Point-of-care estimation of haemoglobin concentration in all age groups in clinical practice

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Abstract

Background: The measurement of haemoglobin (Hb) concentration provides a reliable, primary screening test for the presence and severity of anaemia. The HemoCue® is a point-of-care test for Hb measurement. The introduction of point-of-care testing in hospitals and general practice has improved patient care and accessibility. This study was performed to evaluate the utility of point-of-care Hb measurement with the HemoCue® device for the diagnosis of anaemia.

Method: In this prospective study, we compared the analytical performance of the HemoCue® to the Coulter® LH 750 automated haematology analyser with regard to accuracy, precision and linearity in the measurement of Hb in adult and paediatric patient samples, referred for routine laboratory testing.

Results: Samples from 100 patients were analysed with both instruments, and the results were compared using standard scatter and difference plots. The mean Hb value of the HemoCue® (11.3 g/dl; range 4.6-16.7) was comparable to the Coulter® LH 750 (11.3 g/dl; range 4.7-17.2). The Bland-Altman difference plot revealed good correlation. Bias between the two methods was small, and the imprecision was within acceptable limits. Hb measurement was linear in the range of 4.8-20 g/dl.

Conclusion: In all age groups, the HemoCue® point-of-care device can be used to provide accurate and reliable Hb measurements with a smaller sample volume, improved turnaround time, and long-term cost saving.

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Introduction

Point-of-care testing (POCT), or near-patient testing, is the fastest growing segment of diagnostic laboratories in the developed world. Laboratories have become increasingly involved in supporting testing away from the conventional laboratory setting, to improve the quality and cost of healthcare delivery. POCT has been validated within hospitals and general practice to assist with urgent patient management, by providing rapid laboratory test results.[1-5]

Measurement of haemoglobin (Hb) alone is a valuable screening test for anaemia, and has an important role in POCT.[1] Anaemia is common in pregnant women, infants and preschool children.[6] Anaemia is suspected on the basis of clinical signs and symptoms. If the Hb is below the lower limit of normal for age, gender and altitude, additional laboratory parameters, including red cell indices, a reticulocyte count and review of the peripheral smear, will assist further assessment of the anaemia.

The introduction of POCT for Hb measurement offers distinct advantages.[7-11] These include improved turnaround time, a small sample volume required for testing, and long-term cost savings.[5] The volume required for analysis is very small (10 µl), making this device particularly suitable for paediatric and neonatal Hb measurements, as blood sampling in this age group is often technically difficult and distressing.

More recently, POCT devices that require capillary blood samples have become available for measuring Hb with enhanced speed, simplicity and analytical performance.[3-5] The most popular haemoglobinometer is the HemoCue® (Aktiebolaget Leo Diagnostics, Helsingborg, Sweden), which is a small bench-top device, suitable for use in doctors' offices. It measures Hb by converting haemoglobin into haemoglobinazide.[12] Whole blood collected by capillary or venous sampling (10 µl) is placed into the cuvette (containing dried reagents) in the cuvette holder. Light absorbance is measured at two wavelengths, namely 565 and 880 nm (to compensate for any turbidity in the sample).

The instrument then calculates the Hb in the sample, and displays the results within 45 seconds.

Other locally available small hand-held devices include the STAT-Site® M Hgb (Stanbio Laboratories,Texas, USA) and the Spencer® haemoglobinometer (Buffalo Medical Specialities, Buffalo, New York, USA). In comparison to these devices,[13,14] the HemoCue® shows the highest level of agreement with automated haematology analysers, with a reported correlation of 99% when used by trained operators.[15] It complies with the International Committee on Standardization in Haematology's standards for haemoglobin measurement (ICSH, 1996).[16]

An evaluation of the HemoCue® device was performed to compare its analytical performance with regard to accuracy, precision and linearity in the measurement of Hb with that of the Coulter® LH 750 automated haematology analyser (Beckman Coulter, Miami, Florida, USA).

Method

Ethical approval

Ethical approval for the study was obtained from the University of Witwatersrand human research ethics committee. This validation was performed in accordance with the ICSH 1993, and the method comparison from the Clinical and Laboratory Standards Institute (CLSI EP9, USA).[17]

Study period

The validation was performed at the National Health Laboratory Service at the Charlotte Maxeke Johannesburg Academic Hospital over a two-week period.

Patient samples

Blood samples used were those left after routine diagnosis carried out on adult and paediatric patients at the main hospital laboratory. Ethylenediaminetetracetic acid samples obtained by venepuncture, heel prick, or from arterial lines with volumes more than 20 µl were used.

Evaluation procedure

For the method comparison study, a prospective, side-by-side comparative study of the HemoCue® haemoglobinometer against the Coulter® LH 750 automated haematology analyser was performed. Hb measurement was taken in duplicate on 100 adult and paediatric patient samples that were referred for routine testing. The samples were analysed sequentially by the same technologist on the HemoCue® and Coulter® LH 750 haematology analysers using the respective instruments' standard operating procedures. There was no aliquoting or sample splitting.

Within-run precision evaluation was performed with the normal and abnormal HemoTrol reference control analysed 20 times.

Linearity was assessed by diluting known patient samples with high Hb levels, 1:2; 1:4; 1:8; and 1:16, with isoton or normal saline. The linearity findings were used to determine the analysers' reportable range and lower limit of detection.

Statistical analysis

Results were collated on an Excel spreadsheet, tabulated, and graphically summarised using standard statistical methods. Agreement between results obtained on the different analysers was evaluated using standard scatter and difference plots.

Results

One hundred samples were identified and qualified for analysis by both instruments. The mean Hb value of the HemoCue® (11.3 g/dl; range 4.6-16.7), was comparable to that of the Coulter® LH 750 (11.3 g/dl; range 4.7-17.2). The Bland-Altman difference plot revealed good correlation. Bias between the two methods was small (0.76%). The limit of agreement between the two methods is demonstrated in the difference plot, according to Bland-Altman (see Figure 1). The intra-assay coefficients of variation (CV) were within allowable limits of performance in the normal and pathological range (1.75% and 1.51% respectively). The results of the intra-assay precision for the normal reference control are shown in Figure 2. Hb measurement was linear in the range of 4.8-20 g/dl (see Figure 3).

Seven data points are outside the 95% limits of agreement. However, the bias is small (0.76%).

At the allowable precision limit of 1.4, there is a linear relationship between the observations and mean difference as a function of imprecision.

Hb measurement is linear, in the range of 4.8-20 g/dl.

Discussion

In this prospective study, we demonstrated the clinical utility of the HemoCue® point-of-care device for the diagnosis of anaemia. The HemoCue® is a portable haemoglobinometer that was introduced into the clinical setting over 20 years ago for Hb measurement.

This study demonstrated acceptable agreement between the HemoCue® and laboratory measurement with the Coulter® LH 750 automated haematology analyser. Ninety-five per cent of the values had a clinically significant difference of < 1 g/dl, making this an acceptable method. The HemoCue® was accurate over a wide Hb range

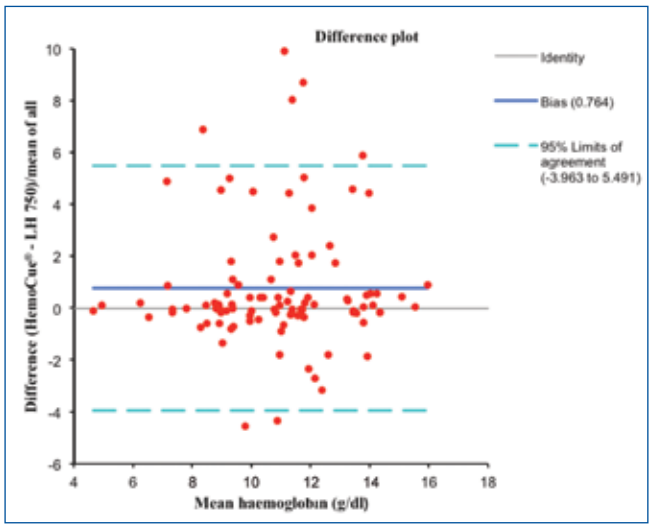

Figure 1: Bland-Altman difference plot for Hb measurement with the HemoCue® and Coulter® LH 750

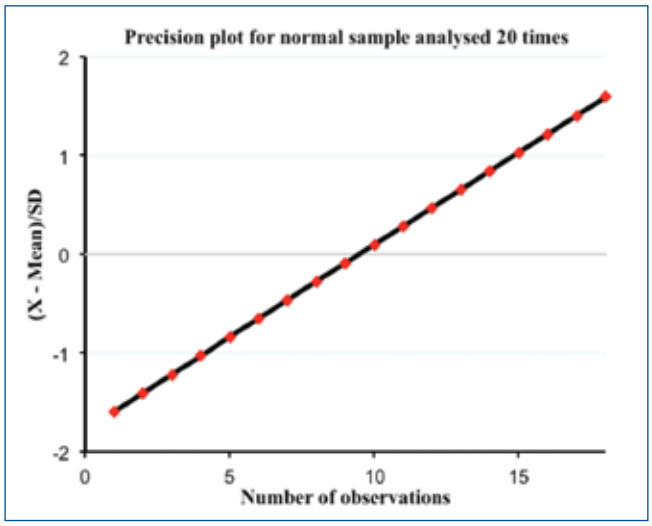

Figure 2: Precision plot of normal Hb measurements

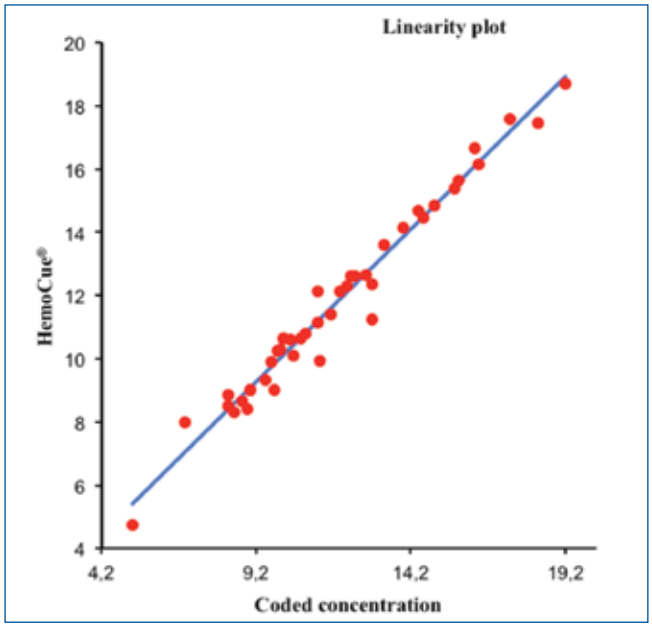

Figure 3: Linearity plot of HemoCue® Hb measurements

(4.8-20 g/dl) for the diagnosis and monitoring of anaemia and polycythemia. When used under standard laboratory conditions, the HemoCue® is an accurate method for determining Hb. In addition, studies performed by non-technical staff in a clinic or general practice, show a similar level of accuracy and precision.[18] Several research groups have demonstrated the advantages of having a simple and reliable POCT for the diagnosis of anaemia without having to perform venepuncture.[7-11] The introduction of POCT has improved patient care and accessibility in these settings.

In South Africa, the highest burden of anaemia occurs in the first year of life.[6] Although this disorder is common, it frequently remains undetected and untreated. This study included a large number of paired neonatal and paediatric samples (n = 50). The introduction of the Hb POCT in paediatric patients would have a number of advantages. The HemoCue® would allow for rapid Hb determination, using small sample volumes (10 µl). The most common error reported when measuring Hb in the laboratory is an insufficient sample, as most analysers require a minimum sample volume of 500 µl.

In addition to being a simple device to operate, the HemoCue® offers potential cost savings. Initially, there would be increased expenses as a result of the cost per unit, which includes analyser, cuvettes and reagents, which would need to be supplied and distributed. The initial introduction might also result in increased over-servicing, and this would need to be closely monitored. However, the literature has demonstrated the potential long-term cost-saving benefits of implementing the HemoCue® in a hospital setting.[5,19-20] These include the elimination of the preanalytical and many of the analytical steps in the diagnostic process, some of which include skilled staff, bar codes, equipment and reagents. Specific to our current local setting, where the power supply is inconsistent, the HemoCue®, which is a battery-operated device, will prove to be highly beneficial.

It is imperative that implementation of POCT is accompanied by guidelines that reflect current best practice.[20] These guidelines should be strictly adhered to by all staff who operate the device. A quality system should be defined, where results are validated by satisfactory performance in internal and external quality-assessment schemes. For example, an internal quality control (IQC) test should be performed at the start of the day before any patient analysis is performed. Further IQC should also be performed with every new batch of cuvettes to ensure there has been no deterioration during storage. Moreover, abnormal results must be appropriately flagged. A system should be established for appropriate referral to the supporting local

reference laboratory for out-of-range results for further investigation. In specific settings, full blood count analysis and repeat samples may be required. Close cooperation with the local laboratory service is also required to ensure adequate training and education of the staff who will be performing the tests.

Conclusion

In this cohort, the HemoCue® provided accurate and reliable Hb measurements for a wide range of Hb for the diagnosis of anaemia. The advantages of HemoCue® over standard haematology analysers are the small volume required, and rapid turnaround times. Although this does not replace full blood count testing, it is a useful adjunct to monitoring anaemia in all age groups.

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Conflicts of interest

None declared.

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