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TRANSLATIONAL RESEARCH

Usefulness of non-invasive spectrophotometric haemoglobin estimation for detecting low haemoglobin levels when compared with a standard laboratory assay for preoperative assessment

A. A. Khalafallah[1,3,4*], C. R. Chilvers[2], M. Thomas[1], C. M. Chilvers[5], M. Sexton[1], M. Vialle[2] and I. K. Robertson[3]

[1] Department of Medicine and Haematology and [2] Department of Anaesthesia, Launceston General Hospital, Launceston, Australia
[3] School of Health Sciences and [4] Menzies Research Institute, University of Tasmania, Hobart, Australia
[5] Medical School, Monash University, Melbourne, Australia

* Corresponding author. E-mail: khalafallah@dhhs.tas.gov.au

Editor's key points

- Instant non-invasive haemoglobin (Hb) measurement has potential to accelerate clinical decision-making.
- Spectrophotometric haemoglobin (SpHb) was compared with standard invasive testing in more than 700 patients.
- SpHb was good at identifying low Hb in males, but less so in females.
- Precision was unacceptable.
- SpHb is useful as a screening tool but needs subsequent measurement of Hb by standard techniques to guide clinical decisions.

Background. Delay in diagnosis of anaemia during preoperative assessment poses logistic problems, leading to multiple clinic visits, inadequate preoperative management, and unnecessary delay of surgery. Therefore, we tested an instant spectrophotometric haemoglobin (SpHb) measurement technique to facilitate this assessment.

Methods. We evaluated portable instant SpHb *vs* standard laboratory screening of anaemia between March 2012 and December 2013. Paired Hb measurements were performed on 726 patients using SpHb (Pronto-7, Masimo Corporation, Irvine, CA, USA) and Hb measured on the same day using an automated analyser. The results were obtained from a group of 638 patients from the pre-anaesthetic clinic with expected normal Hb values, and 88 patients from the oncology clinic with known low Hb.

Results. Median (range) SpHb was 129.5 (67–171) compared with 136 g litre^{-1} (63–178) Hb measured using the automated system. Identifying Hb below a threshold of 130 g litre^{-1} for males had a high sensitivity (93%), while identifying a threshold of 120 g litre^{-1} for females had lower sensitivity (75%). The specificity for males (77%) and females (81%) was similar. Mean measurement bias and agreement: tolerability interval ratio was −8.1 g litre^{-1} and 2.78 for men and −3.1 g litre^{-1} and 2.44 for women.

Conclusions. SpHb was sensitive as a preliminary screening tool for detecting true low Hb values in males, but less sensitive in females. Instant SpHb measurement may enable prompt routine preoperative anaemia management, but its precision was lower than expected.

Clinical trial registration. This study is approved by the Tasmanian Human Ethics Committee, Australia and was registered prospectively in the Australian and New Zealand Clinical Trials Registry (http://www.ANZCTR.org.au/ ACTRN12611001256965) and the World Health Organization Clinical Trials Registry (http://apps.who.int/trialsearch/trial.aspx?trialid=ACTRN12611001256965).

Keywords: laboratory Hb; pre-anaesthetic clinic; preoperative anaemia; preoperative screening; spectrophotometric Hb

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Haemoglobin (Hb) assessment is one of the most common laboratory tests performed, with an estimated 400 million tests yearly.[1 2] The value of a reliable and convenient clinical method to measure Hb in patients who are undergoing major operative procedures[3] is clearly established. An ideal method for clinical use should be easy to perform, accurate, reproducible, fast, and cost-effective.

The standard measurement of Hb involves either venepuncture, and to a lesser extent fingerprick, both of which are invasive methods that may cause pain and create a potential risk of infection for patients, and of needle-stick injury for clinical staff.[1 2] In addition, the laboratory-based standard Hb test entails cost (transportation and processing) and some delay in the reporting of results. Using an instant non-invasive

point of care device reduces discomfort for patients and saves time in patient care, especially in certain clinical circumstances.[1 4] Delays in the identification of patients with preoperative anaemia may delay both proper anaemia management and the operative procedure.[5]

Masimo Pronto-7 (version 2.1.9, Masimo Corporation, Irvine, CA, USA) in conjunction with the Rainbow 4D Sensor or finger probe is a device that has been developed by the manufacturers for the non-invasive estimation of Hb. The technology involved is Rainbow signal extraction technology, or the spectrophotometric estimation of haemoglobin (SpHb), as it is now widely known.[6–8] SpHb has the potential to overcome some of the shortcomings of invasive Hb sampling by enabling fast, accurate, needle-free Hb measurements.[8–10]

The current study arose as a sub-study of a randomized controlled trial of i.v. iron infusion in patients identified as being anaemic before major surgery. The pilot component of this trial identified a logistical problem in the recruitment of patients after initial examination at the pre-anaesthetic assessment clinic, because only a minority of the patients found to be eligible were returning to the clinic for treatment of their anaemia, and therefore, the trial recruitment was poor and potentially biased. SpHb measurement was therefore undertaken in all patients as a screening process to identify potentially anaemic patients, and for recruiting the patients into the trial before they left the clinic.

Objective

The aim of the present analysis was to compare SpHb levels obtained non-invasively using the Masimo Pronto-7 device with Hb values from standard laboratory procedures (LabHb) using venous blood samples taken within 1 h of the SpHb measurement in two groups of patients.

Patients and methods

Patient recruitment

We conducted a parallel prospective assessment of SpHb *vs* standard Hb in 726 consecutive patients seeking care at the Launceston General Hospital (a tertiary referral teaching hospital in Tasmania, Australia) during the period of March 2012 to December 2013. Written informed consent was obtained from subjects taking part in a randomized controlled trial of i.v. iron infusion *vs* oral iron in patients identified as being anaemic before major surgical procedure. Of these, 638 patients had attended the pre-anaesthetic clinic (PAC) before major elective surgery and underwent SpHb in addition to routine laboratory testing that included standard Hb measurement. For the purpose of the study, clinical decisions for treatment were based on standard measurements (LabHb). The SpHb acted here as a screening tool. A further group of 88 consecutive patients with known low Hb was recruited from the oncology clinic (ONC) from January 2013 to March 2013 to expand the number of patients in the study with true low haemoglobin (Hb) levels.

The randomized controlled trial, of which this data collection was a component part, was approved by the Tasmanian Human Research Ethics Committee and registered in the Australian New Zealand Clinical Trials Registry (http://www.ANZCTR.org.au/ ACTRN12611001256965) and the World Health Organization Clinical Trials Registry (http://apps.who.int/trialsearch/trial.aspx?trialid=ACTRN12611001256965).

Haemoglobin measurement

Elective surgery patients had their SpHb measured at the pre-anaesthetic check-up by a senior clinic nurse using the Masimo Pronto-7 device in an 'average of three readings' mode. This was followed by a standard laboratory blood test for Hb within 1 h. Those oncology patients who attended for routine laboratory Hb check had their SpHb measured at the time they had their blood collected. The non-invasive measurement by the SpHb technique and the blood collection occurred within ~1 h of each other for all patients. SpHb was performed by nine different registered nurses in the PAC.

Fresh ethylene-diamineteraacetic acid blood specimens were collected prospectively from all patients and were analysed within 2 h of collection as per routine laboratory turnaround time. The Hb was measured at a National Association of Testing Authorities accredited laboratory using a Sysmex XE®5000™ automated haematology analyser (Sysmex Corporation, Kobe, Hyogo, Japan).

The lower limit of normal Hb was defined as 130 g litre^{-1} for men and 120 g litre^{-1} for women as per routine laboratory procedures. As the coefficient of variation (CV) for the laboratory Hb is routinely performed on quality control material, and as there is no equivalent QC material or process for SpHb measurements, a separate procedure was performed to generate the necessary data. The CV for the SpHb measurement was estimated by performing 30 repeated estimates of Hb over 90 min on each of seven laboratory and research staff who were not subjects in the trial (four females: LabHb 83, 100, 113, and 146 g litre^{-1}; three males: LabHb 81, 117, and 151 g litre^{-1}). The CV for the laboratory Hb assay was estimated by 10 repeated assays on single blood samples from each of 6 persons (four females: LabHb 86, 103, and 123 g litre^{-1}; three males: LabHb 84, 106, and 128 g litre^{-1}).

Statistical methods

Patient characteristics were compared using the T-test (age, BMI standard, and LabHb) and where distributions were strongly non-normal: oxygen saturation, pulse rate, and perfusion index (PI), ordered logistic regression was used.

Two assessments were performed: (i) an assessment of the utility of the SpHb device as a screening tool to identify low Hb levels in men (<130 g litre^{-1}) and women (<120 g litre^{-1}). Sensitivity, specificity, and receiver operating characteristics (ROC) area were estimated using ROC analysis, (ii) a Bland–Altman assessment of the two assay methods as recommended by Mantha and colleagues[11]: repeatability was expressed as the coefficient of variation (CV: calculated as SD/mean) for each test method; the SpHb-laboratory difference between method result pairs of measurements (*y*-axis) were plotted against the mean value of the two methods (*x*-axis);