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Comparison between two portable hemoglobinometers and a reference method to verify the reliability of screening in blood donors

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ABSTRACT

Portable hemoglobinometers are used to determine hemoglobin level, but there are conflicting reports regarding their accuracy. The aim of this study was to compare results from two portable hemoglobinometers (HemoCue® and Hemo-Control) with an automated hematology analyzer (Sysmex XE-2100D) to determine if the screening of blood donors is reliable. A total of 426 blood donors' samples were studied and on average the Hb content measured in capillary blood samples was higher than that found in venous blood samples. Hemoglobinometers can be employed as a method to screen blood donors, but critical values should be confirmed in an automated hematology analyzer.

1. Introduction

In most countries, the assessment of hemoglobin (Hb) levels or hematocrit in blood donors is a well-established requirement and it is the only laboratory screening test routinely performed before donation. These tests are employed to ensure that collected blood units will have the ideal content of hemoglobin [1–3] and to protect donors from being critically anemized after donation [1,3–5]. Brazilian's law establishes that the minimum acceptable value of Hb for blood donation is 125 g/L for women and 130 g/L for men. On the other hand, when Hb level is higher than 180 g/L, donation is prohibited and the person should be referred to clinical evaluation [6]. Thus, selection of donors will broadly depend on the accuracy of the Hb screening method [1]. HemoCue® and Hemo-Control are portable point-of-care systems for hemoglobinometry that measures Hb in arterial, venous or fingerstick capillary blood samples by azide-methemoglobin reaction and photometry absorbance [7–10]. HemoCue® has been used commercially for some years and has been reported to be reasonably reliable [7,8]. Although HemoCue® system has gained popularity worldwide, there are conflicting reports regarding its accuracy [3,7]. Despite the fact that HemoCue® has been a good and rapid method for determination of Hb, the cyanhemoglobin assay performed in venous blood sample by automated hematology analyzers is still the reference method for Hb level determination [1] and is the method recommended by the International Council for Standardization in Hematology [5,11]. In this context, the aim of this study was to compare two portable hemoglobinometers with the reference method to verify the reliability of screening in blood donors.

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2. Materials and methods

Before sample collection, all subjects signed an informed consent that was registered, approved and continually monitored by the Committee on Ethics in Human Research of the Federal University of Santa Catarina. Each sample was identified by a number to protect the anonymity of donors.

Adult blood donors were selected from the Hemotherapy Service of Federal University of Santa Catarina, Brazil. To analyze HemoCue® (HemoCue® B-Hemoglobin System, HemoCue® AB, Angelholm, Sweden) reliability it was compared 326 capillary Hb results obtained by HemoCue® with venous Hb level obtained by the reference method – automated hematology analyzer Sysmex XE-2100D (Sysmex Corporation, Kobe, Japan). Hemo-Control (EKF Diagnostic GmbH, Barleben, Germany) reliability was verified by comparison of another one hundred Hb levels obtained by Hemo-Control in capillary blood samples with those obtained by Hemo-Control, HemoCue® and the reference method (Sysmex XE-2100D) in venous blood samples.

Capillary and venous blood samples were collected in the morning (8 a.m. to 12 a.m.) from Monday to Friday between March 2011 and March 2012. Capillary blood samples were obtained from donors in a seated position with arm at table top level. After clean the area with alcohol and allowed it to dry, the drops were taken from ring finger by using a sterile lancet and the first drop of blood was wiped away and the second drop was used to fill a microcuvette in all 426 donors. Then, Hb level was analyzed by HemoCue® and Hemo-Control in accordance with the manufacturer's instructions. After capillary blood samples collection, the entire arm was cleaned with water and soap and dried. After that, this area was cleaned with alcohol and allowed it to dry for collection of 4 mL of venous blood in an EDTA anticoagulated tube (VACUETTE®, Greiner Bio-One, Frickenhausen, Germany). For venous sample collection, the donor was lying semi-recumbent and their arm approximately at heart level. Hb venous level was measured using the automated hematology analyzer Sysmex XE-2100D, which was considered the reference method. Hb level of venous blood was also tested with HemoCue® and Hemo-Control hemoglobinometers. All these standardized procedures were performed by two trained professionals.

Data were shown as mean ± SD, median, minimum and maximum values (Min/Max). Bland–Altman method and Intraclass Correlation Coefficient (r) were employed to analyze agreement between methods. In Bland–Altman method, differences between both techniques were plotted against the reference method [12] and the limits of agreement of ±10 g/L between methods were considered acceptable [8,13]. Agreement of Intraclass Correlation Coefficient was considered good when the values of (r) were over 0.75, moderate for values between 0.40 and 0.75, and poor for values below 0.40 [1,14,15]. Statistical analyses were performed with Statistical Package for Social Sciences software (SPSS software, version 17.0, Chicago, Illinois, USA) and MedCalc software (version 12.2.1.0, Mariakerke, Belgium).

Quality Control was checked in Hemo-Control and HemoCue® devices daily using the same control microcuvette provided by Hemo-Control manufacturer. The expected Hb value provided by the manufacturer was 121 ± 3 g/L. Hemo-Control always measured 121 g/L and HemoCue®, 124 g/L. Even though Hb levels found with HemoCue® were within the standard deviation (SD) value of control microcuvette, Hb levels were overestimated by 3 g/L. This overestimation of 3 g/L could influence the final Hb level but this influence is minimal when compared with the limit of agreement (10 g/L) because there are samples that exceeded much more than this limit. The automated hematology analyzer Sysmex XE-2100D performance was checked daily using Sysmex e-Check™ control (Sysmex e-Check Hematology Control for Sysmex X-Series Analyzers, Sysmex Corporation, Kobe, Japan) that evaluated Hb in three levels (low, medium and high). All the Hb measures were within the expected range for each level.

3. Results

Hemoglobin of capillary blood samples measured by HemoCue®, and venous blood samples measured by the reference method, was evaluated in 326 adult blood donors (187 males and 139 females). The mean age was 27 ± 9 years old (16–60 years old). The mean value of capillary Hb level of all subjects using HemoCue® was 148 ± 15 g/L and the mean of venous blood using the reference method was 141 ± 13 g/L (Table 1). When subjects were divided by gender into two groups (female and male), the mean Hb measured by HemoCue® in females was 138 ± 9 g/L and by the reference method was 130 ± 8 g/L; mean in males by HemoCue® was 156 ± 13 g/L and by the reference method was 149 ± 10 g/L (Table 2). Evaluation of Intraclass Correlation Coefficient between HemoCue® and the reference method was 0.763 for the total samples (n = 326), 0.758 for the male gender (n = 187), and 0.610 for the female gender (n = 139) (Table 3). Bland–Altman method showed that overall mean bias was −7.2 g/L with limits of agreement from −25.8 to 11.5 g/L (Fig. 1).

Deviation exceeded the acceptable limit of agreement (±10 g/L) in 45.1% (147/326) of all samples and 41.7% (58/139) of female samples and 47.6% (89/187) of male samples. Of total samples that exceeded the limit of agreement of ±10 g/L, 18.4% (27/147) exceeded ±20 g/L and 2.7% (4/147) exceeded ±30 g/L.

HemoCue® results showed that 22.3% (73/326) of female and 4.3% (14/326) of male donors had their blood donation approved based on Hb level measured by the

Table 1
Mean ± Standard deviation, median, minimum and maximum values of hemoglobin in HemoCue® (capillary blood) and in the reference method (venous blood).

	HemoCue® (g/L)	Reference method (g/L)
Mean ± SD	148 ± 15	141 ± 13
Median	147	142
Min/Max	125–193	113–183