REVIEW

CURRENT OPINION

Continuous noninvasive hemoglobin monitoring: ready for prime time?

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Purpose of review
Determination of hemoglobin (Hb) concentration is essential for the detection of anemia and hemorrhage and is widely used to evaluate a patient for a possible blood transfusion. Although commonly accepted as intrinsic to the process, traditional laboratory measurements of Hb are invasive, intermittent, and time-consuming. Noninvasive Hb (NIHb)-monitoring devices have recently become available and promise the potential for detecting sudden changes in a patient's Hb level. In addition to reduced delays in clinical intervention, these devices also allow for a reduction in patient discomfort, infection risk, required personnel, and long-term costs. Unfortunately, it has been shown that many clinical factors can influence their accuracy.

Recent findings
Many studies have been published on the accuracy and precision of NIHb-monitoring devices in various clinical settings. A recent meta-analysis has shown a small mean difference but wide limits of agreement between NIHb and laboratory measurements, indicating that caution should be used by physicians when making clinical decisions based on this device.

Summary
NIHb measurements may currently be considered to be a supplemental tool for monitoring trends in Hb concentration, but are not currently developed enough to replace an invasive approach. Moreover, further studies are still required before implementing NIHb in the clinical decision-making process. Specifically, no studies have demonstrated that this technology improves clinical outcomes or patient safety.

Keywords
accuracy, bleeding, hemoglobin, noninvasive, transfusion

INTRODUCTION

Bleeding is a major complication within perioperative and critical care settings. For example, surgery-related hemorrhagic anemia is difficult to diagnose by physical examination alone, and hemoglobin (Hb) concentration measurements are often required [1]. In addition to the operating room, the rapid assessment of total Hb values is an issue of great importance in the intensive care unit and emergency room, in which life-threatening bleeding often occurs. The rapid measurement of Hb, as well as the tracking of Hb changes to detect occult bleeding, is essential during these periods. Unfortunately, measuring Hb traditionally requires an invasive arterial or venous blood draw for analysis. This sample then requires time and attention to obtain results, which unavoidably delays patient care and only allows for intermittent results. This delay of such sporadic clinical data has the strong potential to negatively impact patient outcomes. Although the measurement of Hb is important, the intervention it precipitates, blood transfusion, has been associated with adverse events in specific clinical settings [2–4]. For example, in patients without anemia who underwent major vascular surgery, transfusion was associated with increased risk of myocardial infarction (hazard ratio 5.05, 95% confidence interval 2.23–11.44; $P = 0.0001$), and 30-day death (hazard ratio 19.20, 95% confidence interval

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KEY POINTS

- Noninvasive hemoglobin (Hb)-monitoring devices have recently become available and promise the potential for detecting sudden changes in a patient's Hb level.
- A recent meta-analysis has shown a small mean difference but wide limits of agreement between noninvasive Hb monitoring and laboratory measurements, indicating that caution should be used by physicians when making clinical decisions based on this device.
- Many clinical factors have an impact on the accuracy of noninvasive Hb monitoring. Of these factors, Hb concentration and peripheral perfusion are the two most important factors required for an accurate measurement.

3.99–92.45, $P=0.007$) [2]. Therefore, it can be inferred that accurate Hb measurement is also crucial to avoid unnecessary transfusion.

Laboratory CO-oximeter is now considered to be a reference method for measuring Hb concentration. However, it requires blood collection and time to process and obtain the results. In addition, the reliability of the capillary-based method, which enables the measurement of Hb at the bedside, has been reported to be controversial, especially in patients with severe hemorrhage [5,6]. Recently, continuous and noninvasive Hb (NIHb) monitoring devices have been introduced, which allow physicians to measure Hb concentration without delay or blood withdrawal. Currently, two systems using multiwavelength CO-oximetry or occlusion spectroscopy are available for blood Hb measurement. Masimo has introduced a continuous-monitoring bedside device (Radical-7) and a hand-held spot-check device (Pronto-7) (Masimo Corp., Irvine, California, USA) using multiwavelength technology. There are validation studies focused on the accuracy of these devices in various clinical settings [7–10]. This technology has been validated in healthy volunteers with normovolemic hemodilution [11], but presents some clinical limitations in patients with either low Hb [8] or reduced peripheral perfusion [7,9,10]. Other devices based on occlusion spectroscopy, NBM-200 and NBM-200MP, have been developed by OrSense (Nies Ziona, Israel). Although several studies of the NBM devices have been conducted, the results are controversial with wide variations of bias [12,13■■,14–16], especially in patients with active bleeding. It can be seen that a variety of clinical variables have an impact on the accuracy of continuous NIHb monitoring. It is, therefore, of major importance for critical-care physicians to understand the clinical factors affecting the accuracy of NIHb monitoring. In this review, we will first describe the statistics used for the assessment of the accuracy of the NIHb monitoring. We will then discuss the reported accuracy of this technology along with the clinical factors affecting its reliability. Last, we will assess the trending ability of these devices.

STATISTICAL METHODS FOR THE ASSESSMENT OF THE ACCURACY OF NONINVASIVE HEMOGLOBIN MONITORING

Many studies concerning NIHb monitoring have focused on its accuracy and precision compared with laboratory Hb measurements in various clinical settings, including the operating room, ICU, and emergency department. Accuracy and precision have been assessed using a correlation coefficient or Bland Altman analysis. The correlation coefficient shows the direction and strength of the relation between NIHb monitoring and the reference method, but provides little clinically useful information. The Bland Altman analysis is the established method for comparing a tested method and a reference method. This approach describes accuracy (mean bias), precision [standard deviation (SD) of the bias], and 95% limits of agreement (LOA) (mean bias $\pm$ 1.96SD of the bias). The reference and tested methods may be used interchangeably when the bias and LOA are 'small' ('small' being predefined by what clinicians would consider acceptable). When evaluating a Bland Altman analysis, one must remember that accuracy and precision are equally valuable and cannot be independently interpreted. In the case of NIHb monitoring, it needs to be stressed that the accuracy over a range of Hb values is not equivalent [17■■]. For example, an accuracy of $\pm$1 g/dl would have a very different impact whether the mean Hb value is 14 g/dl or 7 g/dl. Clinically, NIHb monitoring should be highly accurate at blood Hb concentrations between 6 and 10 g/dl, as patients are potentially transfused when their Hb level drops below a value between 6 and 10 g/dl, depending on the physician. Morey *et al.* [18] introduced the Hb error grid (Fig. 1) for the assessment of the accuracy of NIHb monitoring, although originally introduced by Clarke *et al.* [19] for the evaluation of glucose meter accuracy. Morey *et al.* [18] used an accuracy of $\pm$10% for the assessment of NIHb monitoring in their defined anemic range (Hb level from 6 to 10 g/dl). In zone A of the Hb error grid, the high accuracy of 10% error is required in a range of Hb level from 6 to 10 g/dl so that the zone becomes narrow. The accuracy is less important

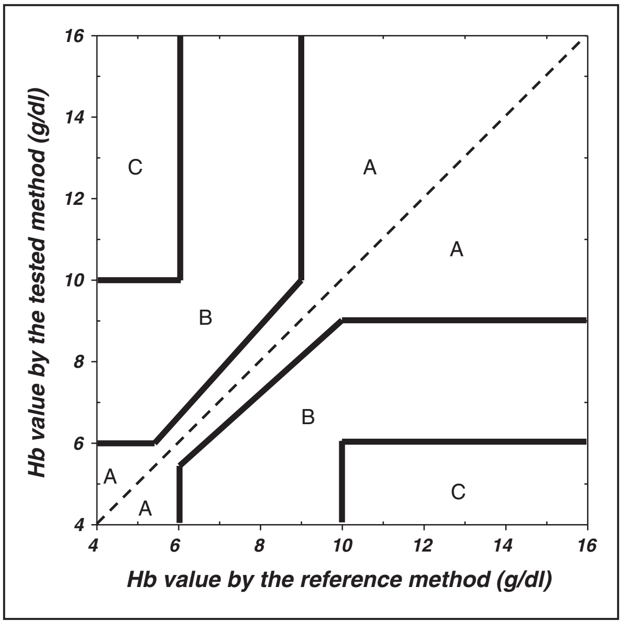

FIGURE 1. Hemoglobin error grid shown by Morey *et al.* An accuracy of ±10% is used for the assessment of noninvasive hemoglobin monitoring in an anemic range (Hb level from 6 to 10 g/dl).

in the range of Hb concentrations below 6 g/dl as the patients will likely receive transfusion. In addition, high accuracy is not required in a range above 10 g/dl as transfusion will likely not occur [17▪▪]. Zone C represents the area for critical errors of unnecessary transfusion and avoidance of necessary transfusion. In this zone, if the true Hb level is above 10 g/dl and the tested Hb level is below 6 g/dl, patients would receive unnecessary transfusion. Similarly, if the true Hb level is less than 6 g/dl and the tested Hb level is more than 10 g/dl, patients may not receive necessary transfusion. Thus, the Hb error grid shows the required accuracy of NIHb monitoring for physicians to make useful clinical decisions. It should be used in conjunction with current statistical methods, including the Bland Altman analysis and correlation coefficient, for the assessment of the accuracy of Hb monitoring.

ACCURACY AND PRECISION OF NONINVASIVE HEMOGLOBIN MONITORING

Up to this point, most of the studies published on the performance of NIHb monitoring have evaluated the accuracy and precision in various clinical settings. Kim *et al.* [20▪▪] conducted a systematic review and meta-analysis on the accuracy and precision of continuous NIHb monitoring. In this meta-analysis, 32 studies (4425 patients) were included, and the overall pooled random-effects mean bias and SD were 0.10 ± 1.37 g/dl. In a subgroup analysis, the pooled mean bias and SD were -0.51 ± 1.59 g/dl in the intensive care unit, 0.39 ± 1.32 g/dl in the operating room, and -0.39 ± 1.73 g/dl in the emergency room. There was no statistical difference in pooled mean bias and SD among the three study settings. The pooled mean difference and SD were -0.02 ± 1.42 g/dl for the Radical-7 monitor, 0.05 ± 1.23 g/dl for the Pronto-7 monitor, and 0.18 ± 1.15 g/dl for the NBM-200 and NBM-200MP. The pooled mean bias and SD were similar among the three device groups. An important limitation to this meta-analysis was that there was significant heterogeneity even after subanalyses and sensitivity analyses, indicating a continued need for further investigations into the accuracy and precision of continuous NIHb monitoring.

Pediatric patients can easily be exposed to anemia and hypovolemia as a result of their decreased intravascular volume as compared with adults. For this population, a minor amount of bleeding can cause a significant decrease in oxygen delivery. In addition, especially in young children, frequent blood withdrawal can lead to iatrogenic anemia. Therefore, an evaluation of the reliability of NIHb monitoring is an important issue in pediatric patients. However, there have only been five studies assessing the accuracy and precision of NIHb monitoring in children [10,21–24]. The characteristics of these studies are listed in Table 1. Park *et al.* [10] assessed the accuracy and precision of NIHb monitoring in 40 pediatric patients undergoing neurosurgery. The overall mean bias and SD were 0.90 ± 1.35 g/dl (limits of agreement -1.74 to 3.54 g/dl). They also investigated the impact of acute volume loading induced hemodilution on the accuracy. The bias and SD immediately after intravascular volume expansion were not significantly different from those before volume administration (after volume loading: 1.18 ± 1.28 g/dl, after administration of colloid: 1.22 ± 1.33 g/dl, and after administration of RBC: 1.09 ± 1.17 g/dl). Patino *et al.* [24] conducted a validation study of NIHb monitoring in children undergoing major surgery. The mean bias and SD were 0.4 ± 1.3 g/dl. After an in-vivo adjustment using a reference value, the bias was significantly improved (0.1 ± 1.2 g/dl, $P = 0.01$), indicating a strong clinical potential for such adjustments in the future. Currently, the data in both the adult and pediatric population have shown a relative agreement although it is quite limited, especially in pediatric patients. In addition, there are significantly limited data on the accuracy of NIHb monitoring in anemic patients, although this is truly required for clinical applicability. As such, further studies are needed to investigate the

Table 1. Patient characteristics in studies including pediatric patients

Authors	Year	Setting	Sample size	Age, mean (SD) or median (range)	Sex (male/ female)	Tested device	Bias (g/dl) (mean ± SD)	LOA (g/dl)
Park *et al.* [10]	2012	Neurosurgery patients	40	6.4 years (3.0 years)	25/15	Radical-7	0.90 ± 1.35	−1.74 to 3.54
Amano and Murakami [21]	2013	Healthy children	43	2.2 years (2.0 years)	21/22	Radical-7	−0.6 ± 1.1	−2.76 to 1.56
Dewhirst *et al.* [22]	2013	Patients undergoing CHD repair	45	13.1 years (12.9 years)	NA	Radical-7	−0.1 ± 1.5	−2.8 to 3.1
Jung *et al.* [23]	2013	Neonatal ICU	56	20 days (1–98 days)	30/26	Radical-7	0.86 ± 1.73	−2.54 to 4.26
Patino *et al.* [24]	2014	Major surgery patients	46	(0.2–17 years)	29/17	Radical-7	0.4 ± 1.3	−2.0 to 3.2

CHD, congenital heart disease; LOA, limits of agreement; NA, not available; SD, standard deviation.

reliability of NIHb monitoring in patients with lower Hb concentrations.

FACTORS AFFECTING THE ACCURACY OF NONINVASIVE HEMOGLOBIN MONITORING

Many clinical factors have an impact on the accuracy of NIHb monitoring. Of these factors, Hb concentration and peripheral perfusion are the two most important factors required for an accurate measurement.

Hemoglobin concentration

The bias of NIHb monitoring is reported to be inversely correlated with Hb concentration [7,9,10,25]. Applegate *et al.* [7] investigated the accuracy and precision of NIHb monitoring in patients undergoing abdominal or pelvic surgery. The average bias was 0.50 ± 1.44 g/dl (LOA: −2.3 to 3.3 g/dl). However, the difference became larger in patients with Hb less than 9.0 g/dl, blood loss more than 1000 ml, and those who underwent an intraoperative transfusion. In pediatric patients, the mean difference was −0.03 g/dl when Hb concentration was more than 11 g/dl, which was significantly less when compared with the biases of patients with Hb concentrations of 9–11 g/dl (1.17 ± 1.35 g/dl), and with Hb concentrations of less than 9 g/dl (1.24 ± 1.19 g/dl) ($P = 0.004$) [10]. In a study by Gayat *et al.* [25], the inverse linear relation between the bias and the true Hb concentration was also found in both the Pronto-7 and NBM-200MP: correlation coefficient was −0.51 for Pronto-7 ($P < 0.0001$), and −0.37 for NBM-200MP ($P < 0.0001$). As shown in these studies, when Hb concentration is low, Hb values measured by NIHb monitoring tend to overestimate the true Hb concentration. This can lead to a serious problem in that the patients with a low Hb concentration may not receive necessary transfusions.

Peripheral perfusion

The perfusion index value, as an indicator of peripheral perfusion, has an impact on the accuracy of NIHb monitoring, with the accuracy improving as perfusion index increases [9,26,27]. Miller *et al.* [28,29] showed that a digital nerve block improved the accuracy of NIHb monitoring by increasing the peripheral perfusion. Patients with a nerve block were much more likely to have a bias of less than 0.5 g/dl (37% with nerve block versus 12% without nerve block) [28]. Coquin *et al.* [8] investigated the accuracy in critically ill patients with gastrointestinal bleeding, and found that the number of unavailable measurements associated with inadequate perfusion index values was significantly higher in patients with noradrenaline administration (42% versus 15%, $P < 0.05$). In addition, as Lee *et al.* [30] indicated in the recent review, the presence of peripheral vascular disorders can affect the accuracy of NIHb measurement. Thus, vasopressor administration and other causes of decreased peripheral perfusion can lead to an inadequate accuracy of NIHb monitoring.

TRENDING ABILITY OF NONINVASIVE HEMOGLOBIN MONITORING

Although most of the studies assessing the reliability of NIHb monitoring have focused on its accuracy and precision when compared with laboratory measurements, the ability to detect Hb changes, or trends, caused by bleeding and transfusion has strong clinical potential. Unfortunately, only a few studies have evaluated these devices' trending ability (Table 2) [10,24,31–33]. Four studies have shown

Table 2. Patient characteristics in studies assessing the trending ability of noninvasive hemoglobin monitoring devices

Authors	Year	Setting	Sample size	Age mean (SD) or median (IQR or range)	Sex (male/female)	Tested device	Intervention	Statistical analysis
Colquhoun *et al.* [31]	2012	Patients undergoing spine surgery	20	NA	NA	Radical-7	None	CR in four-quadrant plot 94% CR in polar plot 90%
Park *et al.* [10]	2012	Neurosurgery patients	40	6.4 years (3.0 years)	25/15	Radical-7	Volume expansion	CR in four-quadrant plot 94.4%
Giraud *et al.* [32]	2013	Patients undergoing major surgery	53	63 years (IQR: 55–75 years)	30/23	Radical-7	None	Angular bias in polar plot $-17.3^\circ \pm 19.2^\circ$ (mean $\pm$ SD)
Patino *et al.* [24]	2014	Major surgery patients	46	(Range: 0.2–17 years)	29/17	Radical-7	None	CR in four-quadrant plot 95%
Toyoda *et al.* [33]	2014	Major surgery patients	56	57 years (17 years)	NA	Four-wavelength pulse oximeter	None	CR in four-quadrant plot 77%

CR, concordance rate; IQR, interquartile range; NA, not available; SD, standard deviation.

a four-quadrant plot analysis, with two studies utilizing a polar plot analysis. In the studies with a four-quadrant plot analysis, Hb change measured by NIHb monitoring showed a certain degree of agreement with the reference method. However, as Pologe [34] indicated, when assessing the trending ability of the Hb monitoring, essential information estimates the magnitude of the change in Hb. To this point, a four-quadrant plot analysis is inadequate as this analysis simply provides the directionality of the Hb changes. Colquhoun *et al.* [31] assessed the tracking ability using a polar plot analysis and found a good agreement with the concordance rate of 90%, whereas Giraud *et al.* [32] reported a poor agreement with angular bias and SD of $-17.3^\circ \pm 19.2^\circ$. It is worth mentioning that most of the studies evaluating the NIHb tracking ability simply compared Hb values between two time points and did not include any clinical interventions, such as volume expansion or transfusion. Such dynamic clinical states would be useful for assessing the technology in a relevant scenario. Because of the small amount of such limited data, we cannot yet make a definite judgement about the trending ability of NIHb monitoring.

CONCLUSION

NIHb monitoring is a recently developed medical technology that has the potential to improve clinical decision making in the perioperative and critical care periods. Currently, validation studies have shown a significant agreement when compared with laboratory measurements. However, the data from this technology are limited, especially in pediatric patients and those with significant anemia. As trending requires multiple time points in a short period, NIHb has strong potential to become the best approach for monitoring acute Hb fluctuations. Currently, invasive Hb measurements should remain as the first choice when dealing with hemodynamically unstable patients. We need to continue developing a broader range of knowledge about these devices, including the optimal statistical approach for evaluating accuracy. We also need to execute additional studies, including randomized controlled trials, to determine the actual clinical impact on patient outcome and safety.

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Conflicts of interest

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