Validation of a Non-Invasive Hemoglobin Estimation in Whole Blood Donors

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Introduction

Pre-donation screening of blood donors are currently based on venous or capillary blood sampling. Adoption of a non-invasive hemoglobin estimation may increase blood donor recruitment. Masimo Pronto-7 Pulse CO-oximetry device is a spectrophotometry based device used to estimate the hemoglobin (Hb) level non-invasively, waiving the need of blood sampling. It has not been validated in normal blood donors. The primary objective of our study was to validate the pulse CO-oximetry based hemoglobin estimation in normal blood donors.

Methods

We conducted a prospective observational study on 106 whole blood donors attending the blood bank of a tertiary care center over 4 weeks. We estimated a Spot Hemoglobin (Sp Hb) concentration using Masimo Pronto-7 Pulse CO-oximetry device (two measurements per donor) and compared it to a venous sample Hb (Reference Hemoglobin; Ref Hb) measured using Abbott CELL-DYN Sapphire hematology analyzer. We calculated Pearson correlation coefficient and coefficient of determination (R2). The multivariable linear regression model of predicting the estimation differences included age, gender, weight, height, blood pressure and reference hemoglobin.

Results

We enrolled 106 donors (98 males, 8 females) with a mean age of 27 years (SD 6.2; 18-49) and a mean Ref Hb of 14.2 g/dL (SD 1.2; 11.5-17). The mean Sp Hb was 14.4 g/dL (SD 1.2; 11.3-16.7). The correlation coefficient between the Sp Hb and Ref Hb was 0.46 (R2 = 21%) with a mean difference of 0.2 g/dL (SD 1.2; -4.5 to 3). In the multivariable model, height ($p = 0.015$) and Ref Hb level ($p < 0.001$) were statistically significant predictors of the difference in measurement. There was a strong correlation between the two CO-oximetry Hb measurements (correlation coefficient 0.78, R2 = 60%).

Conclusions

Our study demonstrated the validity of the CO-oximetry Hb measurement in normal blood donors and with good reproducibility. Larger prospective studies are needed to confirm our findings.