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Evaluation of non-invasive hemoglobin measurement in pediatric intensive care units

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Evaluation of non-invasive hemoglobin measurement in pediatric intensive care units.

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Abréviations

BMI : body mass index

CI : Confidence interval

CBC : Cell blood count, H: Hour

EMR : electronic medical record

ICCA©: IntelliSpace Critical Care and Anesthesia©

H : Hour

Hb : hemoglobin

HR : heart rate

Kg : kilogram

LabHb : hemoglobin measured in the laboratory

PICU : pediatric intensive care units

PIM : pediatric index of mortality

SD : standard deviation

SpHb : noninvasive hemoglobin monitoring by spectrophotometry

SpO2 : oxygen saturation

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Préambule

L'oxymétrie de pouls a été découverte en 1971 par Takuo Aoyagi lorsqu'il étudiait la mesure non invasive du débit cardiaque à l'aide d'une technique de dilution de colorant. Depuis, l'oxymétrie de pouls est devenue la technologie de monitoring la plus couramment utilisée car elle permet la mesure de plusieurs variables : la saturation en oxygène de l'hémoglobine, la fréquence cardiaque pulsée mais aussi le rythme cardiaque. Son utilisation à grande échelle a permis de développer des méthodes de mesure non invasive concernant d'autres caractéristiques sanguines et notamment la concentration en hémoglobine.

L'analyse conventionnelle en laboratoire de la concentration d'hémoglobine est réalisée à l'aide d'un spectrophotomètre et est basée sur la loi de Lambert-Beer. Cette loi stipule que la quantité d'intensité lumineuse absorbée par une solution est appelée "absorbance" (A) et qu'elle est directement proportionnelle :

- Au coefficient d'absorption molaire (ϵ), qui est une propriété physique unique de la solution pour une longueur d'onde spécifique.
- À la longueur du trajet optique (d), qui est la distance que la lumière doit parcourir à travers la solution.
- À la concentration molaire de la solution (c).

Cette relation peut être exprimée comme suit :

$$A = \epsilon dc$$

L'hémoglobinomètre de laboratoire crée d'abord une suspension d'hémoglobine en hémolysant un petit échantillon de sang dans un puit, éliminant ainsi l'absorption de la lumière par la membrane de l'érythrocyte. Une lumière d'une longueur d'onde et d'une intensité connue est ensuite diffusée à travers le puit contenant la suspension d'hémoglobine. Enfin, l'intensité de la lumière transmise est mesurée. Comme toutes les propriétés physiques du puit et de la lumière sont connues, la concentration d'hémoglobine peut ainsi être calculée car il s'agit de l'unique inconnue selon la loi de Lambert-Beer.

Un oxymètre de pouls transillumine les tissus avec deux longueurs d'ondes lumineuses (rouge, 660 nm ; et proche infrarouge, 940 nm) puis utilise un spectrophotomètre pour le calcul de la saturation en oxygène de l'hémoglobine selon l'absorbance de la lumière. S'agissant de la même méthode de mesure que l'hémoglobinomètre de laboratoire, des efforts ont été faits pour modifier l'oxymètre de pouls afin qu'il mesure également la

concentration d'hémoglobine. Plusieurs différences empêchant l'utilisation de la loi de Lambert-Beer ont compliqué le développement de cette technique de mesure :

- Le tissu à travers lequel la lumière est transmise n'est pas homogène à la différence de la suspension d'hémoglobine en laboratoire.
- La taille du doigt change, d'un doigt à l'autre et d'une personne à l'autre, ce qui rend la longueur du trajet optique variable.

Masimo (Irvine, CA) a introduit la technologie SET (Signal Extraction Technology) pour améliorer la précision de l'oxymétrie de pouls à 2 longueurs d'ondes dans des conditions de mouvement et de faible perfusion. Elle comprend des filtres, des capteurs protégés de la lumière et des radiofréquences, et des algorithmes de traitement numérique. La technologie Rainbow SET de Masimo a été introduite en 2008 (ajout de nombreuses longueurs d'ondes) pour mesurer les concentrations totales d'hémoglobine, de méthémoglobine et de carboxyhémoglobine.

Au sein de notre unité, nous utilisons ce dispositif de surveillance non invasive de l'hémoglobine développé par Masimo, et tel que décrit précédemment depuis 2021. Nous avons choisi de réaliser une étude concernant son utilisation dans un service de réanimation pédiatrique. Ce travail de thèse a été rédigé selon un format article en anglais et présente les résultats de nos recherches.

Introduction

Children hospitalized in the pediatric intensive care units (PICU) are at high risk of anemia. In the PICU, the vast majority of children (up to 74%) will have to face anemia at least one time during their stay (33% on admission, 41% during their stay)(1). The causes of anemia in these patients are numerous: excessive or repeated blood loss following abdominal trauma or post-operative complications, chronic diseases, deficiency disorders, liver dysfunction or disseminated intravascular coagulation...(1,2) Besides, pediatric patients are also at risk of iatrogenic anemia due to repeated blood sampling required for proper monitoring, resulting in significant blood loss (3). As a consequence, many patients hospitalized in the PICU may require transfusions, which is associated with worse outcomes (more days on mechanical ventilation, increased mortality, more nosocomial infections and cardiorespiratory dysfunction)(1,4). This makes rapid, reliable diagnosis of anemia all the more important.

However, this diagnosis relies on blood analysis, which presents obvious difficulties in children (5). The traditional method to obtain blood sample is invasive, requiring venipuncture with a needle, a painful procedure sometimes made difficult by poor venous capital or the child's lack of cooperation (6). Such procedures can provoke severe distress and anxiety, especially when repeated. It can therefore be traumatic for patients and their parents, and a source of great discomfort for paramedical staff faced with the child's suffering (6,7).

In addition, technical and time constraints are associated with the conventional invasive method. Indeed, samples have to be transported to the laboratory and then technically processed, resulting in a delay of several minutes to several hours before results are available, not to mention unusable samples (insufficient quantity, coagulated or lost sample...). These constraints have led to the development of measuring devices used directly at the patient's bedside, such as the portable HemoCue system. It provides an estimation of hemoglobin (Hb) using a capillary blood sample taken from a fingertip. However, the reliability of these devices in intensive care units has been questioned in several studies, particularly in conditions where the capillary bed is impaired because of poor peripheral perfusion (hypovolemia, low cardiac output, vasopressor use...)(8,9). Additionally, they only allow intermittent monitoring, which can lead to avoidable errors or delays in diagnosis (8).

For several years now, non-invasive Hb monitoring devices have been developed, such as the Masimo rainbow® pulse co-oximetry sensor (Masimo Corporation, Irvine, CA). It can determine Hb concentration using a finger sensor, based on different light absorption patterns at different wavelengths (10).

Several studies have evaluated the concordance between this non-invasive hemoglobin monitoring (SpHb) and the traditional invasive method with laboratory measurement (LabHb) in healthy pediatric patients (11,12) or per-operatively (13–15). However, only three studies evaluate its use and performance in PICU with results in favor of acceptable concordance(16–18). Of these three studies, none assessed the continuous monitoring, and hence the variations and trends in SpHb values. Beyond simple value correlation, if trend accuracy could be demonstrated, the use of SpHb in PICU could enable close monitoring and help addressing the specific pediatric issues cited above.

The main objective of this study was to assess the reliability of SpHb trend compared with repeated invasive measurements considered as the goal standard. The secondary objective was to assess the reliability of SpHb absolute measurements at different time points.

Materials and methods

We conducted a single-center retrospective cohort observational study from June 1, 2021, to June 30, 2023 in a tertiary university hospital medical and surgical French PICU. This study was approved by the Local Research Ethics Committee for health research of the University Hospital of Caen on 23/06/2022 (ID 3517). The Institutional Review Board waived the need for informed consent.

Population

Patients under 18 years old at admission in the PICU and requiring SpHb monitoring during their stay were included. Patients weighing less than 3 kilograms, or with hemodynamic instability, defined as the use of noradrenaline above 0.25 mcg/kg/min and/or inotropes, or missing data, or whose parents opposed the use of the data for any retrospective study were excluded.

General management in the PICU

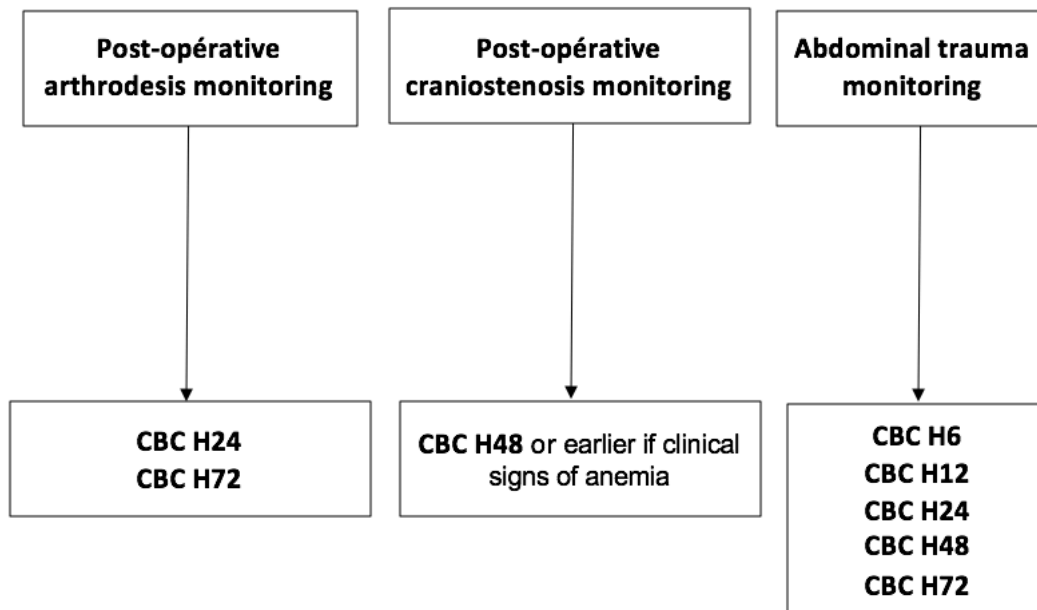


Figure 1. Hemoglobin monitoring protocol used in our PICU

CBC: Cell blood count, H: Hour

In current practice, since the implementation of SpHb monitoring in the PICU, SpHb monitoring is left at the discretion of the physicians in charge of the patient at admission based on evaluation of the risk of bleeding status. Patients considered as high-risk of bleeding and thus, requiring SpHb monitoring are patients with abdominal, orthopedic, or

cranio-facial traumatism or surgery. SpHb levels are continuously monitored using Masimo RD rainbow® SET-2 adhesive pulse co-oximetry sensors (Inf model for children weighing < 30 kg and Neo model for those weighing > 30 kg). The sensor is placed on the ring finger, index finger or hallux, to minimize interference with the child's movements. It is then connected to the Philips Intellivue X3 monitor, which continuously measures SpHb values and retransmits them to the patient's electronic medical record (EMR) (IntelliSpace Critical Care and Anesthesia (ICCA), Koninklijke Philips N.V. Amsterdam, Netherlands) at a rate of 2 values per hour. Heart rate (HR) and oxygen saturation (SpO2) are also recorded and transmitted to the EMR simultaneously. Venous blood samples are prescribed at the discretion of the physicians in charge of the patient based on local practice protocol and LabHb are measured in the central laboratory in accordance with standard operating procedures (Figure 1).

Data extraction

Data were collected from the EMR prospective database. We collected information on the following: 1) Patients' demographic characteristics: age, gender, admission date, discharge date, weight, height, body mass index (BMI); 2) Patients' medical data: reason for admission and pediatric index of mortality (PIM) score(19), SpO2, temperature and HR; 3) Patients' management: ventilatory or aminergic support; 4) Specific data : length of sensor utilization, LabHb and concomitant SpHb.

Endpoints

The primary endpoint was trend of the SpHb, defined as the difference between two measures at two different time points of SpHb, and the corresponding LabHb trend.

The secondary endpoints were the absolute value of SpHb at admission, H6, H12, H24, H48 and H72 and the corresponding LabHb.

Statistical Analysis

The distribution of quantitative variables was analyzed with the Shapiro–Wilk test. The quantitative variables are presented as median [min–max] or mean (SD) as appropriate and qualitative variables as number (percentage). Qualitative variables were compared using a paired T-test or Wilcoxon signed rank tests depending on variable distribution. SpHb measurements were compared to LabHb values, considered as the gold standard. We performed a descriptive analysis and examined the number of SpHb readings within 0-1, 1-2, 2-3 and > 3 g/dl of LabHb measurements. The correlation between SpHb and LabHb was determined by the Pearson correlation coefficient (r) and linear regression

analysis with determination coefficient (R^2). The agreement between SpHb and LabHb was evaluated measuring the mean difference and using the Bland & Altman analysis. In the Bland-Altman analysis, we calculated the bias as the mean difference between the two measures and the limits of agreement as the interval within which 95% of the differences were expected to be (20). The tolerance limit was set at ± 1 g/dl, as it is the accuracy advertised by the manufacturer. The level of statistical significance was set at a p value < 0.05 . All analyses were conducted in the complete-case analysis. Statistical analyses were performed using open-access R software, Version 4.2.1 (R Foundation for Statistical Computing, Vienna, Austria)

Results

Sixty-two patients met the inclusion criteria. Among them, ten were excluded due to missing data and 52 patients were finally included, which represented 109 pairs of SpHb and LabHb values (Figure 2).

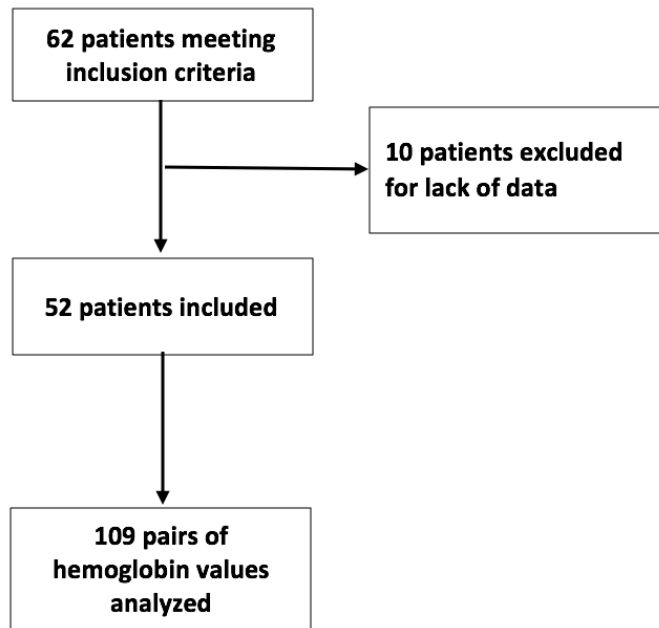


Figure 2. Flowchart

Median age was 13.1 years [7 months - 17.9 years] and median weight was 47 kg [8.5 - 86]. Most patients were admitted for monitoring after abdominal trauma (40%) or arthrodesis (36%). Other reasons (24%) were: open fracture, digestive hemorrhage, post-operative craniostenosis. The median PIM score on admission was 0.4 [0.1 - 6]. Five patients were on ventilatory support and only two patients required aminergic support. The median duration of sensor placement was two days [1 – 8] and the median length of stay was three days [1-10]. Demographic and clinical characteristics are summarized in Table 1.

Table 1. Characteristics of the study participants.

		% or [min-max]
Sexe (n) :		
Male	27	52%
Female	25	48%
Age (years)*	13.1	[0.6 - 17.9]
Weight (kg)*	47	[8.5 - 86]
Body surface (m ²)*	1.4	[0.4 - 2]
Medical history (n) :		
Cardiac	3	6%
Breathing	8	15%
Gastrology	1	2%
Neurology	6	11%
Hematology	1	2%
ORL	2	4%
Metabolic	1	2%
None	30	58%
Admission (n) :		
Arthrodesis	19	36%
Abdominal trauma	21	40%
Others	12	24%
PIM score*	0,4	[0.1 - 6.1]
Ventilatory support (n)	5	9%
Aminergic support (n)	2	4%
Sensor time (days)*	2	[2 - 8]
Length of stay (days)*	3	[1 - 10]

**expressed as median ; n : number of subjects ; PIM : Pediatric index of mortality*

Overall, the mean LabHb was 10.0 g/dl (\pm 2.1) whereas mean SpHb was 11.6 g/dl (\pm 1.5). The mean difference between the two was 1.6 g/dl (\pm 1.3). The overall correlation study showed a Pearson coefficient of 0.77(0,7-0,8) ($p < 0.001$). Correlations at admission, H12, H24, H48 and H72 ranged from 0.66 to 0.9, and all were significant. However, at H6, the correlation was non-significant ($p = 0.064$) with $r = 0.60$ (-0.03 - 0.89) (Table 2). When adjusted to the admission reason, the correlation between SpHb and LabHb remained significant ($p < 0.001$) with : $r = 0.7$ (0.4 - 0.8) in patients admitted after an arthrodesis, $r = 0.8$ (0.6 - 0.9) in patients monitored after an abdominal trauma and $r = 0.7$ (0.5 - 0.9) in other patients (Appendix 1).

Table 2. Correlation between LabHb and SpHb according to the time of measurement.

Time of measurement	Values (n)	LabHb - g/dl (mean ± SD)	SpHb - g/dl (mean ± SD)	Mean delta (SpHb - LabHb)	Correlation LabHb-SpHb (95% CI)	p < 0.001
Admission	14	10.3	11.7	1.4	r = 0.90 (0.71 - 0.97)	p < 0.001
H6	10	10.6	12	1.4	r = 0.60 (-0.03 - 0.89)	p = 0.064
H12	14	9	11.2	2.2	r = 0.82 (0.52 - 0.94)	p < 0.001
H24	37	10	11.5	1.5	r = 0.78 (0.61 - 0.88)	p < 0.001
H48	14	9,9	11.3	1.4	r = 0.66 (0.19 - 0.88)	p = 0.01
H72	20	10.2	11.7	1.5	r = 0.78 (0.52 - 0.91)	p < 0.001
Total	109	10.0 (± 2,1)	11.6 (± 1,5)	1.6 (±1,3)	r = 0.77 (0.7 - 0.8)	p < 0.001

n : number of pairs ; LabHb : hemoglobin measured in the laboratory ; SpHb : noninvasive hemoglobin monitoring by spectrophotometry ; CI : confidence interval ; SD : standard deviation ; r : Pearson correlation coefficient

Linear regression was then used to explore the relationship between the two measures, finding a statistically significant association ($p < 0.001$) with a coefficient of $R^2 = 0.6$ (Figure 3).

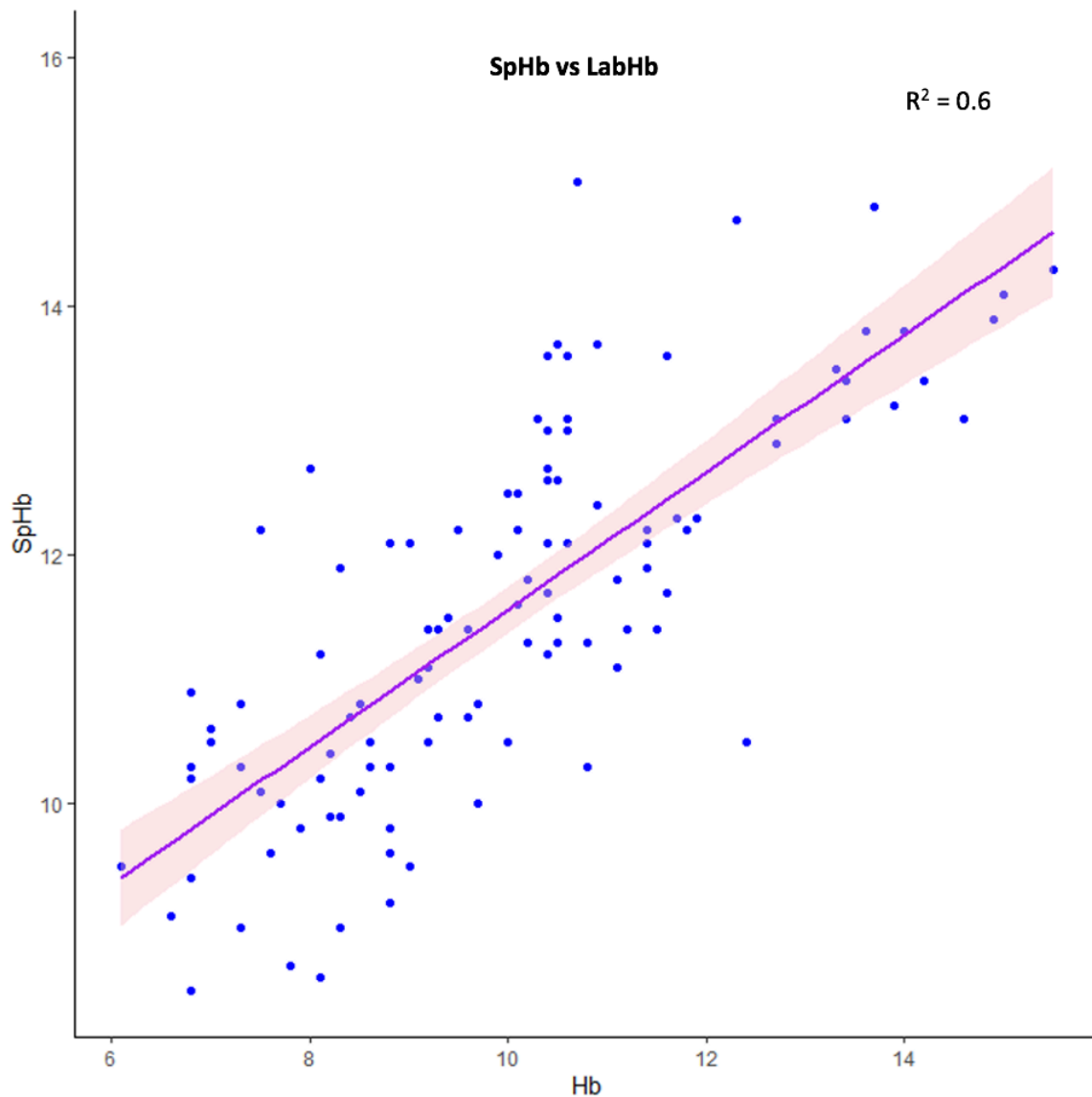


Figure 3. Scatterplot of LabHb and SpHb values. The solid line is the regression line.

We also examined the number of SpHb readings within 0-1, 1-2, 2-3 and > 3 g/dl of LabHb measurements (Table 3). It appeared that only one third SpHb readings were actually within 1 g/dl of the LabHb measurement, and approximately 60% were within 2 g/dl (Table 3).

Table 3. The percentage of patients at each 1g/dl interval difference between LabHb and SpHb measurements.

SpHb - LabHb difference (g/dl)	Number of pairs	Percents	Cumulative frequency	Cumulative percent
0 to 1	36	33%	36	33%
1 to 2	29	27%	65	60%
2 to 3	28	25%	93	85%
> 3	16	15%	109	100%

Bland-Altman analysis showed that most of the differences were within the limits of agreement, with the upper limit (+ 1,96 SD) being 1,1 g/dl and the lower limit (- 1,96 SD) being -4,2 g/dl (Figure 4). Bland-Altman analysis and linear regressions were also performed at each time of measurement (admission, H6, H12, H24, H48 and H72). Details are available in Appendix.

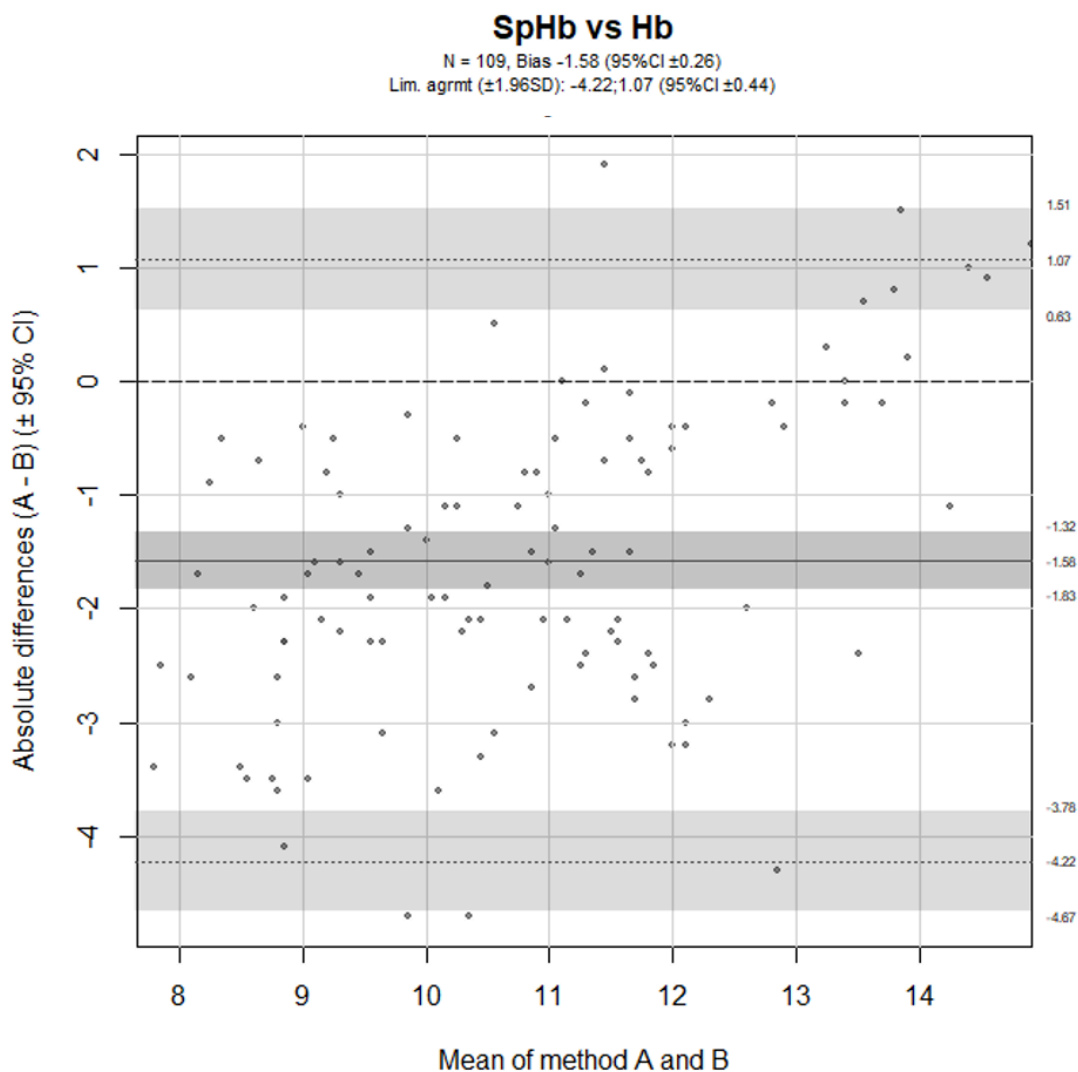


Figure 4. Bland-Altman analysis for SpHb versus LabHb. Each dot indicates the bias of a single patient at a specific time point.

Forty-one patients in our cohort had a double pair of SpHb and LabHb values, allowing us to perform a trend study. For this trend study, we chose to look at the difference between two SpHb measurements at two different times in the same patient and compare it to the difference between the two LabHb measurements using the Bland & Altman analysis. The bias between difference means was 0,3 g/dl (± 1.3), IC95% (-0.1; 0.7). Bland-Altman analysis wasn't significant ($p = 0,13$) with the upper agreement limit (+ 1,96 SD) being 2,8 g/dl and the lower limit (- 1,96 SD) being -2,2 g/dl (Figure 5).

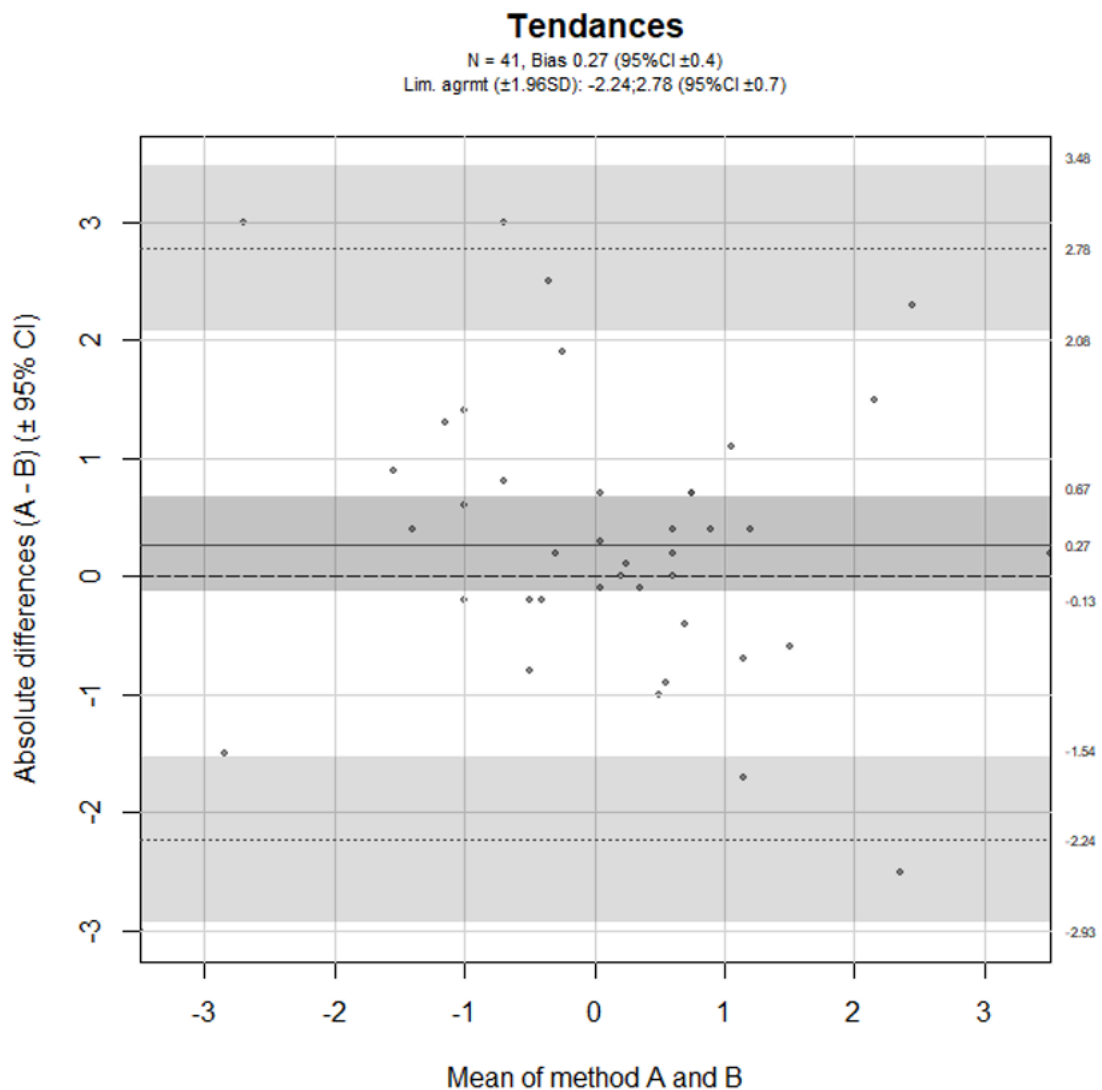


Figure 5. Bland-Altman analysis for trend study. Each dot indicates the bias between difference means of a single patient.

Discussion

This study is the first to evaluate the accuracy of trend of SpHb when compared to LabHb a high-risk of bleeding PICU cohort. This study showed that SpHb is probably able to display the true Hb trend with a mean difference of -0.3 ± 1.3 , IC95% $(-0.1 ; 0.7)$. On the other hand, the extent of the limits of agreement calls into question the precision of the system, and hence its reliability in clinical practice. In this study, SpHb even highly correlated to LabHb appeared inaccurate to predict true Hb.

A few pediatric studies have previously analyzed the accuracy and concordance of this measurement method, but most of them only involved healthy children or ones in peri-operative situations (11–15). Three prospective observational studies have evaluated this device in PICU patients (16–18). The method used and the population studied in these three cohorts are similar to ours, except for age. The median age in our study is significantly higher. These studies and their results are summarized in table 4.

Table 4: Summary of the main studies conducted on SpHb in PICU

	Akyildiz et al	Phillips et al	García-Soler et al
Year	2017	2014	2016
Country	Erciyes University Medical Faculty, Kayseri, Turkey	UNC Children’s Hospital, Chapel Hill, USA	Malaga University Hospital, Malaga, Spain
Age mean - year (SD), median [range]	3 [2-7]	6.8 (\pm NC)	1.2 [0.3 - 5]
Pairs of values	332	83	284
LabHb - g/dl (mean \pm SD)	8.71 (\pm 1.49)	11.1 (\pm 2.01)	11.7 (\pm 2.05)
SpHb - g/dl (mean \pm SD)	9.55 (\pm 1.53)	11.2 (\pm 3.08)	12,32 (\pm 2)
biais (SpHb - LabHb) (mean delta \pm SD)	0.84 (\pm 0.86)	0.07 (\pm 2.59)	0.66 (\pm 1.46)
Correlation LabHb-SpHb (95% CI)	N/A	0,55 (0.38 - 0.68)	0.69 (0.55 - 0.78)

LabHb : hemoglobin measured in the laboratory ; SpHb : noninvasive hemoglobin monitoring by spectrophotometry ; CI : confidence interval ; SD : standard deviation ; N/A : not available

Every study showed a good correlation between SpHb and LabHb ($r = 0,55$ (0.38 - 0.68)(18); $r = 0.69$ (0.55 - 0.78)(17)). However, these three studies found a lower mean difference between SpHb and LabHb (0.07 g/dl (18), 0.66 g/dl (17) and 0.84 g/dl (16) vs 1.6 g/dl in our study). This higher difference is not consistent with the technical specifications announced by the manufacturer of 1 g/dl maximum (21). This result could be due to the SpHb measurement technique. Indeed, the sensor was left in place to allow continuous monitoring with automatic reading, which was not the case in the other studies, and it may have altered the measurements (too much light, sensor poorly positioned or detached, interference, etc)(21). However, we believe that this is a more pragmatic approach and appropriate reflection of the device's use in a PICU.

In addition, this continuous installation of the sensor enabled us to systematically obtain a SpHb measurement within an hour of each blood test, which is a strength of our study. In comparison, *Garcia-soler et al.* failed to obtain a value in 5.2% of cases (17) and *Phillips et al.* had a rate of undetectable readings of 35% (18).

Among other factors likely to affect the accuracy of transcutaneous monitoring, we found greater differences when LabHb levels were particularly low. Although anemia is not specifically mentioned, the device leaflet describes haemoglobinopathies as a potential cause of errors in SpHb reading. This is consistent with other studies that shown worse correlations with extreme LabHb values (18,22).

The trend study we carried out did not find any significant difference and does not allow us to conclude on the reliability of the continuous nature of the monitoring. It is therefore possible that SpHb is not mistaken in following the evolution of LabHb. However, the limits of agreement are important, which is in favor of a poor precision of SpHb measurements. It also showed that patients monitored for high hemorrhagic risk showed little bleeding during their stay. In fact, the mean LabHb difference for the same patient was - 0.2g/dl and the median sensor installation time two days, which is shorter than the median length of stay (3 days). Indeed, hemoglobin monitoring seems to have been stopped earlier than expected in our study, probably due to the absence of bleeding in the patients. This finding raises the question of the timing of hemoglobin monitoring, and perhaps of excessive sampling.

We should acknowledge certain limitations. First, it is a retrospective, monocentric study involving a small population. Secondly, we did not investigate potential confounding

factors whereas *Philips et al.* showed that an increased BMI or skin pigmentation affected the degree of concordance (18). Effects of HR and SpO₂ variations were studied by *Paksu et al.* and no significant change of the correlation was found in healthy children (23). A linear regression study including demographic and clinical data would be useful to target the most appropriate population that could benefit from SpHb monitoring. Thirdly, we did not take into account the economic aspects of using SpHb instead of, or in addition to, laboratory analysis of blood samples. Indeed, the cost of SpHb monitoring is not negligible (95 euros per sensor) whereas the current cost for a complete blood count (CBC) in our institution is 5.20 euros, which means that the device would have to substitute for several LabHb tests to be cost-effective. One previous study involving children undergoing neurosurgery reported that such device could be used to monitor trends in Hb levels and help clinical decision-making regarding the need and timing of LabHb testing(13). Another study demonstrated that the use of the SpHb monitoring resulted in fewer intraoperative blood transfusions during orthopedic surgeries in adults, offsetting the cost of the device (24). A similar prospective study should be conducted to demonstrate the cost-effectiveness of the device in the PICU.

Despite a good correlation, our study does not allow us to define an exact role for SpHb due to a lack of precision. Two meta-analyses, mainly involving studies with adult patients, reported that this technology is not sufficiently accurate to be used as the only indicator of transfusion and clinicians should be cautious when making clinical decisions made on it (25,26). Our study supports these conclusions.

Conclusion

This study shows good correlation between SpHb obtained with the Masimo sensor and LabHb, in the PICU setting. However, there is a non-negligible bias between the 2 measurements, with a mean difference of 1.6 g/dl, which seems to increase for very low hemoglobin values. This bias is higher than that of previous studies and the one announced by the manufacturer. The value of continuous hemoglobin monitoring could not be demonstrated by our study, with a non-significant trend analysis. Target populations and clinical contexts for safe and effective use of the device have yet to be properly defined. Future studies are needed to precisely determine the potential factors altering its functioning and estimate its cost-benefit ratio, taking particular account of its potential impact on transfusion savings.

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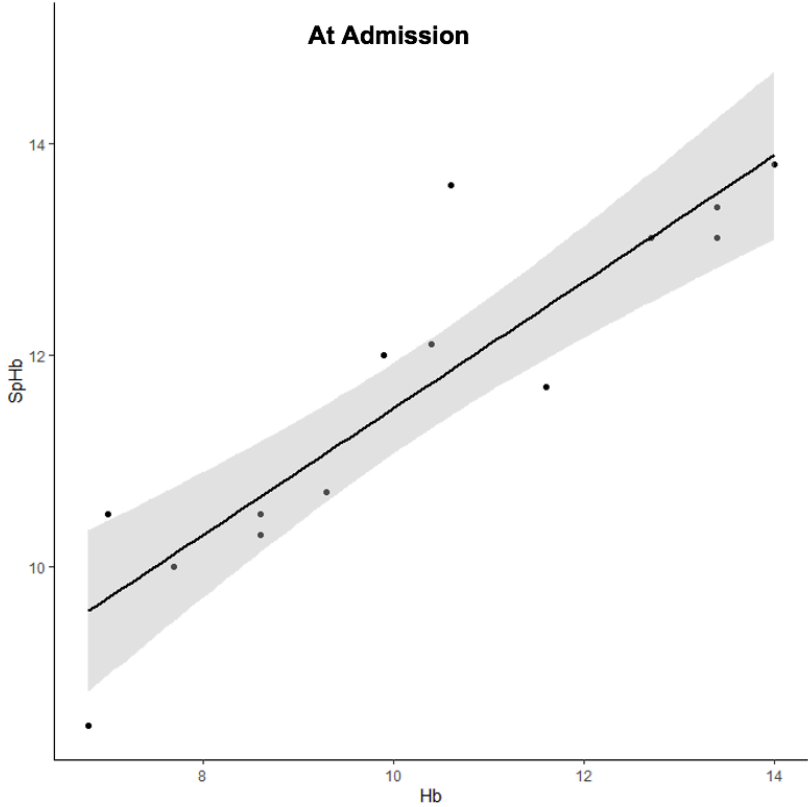
Appendices

Appendix 1: Correlation between LabHb et SpHB according to the admission reason.

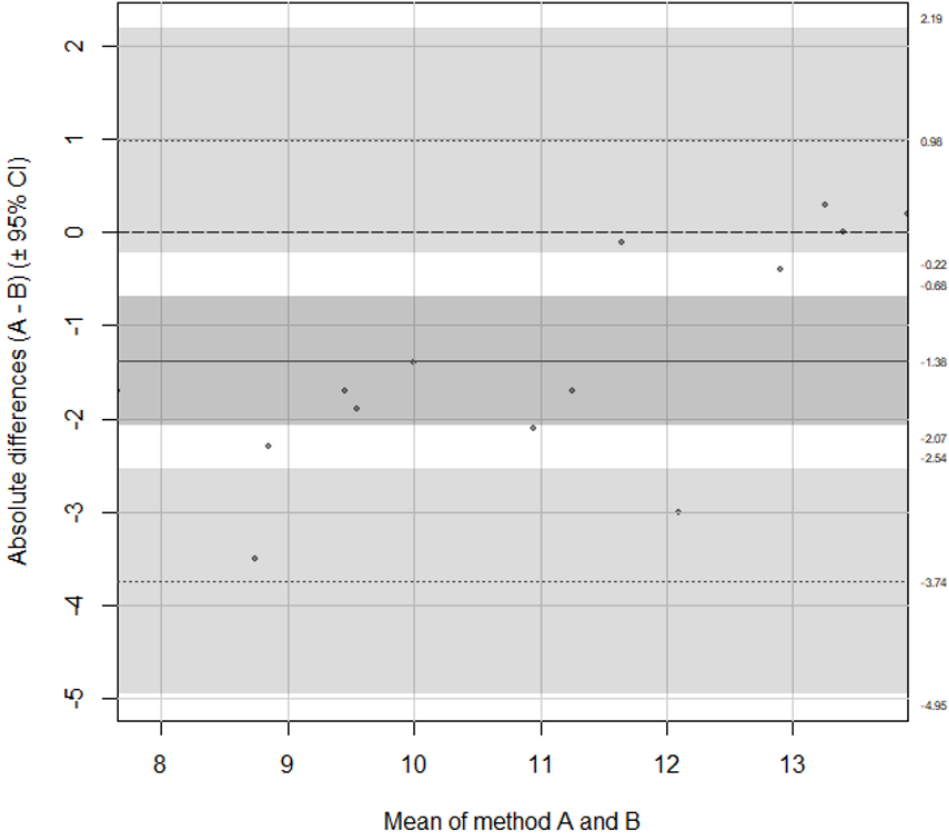
Admission reason	LabHb - g/dl (mean ± SD)	SpHb - % (mean ± SD)	Correlation LabHb- SpHb (95% CI)	
Arthrodesis (n = 33)	11.3 ± 1.4	9.8 ± 1.8	0.7 (0.4-0.8)	p < 0.001
Abdominal trauma (n = 45)	12.1 ± 1.6	10.6 ± 2.33	0.8(0.6-0.9)	p < 0.001
Others (n = 31)	11.0 ± 1.3	9.1 ± 1.8	0.7(0.5-0.9)	p < 0.001

n : number of pairs ; LabHb : hemoglobin measured in the laboratory ; SpHb : noninvasive hemoglobin monitoring by spectrophotometry ; CI : confidence interval ; SD : standard deviation

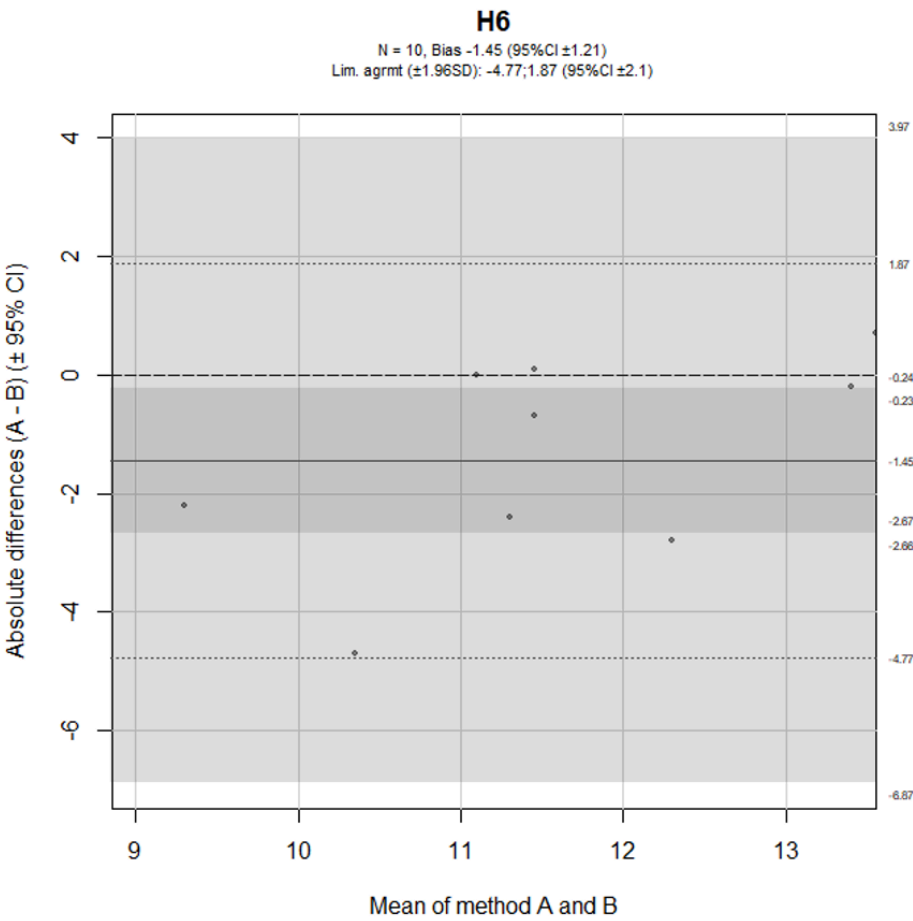
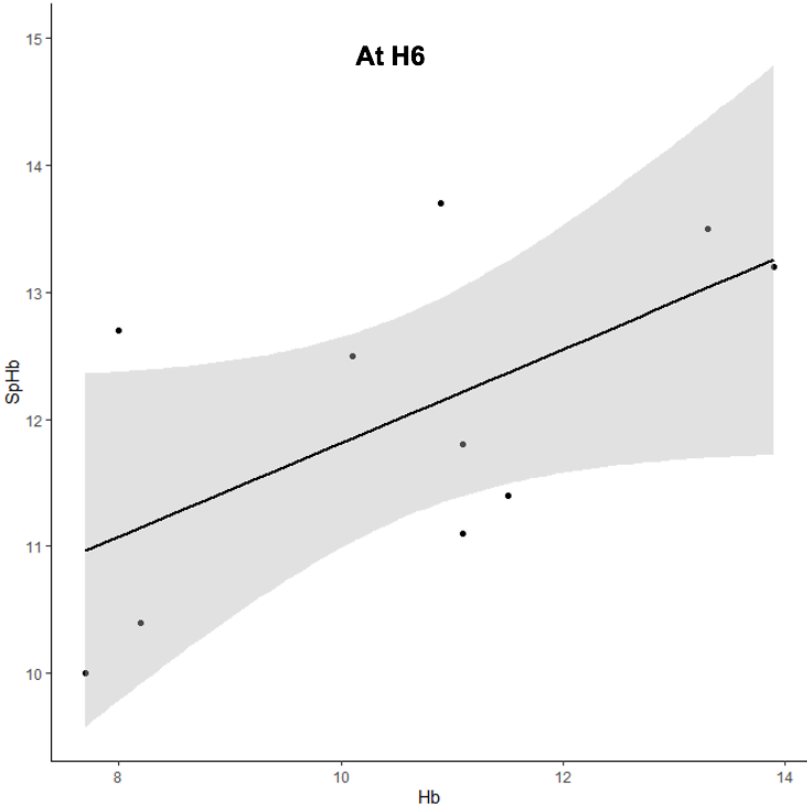
Appendix 2: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at admission.



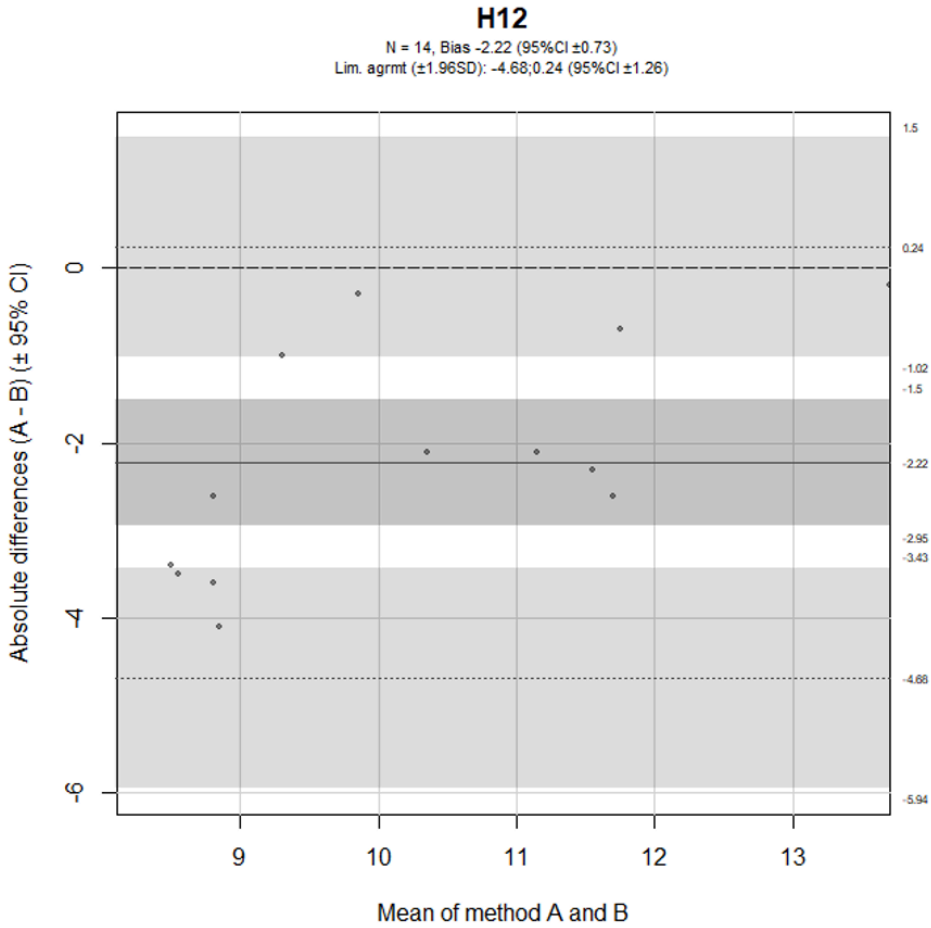
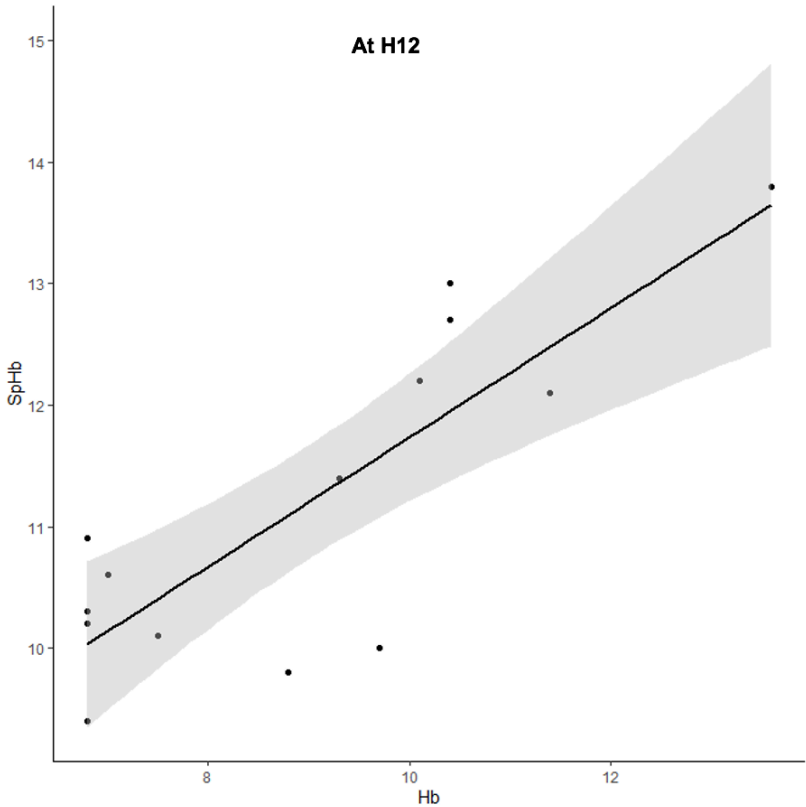
Admission
 N = 14, Bias -1.38 (95%CI ±0.7)
 Lim. agrmt (±1.96SD): -3.74;0.98 (95%CI ±1.21)



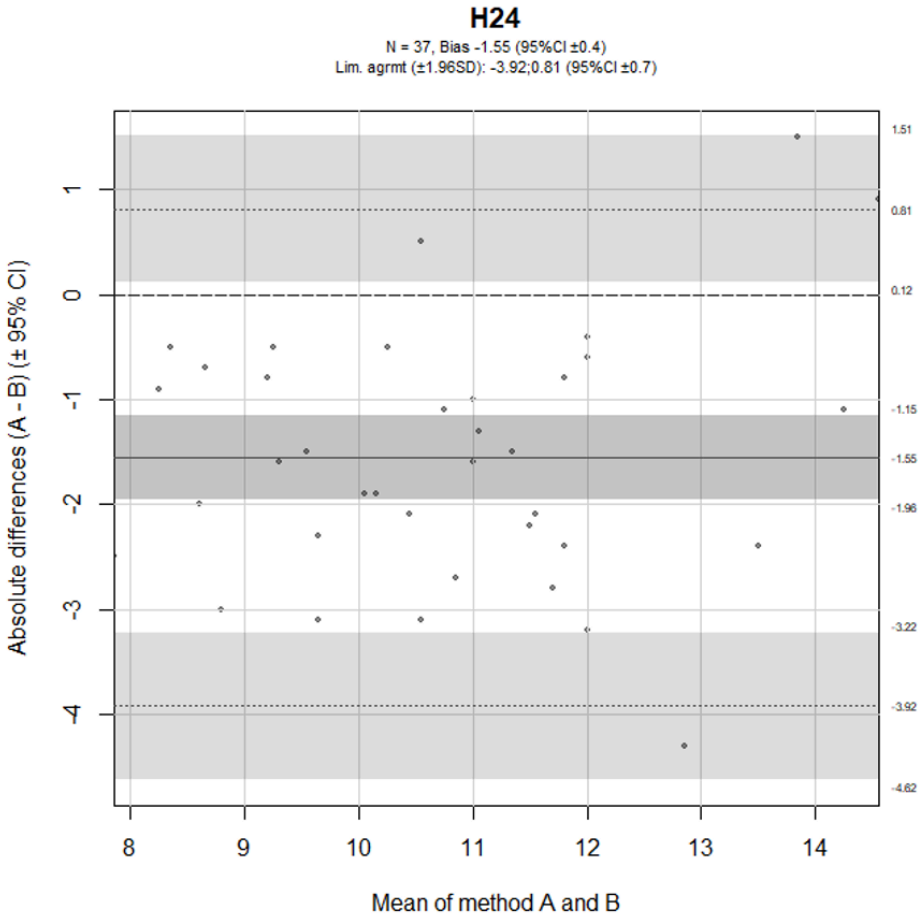
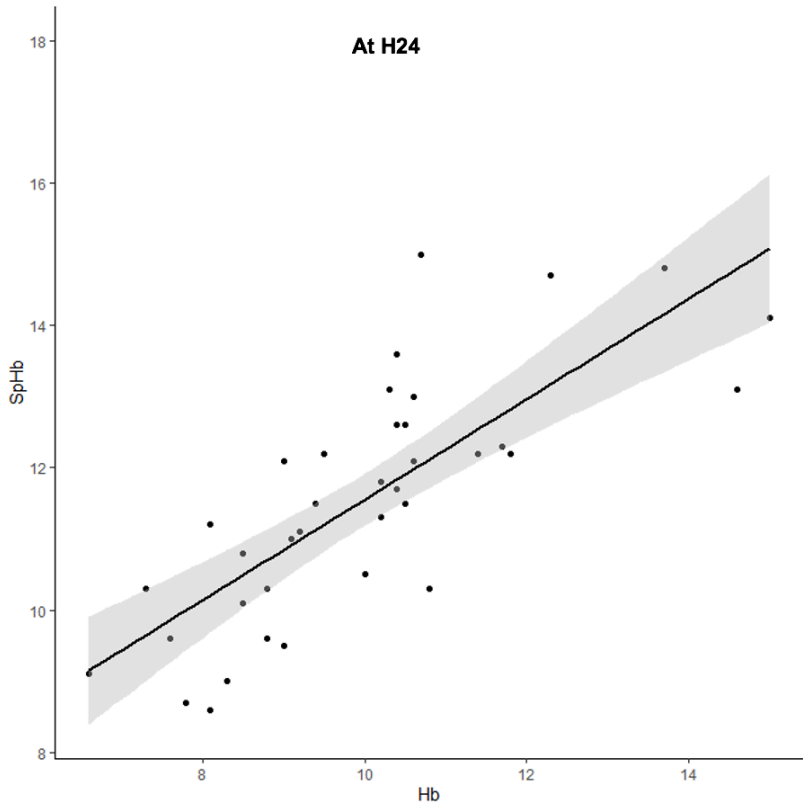
Appendix 3: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at H6.



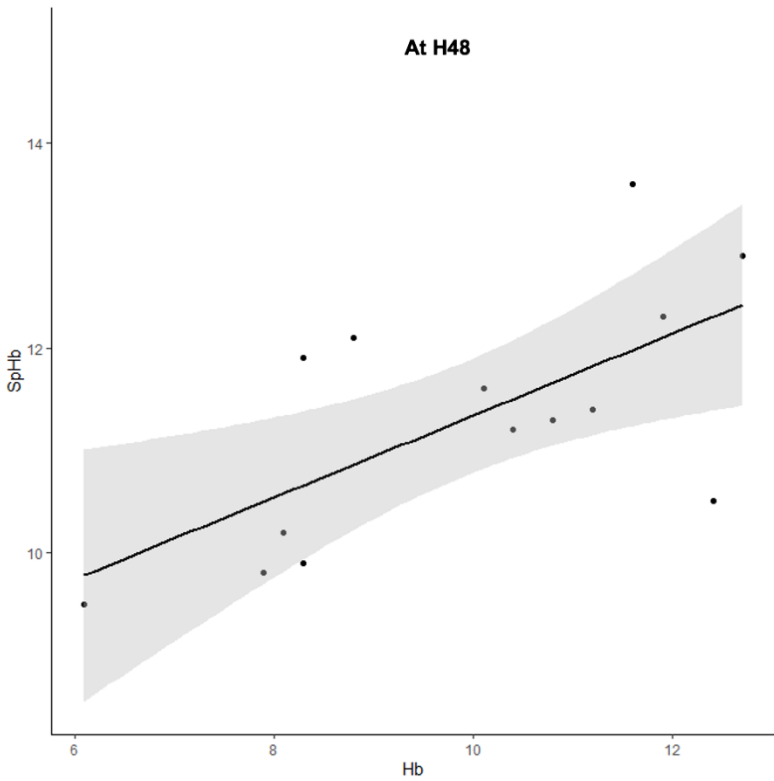
Appendix 4: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at H12.



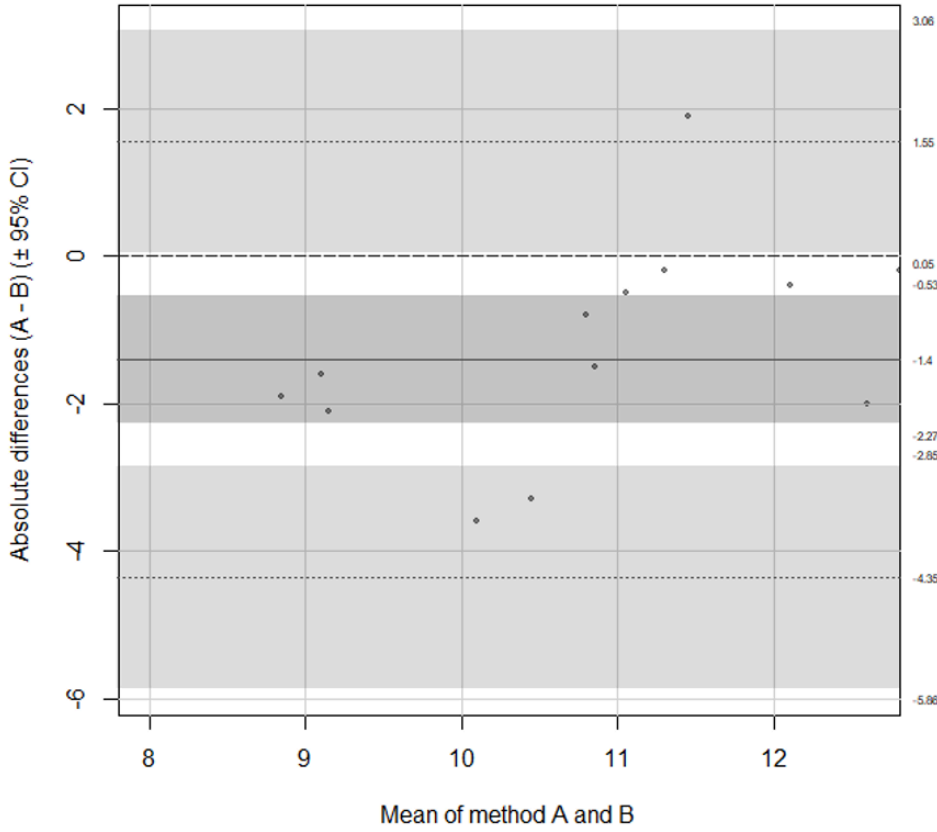
Appendix 5: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at H24.



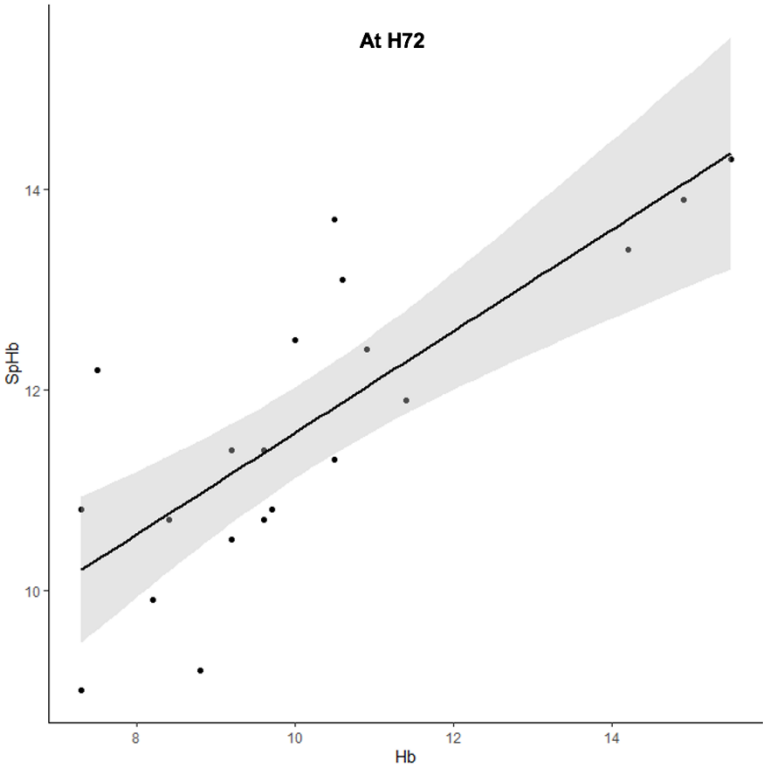
Appendix 6: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at H48.



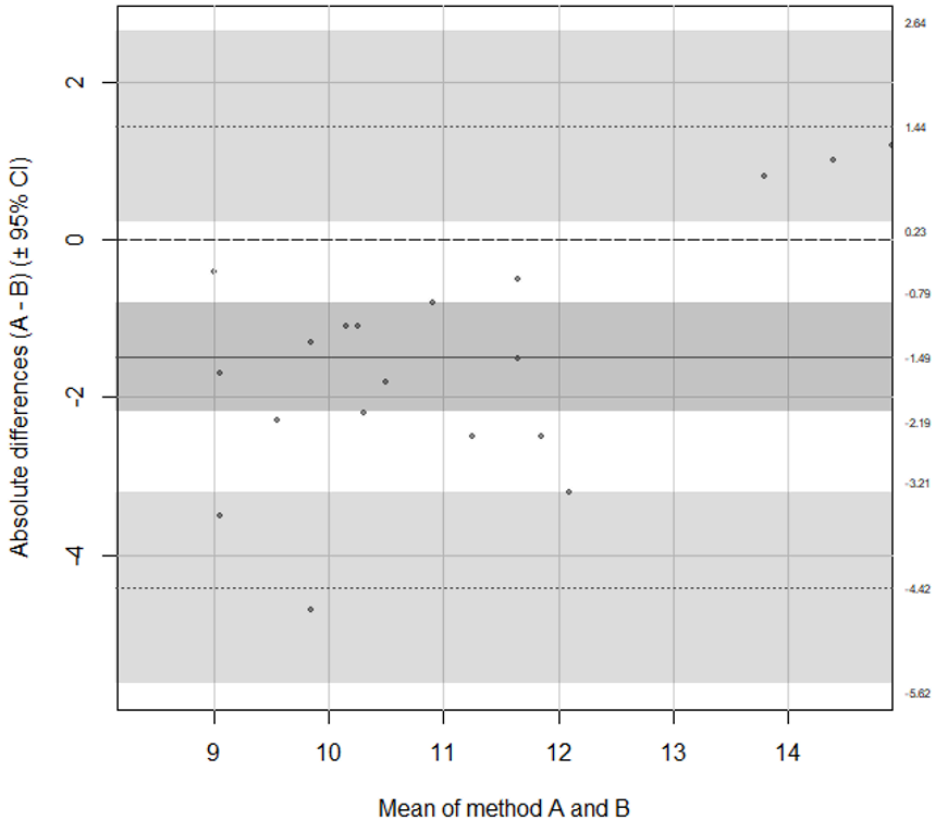
At H48
 N = 14, Bias -1.4 (95%CI ±0.87)
 Lim. agrmt (±1.96SD): -4.35;1.55 (95%CI ±1.51)



Appendix 7: Scatterplot and Bland-Altman analysis for SpHb versus LabHb at H72.



H72
 N = 20, Bias -1.49 (95%CI ±0.7)
 Lim. agrmt (±1.96SD): -4.42;1.44 (95%CI ±1.21)



« Par délibération de son Conseil en date du 10 Novembre 1972, l'Université n'entend donner aucune approbation ni improbation aux opinions émises dans les thèses ou mémoires. Ces opinions doivent être considérées comme propres à leurs auteurs ».

VU, le Directeur de Thèse
(Qui atteste du respect des procédures éthiques et réglementaires)

VU, le Président de Thèse

VU, le Doyen de la Faculté

VU et permis d'imprimer
en référence à la délibération
du Conseil d'Université
en date du 14 Décembre 1973

Pour le Président
de l'Université de CAEN et P.O

Le Doyen

ANNEE DE SOUTENANCE : 2022/2023

NOM ET PRENOM DE L'AUTEUR : DEVRED Matthieu

TITRE DE LA THESE : Évaluation de la méthode de mesure non invasive de l'hémoglobine en unité de réanimation pédiatrique.

RESUME DE LA THESE EN FRANÇAIS :

Introduction : La surveillance de l'hémoglobine dans les services de réanimation pédiatrique est un véritable enjeu. L'utilisation d'une méthode de mesure non invasive permettrait de répondre aux contraintes spécifiques d'une population pédiatrique telles que les difficultés de prélèvement ou la spoliation sanguine. Une technique de mesure par co-oxymétrie de pouls existe mais son utilisation en réanimation pédiatrique est controversée. Notre étude a pour but d'évaluer la corrélation et les tendances entre les valeurs d'hémoglobine estimées par méthode non invasive (SpHb) et celles mesurées par le laboratoire (LabHb).
Matériel et méthodes : Nous avons réalisé une étude rétrospective observationnelle sur une cohorte de 52 patients âgés de 6 mois à 18 ans, présentant un risque hémorragique élevé, hospitalisés en réanimation pédiatrique.

Résultats : 109 paires de valeurs SpHb/LabHb ont pu être étudiées. Les valeurs moyennes de LabHb et SpHb étaient de 10 g/dL et de 11,6 g/dL respectivement. Les résultats montrent une bonne corrélation avec un coefficient de Pearson $r = 0,77$ (0,7-0,8) ($p < 0,001$). L'analyse de Bland-Altman montre une différence moyenne de $1,6\text{g/dL} \pm 2,64\text{g/dL}$, avec seulement 60% des valeurs de SpHb ayant une différence de moins de 2g/dL par rapport à LabHb. L'étude des tendances est non significative ($p = 0,13$) avec une différence moyenne de $0,3\text{g/dL} \pm 1,3\text{g/dL}$ IC 95% (-0,1-0,7).

Conclusion : SpHb présente une bonne corrélation avec LabHb. Cependant, ce dispositif de surveillance manque de précision et son utilité en monitoring continu n'est pas démontré. Des études supplémentaires doivent préciser la population cible et le contexte clinique adéquat.

MOTS CLES : Hémoglobine ; anémie ; surveillance non invasive ; Unité de soins intensif pédiatrique ; Oxymétrie.

TITRE DE LA THESE EN ANGLAIS : Evaluation of non-invasive hemoglobin measurement in pediatric intensive care units.

RESUME DE LA THESE EN ANGLAIS :

Introduction: Hemoglobin monitoring in pediatric intensive care units is a real challenge. The use of a non-invasive measurement method would make it possible to respond to the specific constraints of a pediatric population, such as sampling difficulties or blood spoliation. A pulse co-oximetry measurement technique exists, but its use in pediatric intensive care is controversial. The aim of our study is to evaluate the correlation and trends between hemoglobin values estimated by non-invasive methods (SpHb) and those measured by the laboratory (LabHb).

Material and methods: We carried out a retrospective observational study on a cohort of 52 patients aged 6 months to 18 years at high risk of bleeding, hospitalized in pediatric intensive care.

Results: 109 pairs of SpHb/LabHb values were studied. Mean LabHb and SpHb values were 10 g/dL and 11.6 g/dL respectively. The results show a good correlation with a Pearson coefficient $r = 0.77$ (0.7-0.8) ($p < 0.001$). Bland-Altman analysis shows a mean difference of $1.6\text{g/dL} \pm 2.64\text{g/dL}$, with only 60% of SpHb values having a difference of less than 2g/dL from LabHb. Trend analysis was non-significant ($p = 0.13$), with a mean difference of $0.3\text{g/dL} \pm 1.3\text{g/dL}$ 95% CI (-0.1-0.7).

Conclusion: SpHb correlates well with LabHb. However, this monitoring device lacks precision and its usefulness in continuous monitoring has not been demonstrated. Further studies are needed to define the target population and the appropriate clinical context.

KEY WORDS: hemoglobin; anemia; non-invasive monitoring; pediatric intensive care unit; oximetry.