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Original Article

Accuracy of non-invasive hemoglobin monitoring by pulse CO-oximeter during hepatectomy in living liver donors

Yusuf Ziya Colak, Duygu Demiroz Aslan

Department of Anesthesiology and Reanimation, Faculty of Medicine, Inonu University, Malatya, Turkey

Abstract

Aim: To evaluate the accuracy and agreement of the measurements made with the Masimo Rad7 device in living donor hepatectomy (LDH).

Materials and Methods: A total of 63 living liver donors (LLDs) with ASA I-II scores who scheduled for LDH were included in the study. The Masimo noninvasive measurement probe was inserted to measure SpHb (mg/dL), pleth variability index (PVI, %) and perfusion index (PI,%). Heart rate, mean artery pressure, SpO_2, body temperature, BIS, PVI, SpHb, and PI were recorded as basal, after anesthesia induction, post-intubation, post-intubation plus 5 min, 10 min, and plus 1, 2, 3, 4, 5, 6 and 7h. In addition blood samples were collected for laboratory hemoglobin (Hblab) before the surgery incision and after the surgical procedure, and the values were recorded simultaneously with the other values.

Results: Fifty-five LLDs age between 18 and 55 years were assessed. The mean PI value increased in all measurements compared to baseline, and it was statistically significant at the 5th minute ($p<0.05$). This value prominently decreased after the 20th minute and dropped below the baseline value at the 7th hour. This decrease was statistically significant at the 2nd hour measurements ($p<0.05$). A significant correlation was observed between SpHb and LabHb before the surgical incision ($r=0.694$, $p<0.001$). Correlation decreased in after surgery measurement. In addition, there was a statistically significant difference between the before surgery and after surgery PI measurements ($p<0.001$).

Conclusion: We think that in LDH procedures, surgical process leads to a decrease in PI and reduces the accuracy of SpHb measurement, and thus, intraoperative SpHb monitoring should be evaluated together with PI value.

Keywords: Hepatectomy; living liver donors; non-invasive hemoglobin monitoring; pulse CO-oximeter

INTRODUCTION

Living donor liver transplantation (LDLT) has become widespread with the efforts shown in order to increase organ availability for the treatment of end stage liver disease (1). Donor safety is the most common cause of concern in LDLT (2). LDLT related complications may include bleeding, biliary leaks, vascular thrombosis, infections and incisional hernias. Different methods have been attempted to reduce blood loss, the need for transfusion and morbidity during LDH (3).

Hemoglobin (Hb) concentration decreases due to bleeding during major surgical operations. Invasive Hb measurement has been accepted as the gold standard by the International Committee for Standardization in Hematology (4). Recently developed Masimo Radical-7 Pulse CO-Oximetry (Rad7; Masimo Corp, Irvine, CA, USA) uses spectrophotometry and detects the total hemoglobin (SpHb) immediately, continuously, and noninvasively by placing a sensor on a fingertip. Rad7 can also measure oxygen content, arterial oxygen saturation, pulse rate, perfusion index (PI) and the pleth variable index (PVI) (5,6).

Although different studies have been conducted on the accuracy of SpHb in many patient groups and clinical situations (7), so far there is no study conducted with donors who will undergo LDH. In this study, we aimed to evaluate the accuracy and agreement of the measurements made with the Masimo Rad7 device in this patient population. Our second aim is to examine the effect of surgical stress on accuracy of measurement.

MATERIALS and METHODS

After ethical approval was received (NCT04664777), 63 LLDs aged between 18-55 years, who had no additional disease (American Society of Anesthesiologists physical status I) and were scheduled for LDH were included in the study as a prospective observational, at Inonu University Liver Transplantation Institute. It was calculated that at

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Corresponding Author: Yusuf Ziya Colak, Department of Anesthesiology and Reanimation, Faculty of Medicine, Inonu University, Malatya, Turkey **E-mail:** yzcolak@gmail.com

least 42 subjects should be included in the study so that the mean difference in measuring hemoglobin values of the two methods was 0.4 units (96% agreement). LLDs those who did not want to participate in the study, LLDs who underwent emergency surgery, and those with excessive surgical bleeding (>500 mL) were excluded from the study. In addition, cases using intraoperative vasoactive agents were also excluded. LLDs were taken to the operation room without premedication. Following ECG, NIBP (mmHg), SpO_2 (%), body temperature (°C), (Carescape B650, GE Healthcare, Helsinki, Finland) and BIS (Aspect Med. Systems, Norwood, MA, USA) monitoring, Masimo Radical-7 Pulse CO-Oximetry with a disposable Rad7 sensor (rainbow R2-25a) was attached to their index fingertip, and the sensor was covered with a black, opaque protector as recommended by the manufacturer.

Then the sensor was connected to the Rad7 to measure the SpHb (mg/dL), pleth variable index (PVI, %) and the PI (%). We didn't do in vivo adjustment of the hemoglobin value before surgery. After recording the demographic data and initial values, anesthesia was induced with thiopental 5–8 mg/kg, fentanyl 1–2 mcg/kg, lidocaine 1 mg/kg, vecuronium 0.1 mg/kg. When adequate anesthesia depth was reached, values were recorded and an endotracheal tube of appropriate size was inserted. After the location of the tube is confirmed, invasive artery monitoring was carried out in all cases. Desflurane (Suprane®) was used as the inhalation agent, analgesia management was achieved with remifentanil infusion. All cases were actively heated with heating blankets and normothermia was achieved. Heart rate (HR/min), mean artery pressure (MAP, mmHg), SpO_2, body temperature, BIS, PVI, SpHb, and PI were recorded as basal (Tbase), after anesthesia induction (Tind), post-intubation (Tent), post-intubation plus 5 min, 10 min, and plus 1, 2, 3, 4, 5, 6 and 7h. Also, after surgical site sterilization, before surgery incision blood sample was taken for HbLab and values were recorded simultaneously (Tbs). After the surgical procedure was over, a blood sample was taken for HbLab and values were recorded simultaneously again (Tas). The laboratory Hb was measured by using the automated hematology analyzer XN-9000 (Sysmex Corp. Kobe, Japan) from the patient's arterial blood. The starting time of the surgical procedure was recorded in all cases. LDH procedures were performed as previously described (8).

ΔHb referred to the difference between SpHb and Hblab (ΔHb = SpHb - Hblab), and this calculated value was obtained before (ΔHb1) and after (ΔHb2) the surgery. Investigator who kept records was blinded to the laboratory values. At the end of the surgeries, the total surgery durations and amount of bleeding were recorded.

Statistical Analysis

We used SPSS 20v software (IBM Co., Armonk, NY, USA) to conduct the data analysis. The basic demographic variables were expressed as numbers and percentages. Continuous variables were expressed as means±SD. Pearson's correlation analysis was used to evaluate the correlation between the continuous variables. The Bland-Altman plot and intraclass correlation coefficient (ICC) were used to compare the consistency and the agreement of the continuous data between the SpHb and HbLab measurements. The level of significance was determined as $p < 0.05$.

RESULTS

A total of 63 LLDs were enrolled, and seven of them were withdrawn from the study due to the intraoperative ephedrine use, one of them was withdrawn from study due to the intraoperative atropine use. Data of the remaining 55 LLDs were examined. The mean age was 31±8 years, 49.1% (n=27) of the LLDs were female and the mean operation time was 365±64 minutes (Table 1). The mean total bleeding amount was found as 280±85 mL. Normothermia was maintained in all LLDs. The mean surgery start time was calculated as the 14th minute after the intubation. HR, SpO_2, MAP and PVI (values after mechanical ventilation were used for PVI) value remained within the normal range during the operation (Table 2).

Table 1. Demographic data of the cases and mean operation time

Age (yr)	31±8
Gender (M/F)	28/27
IBW (kg)	62.7±10.9
ASA 1/2	24/31
Operation time (min)	365±64

Table 2. HR, SpO_2, MAP and PVI values of the cases during the operation

	Base	Ind	Ent	5. min	10. min	20. min	40. min	1.hr	2.hr	3.hr	4.hr	5.hr	6.hr	7.hr
HR (beats/min)	83	87	100	88	82	75	78	79	78	86	89	92	96	93
SpO_2 (%)	99	99	99	98	98	98	98	98	98	99	99	99	99	99
MAP (mmHg)	98	82	106	82	77	76	78	82	88	83	78	75	78	78
PVI (%)	na	na	na	10	9	9	12	10	10	11	10	10	9	10

PI value showed an increase at Tind, Tent, 5 min and 10 min, compared to Tbase measurement. This increase was statistically significant at PI 5min measurement ($p<0.05$), prominently reduced after 20 min measurement until 2hr measurement and the decrease continued until the end of the cases, and dropped below Tbase at 7hr measurement. This decrease was statistically significant at PI 2hr measurement ($p<0.05$) (Figure 1).

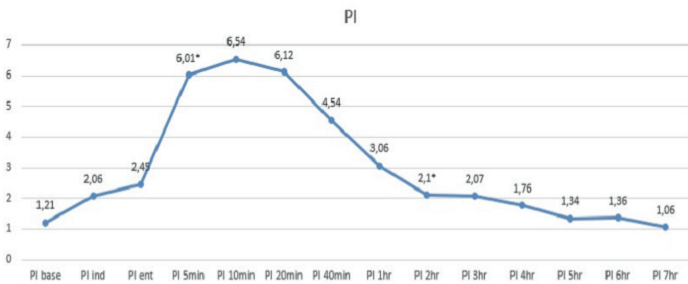

Figure 1. PI value of the cases during the operation

Tbs and Tas values of the subjects are given in Table 3. When the correlations between Tbs (before surgical incision) measurement were examined; a significant correlation was found between SpHb and LabHb values ($r= 0.694$, $p< 0.001$). HbΔ1 was calculated as -0.45 g/dL, and | HbΔ1| as 1.03 g/dL. When Tas (after surgery, before extubation) measurements were examined; there was a moderate correlation between SpHb and LabHb values ($r= 0.531$, $p< 0.001$). HbΔ2 was calculated as -0.67 g/dL and | HbΔ2 | as 1.52 g/dL. | HbΔ |< 1 g/dl values were found in 36 cases according to Tbs measurements, and 23 cases according to Tas measurement, and the difference was statistically significant ($p<0.001$). There was a statistically significant difference also between PI values according to Tbs and Tas measurements ($p<0.001$).

Table 3. SpHb, LabHb, HbΔ, HbΔand PI values at Tbs and Tas measurements

	Tbs	Tas	P value
SpHb (g/dl)	12.5±1.4	12.3±1.5	0.118
LabHb (g/dl)	12.9±1.7	12.9±2.0	0.905
HbΔ g/dl	-0.45±0.12	-0.67±1.73	0.268
| HbΔ | < 1 g/dl (n, [%])	36 (65.4)	23 (41.8)	**<0.001**
PI (%)	5.6±2.9	1.7±1.7	**<0.001**

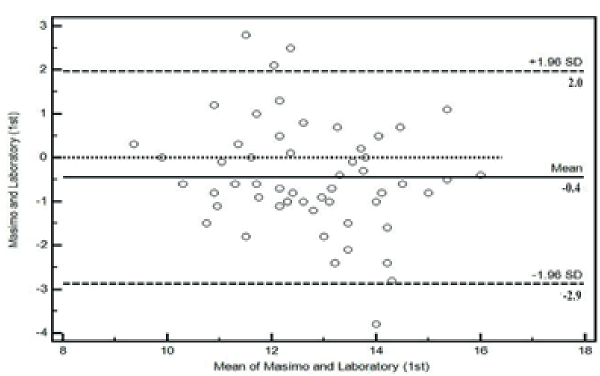

Figure 2. Bland-Altman scatter plot between SpHb and LabHb at Tbs measurement

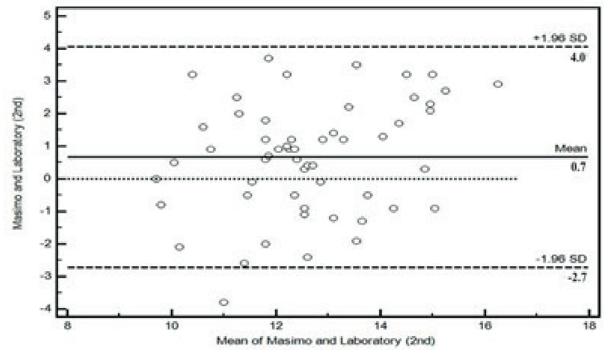

Figure 3. Bland-Altman scatter plot between SpHb and LabHb at Tas measurement

In the Bland-Altman scatter plots drawn to determine the accuracy and agreement of LabHb and SpHb values measured during Tbs and Tas, there was a significant agreement between the values (Figures 2,3). In the intraclass correlation coefficient (ICC) analysis, ICC was 0.826 for the data obtained during Tbs and 0.484 for the data obtained during Tas.

DISCUSSION

The results obtained in this study indicate that (i) HR, SpO_2, MAP and PVI values of the subjects remained within the normal range during the operation, (ii) PI values showed prominent increase at Tind, Tent, 5min and 10min compared to Tbase, markedly decreased after 20min until 2hr measurement and the decrease was gradually continued until the end of the case, and (iii) there was a marked agreement between LabHb and SpHb measured during Tbs and in the Bland-Altman scatter plots, while the agreement during Tas was weaker in the ICC analysis.

Hemoglobin (Hb) concentration decreases due to bleeding during major surgical operations. Invasive Hb measurement has been accepted as the gold standard by the International Committee for Standardization in Hematology. Blood drawn for the laboratory measurements during surgery is an invasive process and since it involves several steps, delays in obtaining laboratory outcomes may delay blood transfusion management decisions (4). Current non-invasive technologies include pulse co-oximetry, occlusion spectroscopy and transcutaneous reflection spectroscopy. Non-invasive transcutaneous pulse co-oximetry has been developed to measure total hemoglobin and its components (oxy, carboxy and met moieties) with one manufacturer, Masimo Corp. developing both continuous (Radical-7TM) and intermittent (Pronto-7TM) devices from 2008 (5). The continuous and noninvasive measurement of hemoglobin enables the rapid evaluation of a patient's status. In our study, we used Masimo (Radical-7TM) data.

Most studies conducted are about the accuracy of Hb values measured with Pulse CO-Oximetry. Berkow et al. (9) compared the outcomes of 130 arterial blood samples collected for laboratory measurements from 29 patients undergoing spinal surgery with Hb values measured with Pulse CO-Oximetry and found the different between them as 0.8 ± 0.6 g/dL, while Linder et al. found a good agreement at 0.81 in 217 patients (7). In their review, Rice et al. (10) emphasized that values measured with the Masimo Radical-7 device in patients with a Hb concentration out of 6-10 g/dL range cannot guide clinicians about blood transfusion. Conversely, Gamal et al. demonstrated a correlation of 0.87 between LabHb and SpHb values in trauma patients with low Hb concentrations evaluated using 184 parameters, and stated that this device can be used in trauma patients with low Hb values (11). Since in our study the cases had ASA 1 status, admission Hb values were not within critical range. In addition, the mean amount of surgical bleeding was 280 cc, and Hb values did not reach critical values since we did not have a patient who developed surgical bleeding that would impair hemodynamics. In their study, Tang et al. reported that the Hb values measured by the co-oximetry method were satisfactory and guide clinicians for invasive sampling (12). Similarly, we think that this method is sufficient and can prevent unnecessary blood sampling.

Frasca (13) studied SpHb and laboratory CO-oximeter measurements in 65 ICU patients. This study gives us the opportunity to learn about the readings during low perfusion states. Frasca showed that when the perfusion index was less than 50% (the manufacturer's cut point for low signal) the bias ± the standard deviation increased. Similar results were seen in patients receiving continuous infusion of noradrenaline. The meaning is that despite the improvements in E Rainbow SET sensor, it cannot be relied upon during peripheral vasoconstriction states. Miller (14) noticed reduced accuracy when the pulse oximeter indicated a low perfusion index. This finding is supported by Gayat et al.'s study (15) where low blood pressure was associated with reduced accuracy. The association between monitor accuracy and peripheral perfusion should not be a surprise, because all pulse oximeters fail to some degree when the patient is peripherally vasoconstricted or hypotensive. Similar to the above mentioned studies, in our study there was a significant correlation between Masimo and LabHb before surgery ($r = 0.694$, $p < 0.001$), while PI decreased with the surgery and the correlation between Masimo and LabHb decreased ($r = 0.531$, $p < 0.001$).

Decreased PI may be related to increased vasoconstriction or decreased tissue perfusion as in hypothermia, bleeding and shock. Pulse CO-Oximetry analyzer may not give sufficiently accurate outcomes in such conditions (16). Park et al. showed in their study that sevoflurane anesthesia increased PI and increased the accuracy of SpHb measurement (17). Similarly in our study we found an increase in PI values after induction compared to the basal values, and this increase became dramatically marked following anesthesia application with desflurane and reached maximum at the 10^{th} minute. We observed a significant correlation between SpHb and LabHb in the comparison we made under desflurane anesthesia before the beginning of the surgical procedure.

In our study, PI values decreased after surgery. Surgical stress might cause this decrease since the cases that we have selected were ASA 1 and HR, SpO_2, MAP and PVI values remained within the normal range, normothermia was maintained and data of the patients using ephedrine and atropine intraoperatively were excluded. The nervous system activates the stress response by sending impulses to the hypothalamus after the surgical trauma. Catecholamines are involved in this response (18). With the sympathetic activation of the adrenal medulla, epinephrine and norepinephrine are released and this situation can cause a decrease in PI. According to our results, PI decreased dramatically with the starting of the surgical procedure. This decrease continued until the end of surgery and fell below the baseline value at the 7th hour measurement.

In addition, in our study we found that the ability of Masimo to detect Hb decreases as PI measured by Masimo decreases. Tas PI values were significantly lower than Tbs values, and the lowness of PI value and the difference between SpHb and labHb values were inversely proportional. We think that this might be caused by surgical stress, because we eliminated the factors that may reduce intraoperative PI as much as possible (normotensive and normovolemic course of the cases, prevention off hypothermia, excluding the cases using vasoactive agents) and intraoperative blood loss was acceptable for this type of surgery. Furthermore, the gradual decrease of PI during monitoring suggests that operational time may also affect the accuracy of SpHb measurement.

CONCLUSION

We think that surgical process of hepatectomy leads to a decrease in PI, reducing the accuracy of SpHb measurement, and thus, intraoperative SpHb monitoring should be evaluated together with PI values in this patient group and it should be taken into account that the correlation between SpHb and LabHb may decrease at low PI values in donor hepatectomy procedures. Furthermore comprehensive randomized controlled studies are needed in order to explain the etiopathogenesis of our results more clearly.

Competing Interests: The authors declare that they have no competing interest.

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Ethical Approval: Malatya Clinical Research Ethics Committee: 2017/115.

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