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Accuracy and Trending of Continuous Noninvasive Hemoglobin Monitoring in Patients Undergoing Liver Transplantation

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ABSTRACT

Background. Shift in large fluid volumes and massive blood loss during liver transplantation frequently leads to rapid changes in hemoglobin (Hb) concentration; thus, to ensure adequate tissue oxygenation, accurate and rapid determination of Hb concentration is essential in transplant recipients. The Radical-7 Pulse CO-Oximeter provides a noninvasive and continuous way to monitor Hb concentration (SpHb) in real time and is an ideal candidate for use during liver transplantation. In this study, we assessed the relationship between SpHb and total Hb (tHb) obtained from arterial blood samples during surgery.

Methods. Forty patients undergoing liver transplantation were enrolled in this study. tHb and time-matched SpHb were measured at 5 different phases throughout surgery. Paired SpHb and tHb levels were assessed using linear regression, Bland-Altman analysis, and the Critchley polar plot method.

Results. A total of 161 paired measurements with sufficient signal quality were analyzed. The correlation between SpHb and tHb was 0.59 ($P < .001$). Bland-Altman analysis revealed that a bias between SpHb and tHb was 2.28 g/dL, and limits of agreement (LoA) were from −0.78 to 5.34 g/dL. Trending analysis showed that 87% of data were located within the acceptable trending area, indicating that the trending ability was not satisfied.

Conclusions. The Radical-7 Pulse CO-Oximeter was not sufficient to monitor Hb levels and trends during liver transplantation surgery in our cohort. In particular, in critical patients and in those with low Hb levels, invasive Hb measurement should be used for assessment.

TOTAL HEMOGLOBIN CONCENTRATION (THB) is one of the key parameters to ensure adequate tissue oxygenation; it also provides a basis for decision-making in blood transfusion in clinical practice. During liver transplantation, patients may have shifts in large fluid volumes and massive blood loss, which are reflected in severe and rapid fluctuations in hemoglobin (Hb) concentrations during surgery. Both peri-operative anemia and unnecessary blood transfusion are associated with adverse effects [1,2]. Therefore, accurate and rapid determination of Hb concentration is essential for transplant recipients during surgery.

The conventional and standard method of tHb measurement is performed in the laboratory; it requires invasive blood sampling and is costly and often time-consuming. It does not provide real-time data on changes in Hb levels. The Radical-7 Pulse CO-Oximeter (Masimo Corporation,

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Irvine, Calif, United States) is now available to provide a noninvasive and continuous way to monitor Hb (SpHb) in real time. Several studies have evaluated the accuracy and trending ability of SpHb during various surgeries and in different patient populations; however, the results are conflicting [3–6].

Liver transplant recipients are a unique and complex patient population. The disease severity varies case by case, and the clinical condition of patients is more critical than those undergoing elective surgery. Intense hemodynamic changes often occur throughout the surgical procedure and need to be quickly addressed. Currently, data on the use of noninvasive Pulse CO-Oximeter in this complicated population are limited. The purpose of this study was to assess the accuracy and trending ability of SpHb in patients during liver transplantation surgery with the Pulse CO-Oximeter.

METHODS

Patients undergoing orthotopic liver transplantation between August 2014 and June 2015 at Chang Gung Memorial Hospital were included in this prospective study. Patients with arrhythmia and cardiopulmonary, hematologic, or peripheral vascular diseases were excluded. This study was approved by the Institutional Ethics Committee of Chang Gung Memorial Hospital (103-3322B), and written informed consent was obtained from all patients.

All patients underwent a routine anesthesia protocol used during liver transplantation surgery [7]. Propofol at 1.5 to 2 mg/kg, fentanyl at 1 to 2 μg/kg, and cisatracurium at 0.2 mg/kg were administered as induction anesthetics. The ventilator was adjusted to keep end-tidal CO_2 between 30 and 35 mm Hg with a basal tidal volume of 6 to 8 mL/kg, a respiratory rate of 8 to 14 breaths per minute, and an end expiratory pressure of 5 cm H_2O. After induction of general anesthesia, a radial arterial line with a 20-gauge catheter was inserted to sample blood for tHb, using a blood gas analyzer (Stat Profile Critical Care Xpress, Nova Biomedical, Waltham, Mass, United States). The contralateral index finger was connected to a Masimo adult adhesive sensor (R2 25, rev E) for the Radical-7 Pulse CO-Oximeter (software version 1.1.6.3i) to continuously monitor SpHb. An impermeable black shield was applied to cover the Masimo sensor to avoid any optical interference. In addition, simultaneous SpHb values were recorded each time a blood sample was obtained.

The data collection for tHb and time-matched SpHb were performed at 5 different phases throughout surgery: (1) 30 minutes after the anesthesia induction, (2) 2 hours after the start of operation during dissection, (3) 20 minutes after the start of anhepatic phase, (4) 30 minutes after the reperfusion of graft, and (5) at the end of surgery.

Subgroup Analysis

To elucidate factors that may affect SpHb accuracy, patients were classified into subgroups for further analysis: disease severity as assessed by the Model for End-Stage Liver Disease (MELD) score <20 or ≥ 20 [8], pre-operative total bilirubin level (normal, ≤ 1.3 mg/dL; hyperbilirubinemia, >1.3 mg/dL), and tHb concentration of ≤ 10 g/dL or >10 g/dL [3].

Statistical Analysis

As disclosed by the Masimo Corporation, low perfusion index (PI) influences measurement accuracy. Therefore, any SpHb data recorded under a PI <1.0 were excluded from the final analysis. Descriptive statistics were applied for demographic and clinical data. Linear regression analysis was used to test correlations between paired SpHb and tHb values. Bland-Altman analysis was performed to assess the accuracy of SpHb, which was reported as the bias (average difference between SpHb-tHb pairs), with ±1.96 standard deviation (SD) limits of agreement (LoA). Trending analysis was performed by use of the Critchley polar plot method [9], which tests both the magnitude and directionality of Hb changes. Statistical analysis was performed, using the Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS, Chicago, Ill, United States) and R 2.15.2 statistical software (R Foundation for Statistical Computing, Vienna, Austria); a value of $P < .05$ was considered statistically significant for all analyses.

RESULTS

Forty patients were enrolled in this study. The patient characteristics are shown in Table 1. Eleven SpHb-tHb data pairs were not recorded because of equipment error (eg, failure of the device to record SpHb value), and 28 paired measurements were excluded because SpHb was recorded under a PI <1.0. Thus, for the final analysis, 161 paired measurements were available.

The tHb values ranged from 7 to 15.8 g/dL, and SpHb ranged from 6.5 to 18 g/dL. Linear regression analysis showed a moderate correlation between SpHb and tHb [correlation coefficient (r) = 0.59, $P < .001$]. The bias revealed by use of Bland-Altman analysis was 2.28 g/dL [with ±1.96 SD LoA, −0.78 to 5.34 g/dL (Fig 1A)]. To evaluate trending, the Critchley polar plot method was applied, as shown in Fig 1B. Only 87% (27/31) of data was within the limits of acceptable trending (outside of a central

Table 1. Demographic Characteristics of the 40 Patients

	Mean ± SD	Range
Age (years)	53.00 ± 9.34	30–68
Height (cm)	166.43 ± 9.23	150–195
Weight (kg)	71.85 ± 13.04	49–106
BMI (kg·m^2)	25.92 ± 4.14	19.14–35.88
Blood loss (mL)	1982.50 ± 1470.54	100–6700
Total bilirubin (mg/dL)	5.95 ± 9.19	0.4–40
MELD score	19.18 ± 9.59	6–52
Sex		
Male	32 (80%)	
Female	8 (20%)	
Underlying disease		
Liver cirrhosis		
HBV-related	17	
HCV-related	11	
Alcohol-related	17	
Autoimmune-related	2	
Wilson's disease	1	
Hepatocellular carcinoma		
Present	15 (37.5%)	
Absent	25 (62.5%)	
MELD score		
<20	25 (62.5%)	
≥20	15 (37.5%)	

Abbreviations: BMI, body mass index; HBV, hepatitis B virus; HCV, hepatits C virus; MELD, Model for End-Stage Liver Disease.