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# Accuracy and precision of non-invasive continuous haemoglobin concentration monitoring in diabetic patients

Rosanna Carmela De Rosa<sup>1\*</sup> and Antonio Romanelli<sup>2</sup>

## Abstract

**Background:** Accuracy and precision of non-invasive continuous haemoglobin concentration (SpHb) provided by Masimo device in diabetic patients is poorly studied. This retrospective analysis aimed to provide data on SpHb accuracy and precision in diabetic patients.

**Results:** The sample size population consisted of 14 patients, with 56 SpHb/Lab data pairs. Lab value showed a mean  $\pm$  standard deviation (SD) of  $13.2 \pm 1.2$  g/dL, whilst SpHb showed a mean  $\pm$  SD of  $11.8 \pm 1.1$  g/dL. Linear regression analysis between Lab/SpHb data pairs showed a  $r$  of 0.8960 (CI<sub>95%</sub> 0.8281-0.9379,  $p$  value  $< 0.0001$ ). SpHb underestimated the real Hb values provided by Lab. Bland-Altman analysis showed that SpHb accuracy was  $-1.37$  g/dL (CI<sub>95%</sub>  $-1.51$  to  $-1.22$  g/dL,  $p$  value  $< 0.0001$ ), precision of 0.55 g/dL, lower LOA  $-2.45$  g/dL (CI<sub>95%</sub>  $-2.71$  to  $-2.20$  g/dL) and upper LOA  $-0.28$  g/dL (CI<sub>95%</sub>  $-0.53$  to  $-0.02$  g/dL).

**Conclusions:** For the first time, we provided data on SpHb accuracy and precision in the diabetic population. SpHb showed a high correlation coefficient when compared with Lab values, but the wide LOA limits its accuracy.

**Keywords:** Haemoglobin, Non-invasive monitoring, Diabetes, Aortic surgery

## Background

Intraoperative haemoglobin monitoring is essential in surgeries characterised by volume variations and blood loss, as orthopaedic and vascular cardiac surgery, to limit the risks and costs associated with unnecessary blood transfusions. It is recommended that a threshold of haemoglobin (Hb) level of 8 g/dL (Carson, Guyatt et al. 2016). Although laboratory Hb measurement is considered the reference method, it has limitations because it provides a single time-related reading and requires 30-60 min before the result is available. A second faster option is offered by CO-oximetric blood gas analysis, allowing the evaluation of Hb value in 1-2 min. However, both methods are the simple “static” picture of an

evolving landscape, and multiple blood samples are needed to evaluate the Hb trend.

The clinicians can consider a third option to provide helpful information: the non-invasive, continuous monitoring of Hb concentration (SpHb). SpHb monitoring device, as Masimo rainbow SET<sup>®</sup> Radical 7 Pulse CO-Oximetry™, is based on pulse CO-Oximetry and uses multiwavelength technology that provides continuous, non-invasive measurement of Hb in arterial blood. The measurement is taken by a sensor able to measure Hb, usually on the fingertip. An optical shield that covers the sensor prevents optical interference by other light sources. A stable SpHb reading is associated with corrected sensor placement and acceptable levels of arterial perfusion at the measurement site. A meta-analysis (Shabaninejad, Ghadimi et al. 2019) concluded that, after the first Hb assessment by laboratory method, the clinician could follow the trend of variations in Hb using the non-invasive method.

\* Correspondence: [rosderosa.rdr@gmail.com](mailto:rosderosa.rdr@gmail.com)

<sup>1</sup>Anaesthesia and Intensive Care Monaldi Hospital, AORN dei Colli, Via Leonardo Bianchi, 80131 Naples, Italy  
Full list of author information is available at the end of the article

One factor that influences the accuracy and precision of SpHb measurements is the local perfusion. Clinical conditions and diseases, altering local blood flow, can be related to artefacts or misreadings (Lee, Park et al. 2014). As stated by Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™ instruction manual (Corporation 2012), peripheral vascular disease (PVD) may be related to inaccurate readings of SpHb. DM causes generalised vascular damage and represents the strongest risk factor for the development of arterial PVD (Newman, Rockman et al. 2017). Arterial PVD involves the lower extremity artery, whilst the SpHb probe site is a hand finger, and arterial PVD is rare at this site. However, in the literature, there is a lack of data about the relationship between the presence of DM and clinical performance of Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™.

The aim of this retrospective study is to analyse the SpHb accuracy and precision provided by Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™ in diabetic patients scheduled for elective vascular surgery.

## Methods

The present study is a retrospective analysis. We used data collected from 72 patients scheduled for elective open abdominal (sub-renal) aortic aneurysm repair in a single surgery centre (AORN dei Colli, Monaldi Hospital, Naples).

During the anesthesiologist consultation, the following data were collected: age, sex, weight, height, body mass index (BMI), American Society of Anesthesiology (ASA) physical status and comorbidities [coronary heart disease (CAD)], previous coronary aortic bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA), cardiomyopathy, arterial hypertension, diabetes mellitus, obesity (defined as  $BMI \geq 30 \text{ kg/m}^2$ ), chronic kidney disease [CKD, according to KDIGO clinical practice guideline (Andrassy 2013)], chronic obstructive pulmonary disease [COPD, according to GOLD guideline (Mirza, Clay et al. 2018)], transient ischemic attack (TIA) or stroke. In addition, the Vascular-Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity score (V-POSSUM) was used to provide more information on morbidity and mortality rates (Reis, Lopes et al. 2020). The exclusion criteria were as follows: age  $\geq 85$  years, ASA  $\geq$  IV, NYHA  $\geq$  III, a predicted morbidity rate with V-POSSUM  $< 15\%$ .

Before entering the operating room, all patients were premedicated with morphine (10 mg, im). Intra-operative standard monitoring included ECG, SpO<sub>2</sub>, end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>), non-invasive blood pressure and diuresis. A 16-14 gauge venous access was placed at the left arm, and the radial or humeral artery was cannulated for invasive blood pressure monitoring. In addition, we monitored the depth of anaesthesia with

bispectral index (BIS™, Medtronic, Minneapolis, MN, USA), neuromuscular blocking (TofCuff®, RGB Medical, Madrid, Spain), skin temperature.

For SpHb measurement, we used the Masimo Rainbow SET Radical 7°. The model was VKF-RAD7A, and the sensor was composed of disposable optical sensor (DOS-Rainbow R2-25a) and reusable optical sensor (ROS-Rainbow R2-25r). We applied the Masimo platform (with a cover to avoid optical interference) to the middle or index finger of the patient's hand, free from venous and arterial lines or monitoring devices, in the absence of nail polish or acrylic nails.

We induced general anaesthesia with propofol (0.7 mg/kg), midazolam (0.07 mg/kg), sufentanil (0.4 mcg/kg) and rocuronium (0.6 mg/kg). After oro-tracheal intubation, the patient was connected to the mechanical ventilator (Dräger Zeus®, Drägerwerk, Lubeck, Germany) in volumetric mode (tidal volume 6 mL/kg of ideal body weight, Auto Flow system, PEEP 5 cmH<sub>2</sub>O, respiratory rate 12-16/min keeping an EtCO<sub>2</sub> between 35 and 40 mmHg, FiO<sub>2</sub> 50%, closed circuit with automatic gas control). For the maintenance of anaesthesia, we used desflurane (expired values 3-4%, BIS target value between 40 and 60%), continuous infusion of remifentanil (0.15 mcg/kg/min) and rocuronium (0.2 mg/kg) guided by neuromuscular monitoring.

After induction, to monitor central venous pressure (CVP) and continuous central venous O<sub>2</sub> saturation (ScvO<sub>2</sub>), we placed in the internal jugular vein the PreSep central venous catheter (Edwards Lifesciences, Irvine, CA, USA).

For a "tailored" use of fluids and drugs (vasoconstrictors, vasodilators, inotropes and  $\beta$ -blockers), we adopted a goal-directed therapy (GDT) protocol. Haemodynamic parameters were monitored by EV 1000™ platform (Edwards Lifesciences, Irvine, California, USA), using the pulse-contour method with FloTrac or Volume View module. The GDT protocol was based on optimising the stroke volume index (SVI) (Johnson and Mohajer-Esfahani 2014).

The basal crystalloid infusion rate (balanced electrolyte solution) was 1-3 mL/kg/h. After induction, in stable haemodynamic conditions, we calculated the maximal SVI using the following protocol: the initial SVI value was noted, and a colloid bolus (fluid challenge, 3 mL/kg, with Voluven®) was made; the new SVI value was noted, and the variation from baseline ( $\Delta\text{SVI}\%$ ) was calculated. In the case of a positive response to the fluid challenge ( $\Delta\text{SVI}\% > 10\%$ ), another fluid challenge was performed after 10-15 min to reach  $\Delta\text{SVI}\% < 10\%$ . The last SVI value with a positive response to the fluid challenge represented the maximum SVI, and the SVI trigger was calculated as follows:

$$\text{SVI}_{\text{Trigger}} = \text{SVI}_{\text{Max}} - 10\% \text{SVI}_{\text{Max}}$$

A fluid challenge was performed when the SVI reached a value below the SVI trigger.

If, despite SVI optimisation, mean arterial pressure (MAP) was  $< 65$  mmHg (i.e. after aortic declamping), intravenous norepinephrine (0.01–0.02 mg) was administered to maintain adequate organ perfusion (Salmasi, Maheshwari et al. 2017).

Whenever possible, intraoperative blood salvage was adopted. The volume of blood in the suction chamber represented an estimation of the blood loss volume.

To avoid hypothermia, we used the HOTLINE® fluid and blood heater (temperature range between 37 and 39 °C).

We recorded total volumes of crystalloids, colloids, blood products, the percentage of patients receiving blood products, and vasopressor drugs.

We collected three simultaneous Hb measurements for each patient: laboratory (Lab), blood gas analysis (BGA) and SpHb.

For invasive methods, BGA with the GEM Premier 4000 Blood Gas Analyser (Instrumentation Laboratory) and conventional laboratory analysis with the COULTER® LH 780 (Beckman Coulter, Inc.), we took a sample of 5 mL of blood from the arterial line, after discarding 10 mL of blood. The arterial line was 44 cm in length with a dead volume of about 1 mL. At the same time, we registered the SpHb value.

For each patient, we performed four measurements of Hb concentration at specific times: after the induction of anaesthesia ( $T_0$ ), pre and post-aortic cross-clamping ( $T_1$  and  $T_2$ ) and at the end of surgery ( $T_3$ ). GDT protocol started at  $T_0$ , and the anesthesiologist noted SpHb value. According to the sample times, the anesthesiologist noted the haemodynamic (MAP, CVP, heart rate, SVI, CI, body temperature, ScvO<sub>2</sub>), BGA parameters (pH, base excess, lactate) and body temperature.

The anesthesiologist was the same in all interventions, and the value obtained from BGA and not the value of SpHb was the parameter for intraoperative clinical decision.

### Statistical analysis

Due to retrospective nature of the study, no sample size calculation was performed and statistics was computed based on available data.

According to the aim of the present retrospective analysis, we considered only diabetic patients. Moreover, to avoid bias, we excluded patients that required intraoperative pure red blood cell (PRBCs) transfusions.

We performed statistics with Microsoft Excel 2016 (Microsoft Corp., Redmond, WA, USA) and MedCalc® Statistical Software version 20 (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2021).

Categorical variables were reported as absolute number and percentage (%), whilst continuous data were

tested for normal distribution with Shapiro-Wilk test ( $\alpha = 0.05$ ), and reported as mean  $\pm$  standard deviation (SD) or median, first and third quartile [ $Q_1$ – $Q_3$ ], minimum (min) and maximum (max) values.

We used only the Hb values provided by Lab, considered as the reference method, and SpHb. Due to the present study's retrospective nature, we verified the assumption of the normal distribution with the Shapiro-Wilk test to perform Bland-Altman analysis (Giavarina 2015, Dogan 2018). In the case of not normal distribution, we calculated Spearman's correlation coefficient. If normally distributed, we performed regression analysis between the measurement methods (Lab vs SpHb) and calculated Pearson's correlation coefficient ( $r$ ). We proceeded with Bland-Altman analysis and calculate accuracy, confidence intervals of 95% (CI<sub>95%</sub>), precision and the limits of agreement (LOA) between SpHb/Lab data pairs. A  $p$  value  $< 0.05$  was considered statistically significant.

We presented the data in tables and plots.

### Results

After excluding non-diabetic and patients required intraoperative PRBCs transfusions, our sample size consisted of 14 patients. Table 1 shows the details on demographic, clinical characteristics and intraoperative fluid management. All patients were ASA III, and the three most frequent comorbidities associated with DM were hypertension (85.7%), coronaropathy (50.0%) and COPD (50.0%). During the intraoperative time, blood salvage was adopted in 13 patients (92.9%) and  $615 \pm 234$  mL (min 300 mL, max 1200 mL) of blood volume was reinfused to the patients. Intraoperative blood loss showed a median of 1000 mL ([900–1000 mL], min 500 mL and max 2200 mL).

According to our GDT protocol, 9 patients (64.3%) required noradrenaline bolus ( $37.7 \pm 9.7$  mcg, min 20.0 mcg and max 50.0 mcg) to achieve MAP  $> 65$  mmHg despite SVI optimisation.

Table 2 shows haemodynamic and arterial blood gas analysis parameters performed during specific sample times (from  $T_0$  to  $T_3$ ).

About Hb measurements, we obtained 56 values for Lab and SpHb methods. Lab value showed a mean  $\pm$  SD of  $13.2 \pm 1.2$  g/dL (min 10.0 and max 15.7 g/dL), whilst SpHb showed a mean  $\pm$  SD of  $11.8 \pm 1.1$  g/dL (min 9.3 and max 14.7 g/dL). Linear regression analysis between Lab and SpHb values showed a  $r$  coefficient of 0.8960 (CI<sub>95%</sub> 0.8281–0.9379,  $p$  value  $< 0.0001$ ).

SpHb values provided by Masimo Radical-7 underestimated the real Hb values provided by Lab measurements. Bland-Altman analysis between SpHb and Lab values showed that SpHb accuracy was  $-1.37$  g/dL (CI<sub>95%</sub>  $-1.51$  to  $-1.22$  g/dL,  $p$  value  $< 0.0001$ ), with a precision of 0.55 g/dL, lower LOA  $-2.45$  g/dL (CI<sub>95%</sub>  $-2.71$

**Table 1** Demographic, clinical characteristics and fluid intraoperative management data. The table reports demographic, clinical characteristics and fluid intraoperative management data. Categorical variables are expressed as numbers and percentages (%). According to their distribution, continuous data are expressed as mean  $\pm$  standard deviation, median and first and third quartile [Q<sub>1</sub>-Q<sub>3</sub>], minimum and maximum values. †Chronic obstructive pulmonary disease. \*Coronary artery bypass graft. †Percutaneous transluminal coronary angioplasty. ‡Transient ischemic attack

Variables	Result	Minimum	Maximum
Male (%)	12 (85.7%)	-	-
Age	70.3 $\pm$ 5.5	58	77
BMI (kg/m <sup>2</sup> )	26.0 $\pm$ 4.1	19.5	33.9
<b>Comorbidity</b>			
Hypertension (%)	12 (85.7%)	-	-
Coronaropathy (%)	7 (50.0%)	-	-
COPD <sup>†</sup> (%)	7 (50.0%)	-	-
Chronicrenal failure (%)	5 (35.7%)	-	-
Cardiomiopathy (%)	4 (28.6%)	-	-
CABG*/PTCA <sup>†</sup> (%)	3 (21.4%)	-	-
Obesity (%)	2 (14.3%)	-	-
TIA <sup>‡</sup> /Ictus (%)	0 (0.0%)	-	-
Time of surgery (minutes)	235 $\pm$ 75	150	390
Crystalloid (mL)	607 $\pm$ 236	300	1000
Colloid (mL)	839 $\pm$ 288	250	1250
Intraoperative blood savage, "yes"	13 (92.9%)	-	-
Intraoperative blood savage volume (mL)	615 $\pm$ 234	300	1200
Total blood loss (mL)	1000 [900-1000]	500	2200
Total fluid input (mL)	2293 $\pm$ 612	1450	3850
Total fluid output (mL)	1825 [1500-2250]	1350	3500
Diuresis (mL)	607 $\pm$ 264	200	1100
Patients required noradrenaline bolus (%)	9 (64.3%)	-	-
Noradrenaline bolus (mcg)	37.7 $\pm$ 9.7	20.0	50.0
Final fluid balance (mL)	336 $\pm$ 309	-200	1050

to  $-2.20$  g/dL) and upper LOA  $-0.28$  g/dL (CI<sub>95%</sub>  $-0.53$  to  $-0.02$  g/dL). Figures 1 and 2 show scatter and Bland-Altman plots for SpHb vs Lab.

## Discussion

Nowadays, more than 170 million people worldwide have DM, and this number is projected to increase to nearly 370 million people by 2030 (Wild, Roglic et al. 2004). A prevalence study of DM in 2603 surgical patients showed that DM was present in 21% of the surgical population, increasing to 40% in patients aged 65 and over. The surgical procedures most frequently required by DM patients were general surgery (36%), colorectal surgery (22%), vascular surgery (16%) and oncologic surgery (14%). Complications and postoperative mortality were significantly higher in the diabetic patients than non-diabetic group (Cruz, Santiago et al. 2016). The highest rate of complications and postoperative mortality can be explained by the fact that

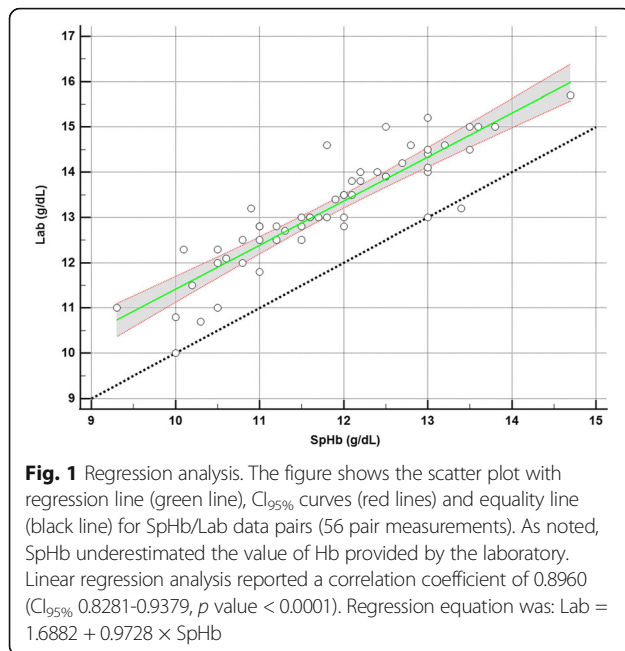
hyperglycemia, dyslipidemia and insulin resistance related to DM enhance vascular inflammation, endothelial dysfunction, vasoconstriction, platelet activation and thrombotic risk. DM represents the major risk factor for all forms of cardiovascular disease (Fox, Golden et al. 2015). According to this evidence, when intraoperative anaemia develops in this cluster of patients, the correct blood product administration can avoid additional risks related to unnecessary PRBCs transfusions (Carson, Guyatt et al. 2016).

Technology able to provide SpHb monitoring represents a useful tool for clinical decision-making about patients' selection and timing of PRBCs transfusions, likely reducing postoperative complications and mortality rates.

The Masimo rainbow SET<sup>®</sup> Radical 7 uses pulse CO-oximetry technology to provide SpHb. Whereas pulse oximetry uses red (660 nm) and infrared (950 nm) light-emitting diodes, pulse CO-oximetry uses 8 wavelengths of light in the 500 to 1300 nm range to measure

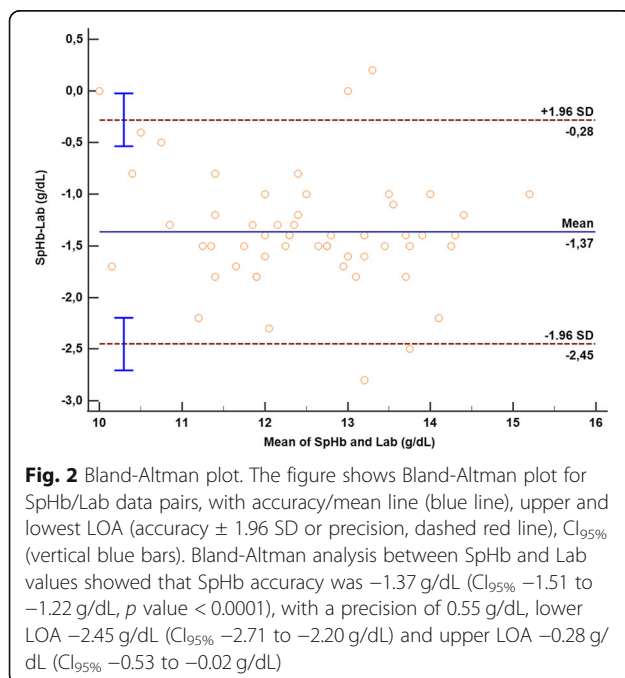
**Table 2** Haemodynamic and arterial blood gas analysis parameters. The table reports haemodynamic, arterial blood gas analysis parameters and body temperature noted during specific sample times ( $T_0$  to  $T_3$ ). Data are expressed as mean  $\pm$  standard deviation, minimum and maximum values

Variable	Time	Result	Minimum	Maximum
Mean arterial pressure (mmHg)	$T_0$	74.3 $\pm$ 5.5	65.0	80.0
	$T_1$	71.1 $\pm$ 3.5	65.0	75.0
	$T_2$	72.9 $\pm$ 3.5	68.0	80.0
	$T_3$	78.5 $\pm$ 3.4	70.0	85.0
Central venous pressure (mmHg)	$T_0$	7.2 $\pm$ 1.5	5.0	10.0
	$T_1$	7.4 $\pm$ 1.6	6.0	10.0
	$T_2$	7.1 $\pm$ 1.4	5.0	9.0
	$T_3$	7.6 $\pm$ 1.7	5.0	11.0
Heart rate (bpm)	$T_0$	73.2 $\pm$ 4.1	65.0	78.0
	$T_1$	71.3 $\pm$ 5.0	60.0	80.0
	$T_2$	72.6 $\pm$ 4.4	60.0	78.0
	$T_3$	78.5 $\pm$ 3.4	60.0	80.0
Stroke volume index (mL/m <sup>2</sup> )	$T_0$	35.3 $\pm$ 3.6	30.0	43.0
	$T_1$	39.6 $\pm$ 5.7	27.0	50.0
	$T_2$	36.3 $\pm$ 5.3	25.0	46.0
	$T_3$	40.3 $\pm$ 3.9	30.0	47.0
Cardiac Index (mL/min/m <sup>2</sup> )	$T_0$	2.6 $\pm$ 0.2	2.3	3.2
	$T_1$	2.8 $\pm$ 0.5	2.0	3.7
	$T_2$	2.6 $\pm$ 0.4	1.9	3.4
	$T_3$	2.9 $\pm$ 0.3	2.2	3.5
Body temperature (°C)	$T_0$	36.2 $\pm$ 0.4	36.0	37.0
	$T_1$	35.8 $\pm$ 0.6	35.0	37.0
	$T_2$	35.3 $\pm$ 0.5	35.0	36.0
	$T_3$	35.8 $\pm$ 0.7	35.0	37.0
Central venous O <sub>2</sub> saturation (%)	$T_0$	82.1 $\pm$ 2.9	75.0	85.0
	$T_1$	80.1 $\pm$ 2.8	73.0	83.0
	$T_2$	80.5 $\pm$ 2.7	75.0	85.0
	$T_3$	80.8 $\pm$ 2.3	75.0	84.0
pH	$T_0$	7.40 $\pm$ 0.03	7.35	7.45
	$T_1$	7.39 $\pm$ 0.02	7.35	7.42
	$T_2$	7.37 $\pm$ 0.03	7.28	7.41
	$T_3$	7.41 $\pm$ 0.02	7.39	7.44
Lactate (mmol/L)	$T_0$	0.7 $\pm$ 0.1	0.5	0.9
	$T_1$	0.8 $\pm$ 0.1	0.6	1.1
	$T_2$	1.4 $\pm$ 0.1	1.2	1.5
	$T_3$	1.4 $\pm$ 0.3	1.0	2.0
Base excess (mEq/L)	$T_0$	0.4 $\pm$ 1.5	-3.0	2.0
	$T_1$	-0.5 $\pm$ 1.3	-3.0	2.0
	$T_2$	-1.3 $\pm$ 0.7	-2.0	0.0
	$T_3$	0.6 $\pm$ 1.1	-1.0	2.0



fractional haemoglobin. The different optical densities of light at different wavelengths are analysed and converted to a digital signal using a proprietary algorithm (Lee, Park et al. 2014).

Our retrospective analysis, based on data derived by 14 diabetic patients scheduled for open abdominal aortic aneurysm repair, showed a high  $r$  correlation coefficient (0.8960,  $CI_{95\%}$  0.8281-0.9379,  $p$  value < 0.0001) between SpHb and Lab values.



Causey et al. (2011) analysed the correlations within different surgical specialities and showed that the correlation coefficient for SpHb was the lowest in vascular surgery (0.44,  $p$  value < 0.001). The high correlation coefficient founded in our study could be explained by the adoption of the GDT protocol. As demonstrated by Miller et al. (2012), digital nerve block increased the local perfusion and, consequently, the accuracy of SpHb. The same effect can be reached by adopting a GDT protocol based on SVI optimisation. Cros et al. (2020) demonstrated that adopting an algorithm for fluid and blood transfusions based on SpHb and PVI measurement is associated with reduced mortality. Further studies are needed to explain the relationship between SpHb clinical performance and adopting a GDT protocol.

Peripheral perfusion influences SpHb accuracy, and Lee et al. (2014) stated that any condition comporting the reduction in upper extremity perfusion could affect the accuracy and availability of data. Particularly vasospastic diseases, such as Raynaud's disease, also lead to inappropriate SpHb values. However, in the literature, there are no data to support a relationship between DM and SpHb accuracy. As showed by Bland-Altman analysis, SpHb underestimated the real Hb values provided by Lab, with an accuracy of  $-1.37$  g/dL ( $CI_{95\%}$   $-1.51$  to  $-1.22$  g/dL,  $p$  value < 0.0001), precision of 0.55 g/dL, but a wide LOA (from  $-2.45$  to  $-0.28$  g/dL). The wide LOA range limits SpHb accuracy. Adel et al. (2018) demonstrated that SpHb showed good performance as a trend monitor. However, the authors excluded patients suffering from diabetes. The application of this exclusion criterion may be related to the concern about the impairment in perfusion. Due to the lack of data in the literature, the exclusion of patients suffering from DM is based only on theoretical assumptions without any clear evidence.

DM is a strong risk factor for arterial PVD (Newman, Rockman et al. 2017). The pathophysiology of arterial PVD in the diabetic population is analogous to that in the non-diabetic population (Marso and Hiatt 2006) but is potentiated by concomitant DM (Newman, Schwartzbard et al. 2017). The clinical manifestations of arterial PVD typically involve the lower extremity artery and include claudication, rest pain, ulceration and gangrene. These are predominantly due to progressive luminal narrowing (stenosis/occlusion), although thrombosis or embolism of unstable atherosclerotic plaque can occur. Typically, the site for the application of the probe of Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™ is a hand finger, and arterial PVD is rare at this site. So, the anatomical site where SpHb's probe is always placed can be considered "safe."

## Limitations

This study is a retrospective analysis based on small numbers of patients. This aspect represented the main limitation. Moreover, we did not perform any evaluation about the SpHb trend in this cluster of patients.

## Conclusions

For the first time, we provided data on SpHb clinical performance in the diabetic population. SpHb provided by Masimo rainbow SET® Radical 7 Pulse CO-Oximetry™ showed a high correlation coefficient when compared with Lab values. However, Bland-Altman analysis showed a wide LOA, limiting the SpHb accuracy.

Further well-designed trials, enrolling a large cohort of patients, are needed to demonstrate if the presence of DM could alter the accuracy and precision of SpHb and its ability as a trend monitor.

## Abbreviations

ASA: American Society of Anaesthesiology; BGA: Blood gas analysis; BIS: Bispectral index; BMI: Body mass index; CABG: Coronary aortic bypass graft; CAD: Coronary heart disease; CI: Cardiac index; CI<sub>95%</sub>: Confidence intervals of 95%; CKD: Chronic kidney disease; COPD: Chronic obstructive pulmonary disease; CVP: Central venous pressure; DM: Diabetes mellitus; DOS: Disposable optical sensor; ECG: Electrocardiogram; EtCO<sub>2</sub>: End-tidal CO<sub>2</sub>; GDT: Goal-directed therapy; Hb: Haemoglobin; Lab: Laboratory; LOA: Limits of agreement; Max: Maximum; MAP: Mean arterial pressure; Min: Minimum; NYHA: New York Heart Association; PEEP: Positive end expiratory pressure; PRBCs: Pure red blood cells; PTCA: Percutaneous transluminal coronary angioplasty; PVD: Peripheral vascular disease; Q<sub>1</sub>: First quartile; Q<sub>3</sub>: Third quartile; ROS: Reusable optical sensor; ScvO<sub>2</sub>: Continuous central venous O<sub>2</sub> saturation; SD: Standard deviation; SpHb: Non-invasive continuous haemoglobin concentration; SpO<sub>2</sub>: Peripheral oxygen saturation; SVI: Stroke volume index; TIA: Transient ischemic attack; V-POSSUM: Vascular-Physiological and Operative Severity Score for the enUmeration of Mortality and Morbidity

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None

## Authors' contributions

Conception and design, RCDR; Data collection, RCDR; Statistical analysis and interpretation, RCDR and AR; Writing-original draft preparation, RCDR and AR; Writing-review and editing, RCDR and AR; Supervision, RCDR; Project administration, RCDR; RCDR and AR read and approved the final manuscript.

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## Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

The local ethics committee (University of Naples "Luigi Vanvitelli"), on September 27, 2017, approved data collection (protocol number 544/2017), and every patient signed written informed consent.

### Consent for publication

Not applicable

### Competing interests

The authors declare that they have no competing interests.

## Author details

<sup>1</sup>Anaesthesia and Intensive Care Monaldi Hospital, AORN dei Colli, Via Leonardo Bianchi, 80131 Naples, Italy. <sup>2</sup>Department of Anaesthesia and Intensive Care, AOU San Giovanni di Dio e Ruggi D'Aragona, Via San Leonardo, 1, 84131 Salerno, Italy.

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