the estimated relationship between the differences and PI along with the raw data and to assess the association of variability with PI.

We conducted a secondary analysis of the effect of the DNB on the PI itself, using a linear regression model and generalized estimating equations to accommodate the repeated measures on patients [10].

Results

A total of 57 paired differences of SpHb–tHb were collected and analyzed from the 20 patients in this study who received a DNB and compared with 78 paired differences from our previously reported data from patients without a DNB [2].

The demographic variables (age, American Society of Anesthesiologists physical classification, weight, preoperative blood pressure, smoking history, and the presence of diabetes or coronary artery disease) were not significantly different between the two groups (Table 1). All patients in the present study received a DNB before the SpHb–tHb data were obtained. Each patient had between 2 and 4 paired differences.

A higher percentage of measurements were in the most accurate category (<0.5 g/dL) using the DNB (37 %) compared with not using the DNB (12 %) ($P = 0.002$). In contrast, the patients who had a DNB tended to have fewer "inaccurate" (SpHb–tHb > 2.0 g/dL) measurements than were found for those patients without a DNB (Table 2). However, these results were not statistically significant ($P = 0.43$). Overall, 74 % of the SpHb–tHb values were <1.5 g/dL in patients with a DNB (Table 2). These values were similar to the data from patients who did not receive a DNB as previously described [2]. Specifically, 73 % of the data in patients without a DNB had SpHb–tHb values <1.5 g/dL (Table 2) [2].

The mean PI was 0.55 higher in patients who received a DNB (Fig. 1). The overall variability and absolute differences in SpHb–tHb values also tended to decrease with

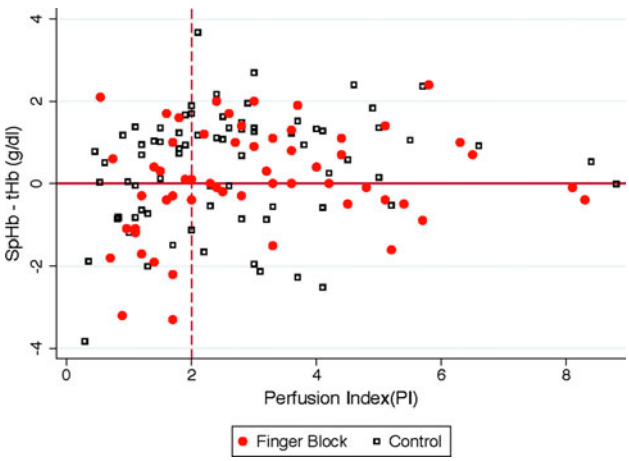

Fig. 1 Relationship between the error in using the Masimo Radical 7 Pulse Co-Oximeter (SpHb) as an estimate of tHb (*vertical axis*) and the perfusion index (*PI*; *horizontal axis*). Each *open square* represents data from a patient without a finger digital nerve block [2] and the *red filled circles* represent data from patients who did receive a block. The *dashed vertical line* was inserted to facilitate comparisons of the SpHb–tHb values with a PI <2.0 versus >2.0

increasing PI (Fig. 1). Yet, when comparing the variability and absolute differences in SpHb–tHb values, only the DNB group was significantly different ($P = 0.012$) with a PI <2.0 versus >2.0 (Table 2; Fig. 1).

We then analyzed whether a larger number of "acceptably accurate" SpHb–tHb values could be achieved by eliminating all SpHb–tHb values with a PI < 2.0 (Table 2). SpHb–tHb values in patients with a DNB strongly trended to have a higher percentage of accurate values compared with those without a DNB, but the trend did not reach statistical significance ($P = 0.056$). The estimated rates of inaccurate values with PI > 2.0 were 17.8 % without a DNB (95 % exact binomial confidence interval 8.0–32.0 %), and 2.9 % for values with a DNB (95 % exact binomial confidence interval 0.1–14.9 %). Therefore, using only the data with a PI value >2.0 and a DNB, inaccurate values should occur <15 % of the time. Specifically, of all the data with a PI > 2.0 and a DNB, 83 % ($n = 29$) were "accurate" (SpHb–tHb < 1.5 g/dL) and only 3 % ($n = 1$) were "inaccurate" (SpHb– tHb > 2.0 g/dL) (Table 2).

Discussion

Hb values have been and continue to be important guides to transfusion medicine. Until recently, tHb has been measured using a Co-Oximeter, or a point-of-care-HemoCue (HemoCue AB, Ängelholm, Sweden) device [11–13]. These devices provide data on an intermittent basis, so either arbitrarily defined measurement intervals or sufficient clinical suspicion of blood loss or change in Hb are required to warrant measurement. The SpHb provides continuous and noninvasively monitored Hb values and, as such, should facilitate more timely transfusion decisions.

Previous studies have defined the clinical situations in which SpHb is a potentially useful monitor in an imprecise manner. For example, several studies state that SpHb provides "clinically acceptable" [4, 14] values in patients with a low Hb value [14] and during selected surgical procedures, such as complex spinal surgery [4]. "Clinically acceptable" was not defined. Lamhaut et al. [15] and Causey et al. [3] found the correlation between SpHb and tHb was good "suggesting" the routine use or continued study of this device. Ehrenfeld et al. [16] concluded that routine use of SpHb would decrease the use of blood transfusions. However, in that study only 8 of 327 patients studied required a blood transfusion, which suggests that their patient population rarely needed a blood transfusion, independent of the method of monitoring. None of these studies adequately addressed the degree of accuracy needed for clinical purposes.

In our previous study [2], we arbitrarily defined a SpHb–tHb difference of <1.5 g/dL as "sufficiently accurate" and found that SpHb was not sufficiently accurate 27 % of the time (Table 2). We then concluded that SpHb was not sufficiently accurate to be a guide for transfusion decisions. Applegate et al. [17] came to the same conclusion in regard to patients who experienced large blood losses. Gayat et al. [18] also concluded that SpHb was "too unreliable to guide transfusion decisions". The above studies raise serious reservations about making transfusion decisions based on SpHb values.

The evaluation and comparison of SpHb values require at least two variables to be considered. The first variable, which was the purpose of the present investigation, is the PI. The PI is dependent on the overall physiology of the finger. Our question was whether the PI could be influenced by and increase with improved perfusion of the finger. The DNB significantly increased the percentage of patients whose SpHb values were "very accurate" (SpHb–tHb <0.5 g/dL) (Table 2). Of equal importance is the percentage of SpHb–tHb values that were "inaccurate" (SpHb–tHb >2.0 g/dL) (Table 2). The overall trend (not statistically significant) was for fewer patients to have SpHb–tHb values in the "inaccurate" category if they had a DNB. However, eliminating all data with a PI of <2.0 resulted in only 1 of 35 patients with a DNB who was in the "inaccurate" category, whereas 8 of 45 patients without a DNB were in the "inaccurate" category [2]. These findings allowed us to consider the use of combinations of PI and SpHb values for assessing the need for a blood transfusion.

By improving PI with the administration of a DNB, we were able to improve accuracy. For purposes of data accuracy, the manufacturer (Masimo) recommends not relying on the SpHb values for clinical decision-making when the PI is <1.4. Our results indicate that some large SpHb–tHb differences persisted up to PI values of at least 2.0 (Fig. 1). We conclude that if the PI is >2.0 after a DNB, SpHb is more consistently accurate and more likely to provide meaningful information to guide transfusion decisions. While this study utilized a DNB with lidocaine to optimize perfusion, we predict that other methods of increasing perfusion to the finger might be as effective at improving SpHb accuracy. Such methods include the use of a transcutaneous local anesthetic [e.g., EMLA (Astra-Zeneca Pharmaceuticals, Wilmington, NC, USA)], using a local anesthetic with a longer duration (e.g., bupivacaine), or warming the finger. Further study may be warranted to validate these types of suggestions.

Berkow et al. [4] used a different method to assess the strength of the monitoring signal as a guide to the quality of the data. They used the Signal-Indicator Quality (SIQ) to monitor the "strength" or quality of the signal and by inference, the accuracy of the SpHb. The SIQ threshold of <50 % is the trigger for the low signal strength to appear. Yet, Berkow et al. found only a slight improvement

in the accuracy of the SpHb data when the SIQ was >50 %. Thus, the SIQ does not appear to facilitate assessment of SpHb's accuracy. In contrast, the accuracy of SpHb is more clearly related to the PI [2, 6]. With a PI of <2.0, the SpHb values are less accurate and more variable (Fig. 1; Table 2). Our study indicates that with a DNB the SpHb value needs to be combined with a PI of >2.0 for transfusion decisions.

A second important variable that must be considered when evaluating the accuracy of the SpHb measurements relates to the version of the SpHb sensor being used in each investigation. Masimo has continued to refine the algorithm for assessment of SpHb. The most recent version is RevF. However, studies published as recently as 2011 used a variety of sensors and algorithms including RevC [3], RevE [2, 4, 17], and the most recent version RevF [2]. As importantly, some studies do not report what version of the SpHb sensor was used [6]. Recently, the version of the sensor that was used in various studies has been raised as a concern in interpreting the findings. For example, Berkow et al. [4] expressed concern about the data from Gayat et al. [18] because they used an earlier version of the SpHb sensor. Ironically, Berkow et al. [4] also used an older version of SpHb (RevE). In the present study we utilized the most current sensor, RevF [1]. We have assumed that there are differences between the older and newer versions of the SpHb sensors. However, because the sensor characteristics and algorithms used to monitor SpHb are proprietary, we cannot determine whether these differences are significant and whether they affect the interpretation of the data from any of the previously published studies.

Our study design has the limitation of dependency on control data (i.e., patients without a DNB) obtained from our recently performed and published study [2, 19]. A randomized controlled study would have been preferred. However, based on the data from our original study [2], we were not aware of the degree of variability in SpHb and the potential impact of perfusion. We considered using each patient as his/her own control. For logistical reasons, we were not able to do so. Owing to the surgical approach, the opposite hand was not accessible for additional monitoring. We did use the same methodology and same version of the sensor as that used with the control data from our recent study [2], using appropriate caution in the statistical analysis of the findings [20].

We conclude that "adequate" peripheral perfusion to the finger, as estimated by the PI, is an important requirement for obtaining reliable noninvasive SpHb data. Many other studies do not report the PI values, making it difficult to relate the accuracy of the monitor to finger perfusion [4, 17]. Based on our findings, we conclude that when the PI is 2.0–3.0 or higher after DNB for surgical patients it will usually produce accurate SpHb values.

The reason that the increase in PI seems to improve accuracy, at least in some patients, appears to be related to improved perfusion to the finger. Despite the DNB, however, the degree to which the block increased perfusion to the finger could not be directly assessed, nor could the duration of the block. In our study the mean increase in PI was rather small (0.55), which may be related to the extent of the block. Perhaps additional explanations are possible, including an anesthetized finger not responding to the stimuli that would cause vasoconstriction. Nevertheless, our study demonstrates that the physiology of the finger is an important variable in assessing the accuracy of the SpHb. At the same time, even though our data support the use of a PI of >2.0, we speculate that further improvement of the PI (e.g., PI >3.0) may provide added confidence in relying on the SpHb as a guide for transfusion decisions.

The findings from this study demonstrate the value of this technology in assessing Hb levels in surgical patients, but also some of its limitations, both related to the technology and to the underlying patient physiology at the time of monitoring. Our purpose was to use the DNB as a method to improve digital perfusion. While the DNB did improve SpHb accuracy, we did not establish that the DNB should be a routine clinical approach to optimize the performance of the SpHb monitor as a guide to transfusion therapy in surgical patients. What the study demonstrates is that with a better understanding of the influence of digital perfusion on SpHb accuracy, as well as further refinements in the technology, this noninvasive monitor could become an even more important and useful guide to patient care decisions in the perioperative area and many other settings.

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Conflict of interest Ronald D. Miller received honoraria from Masimo. Dr. Miller is a paid member of the Masimo Scientific Advisory Board, the manufacturer of the SpHb, and has received travel reimbursement in the past. The Masimo Corporation provided the Radical 7 Pulse Co-Oximeter with SpHb™, sensors, and software for the study. The other study investigators report no conflict of interest.

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