Point-of-Care Hemoglobin/Hematocrit Testing: Comparison of Methodology and Technology

Andrew Maslow, MD,* Arthur Bert, MD,* Arun Singh, MD,† and Joseph Sweeney, MD‡

Objective: **Point-of-care (POC) testing allows rapid assessment of hemoglobin (Hgb) and hematocrit (Hct) values. This study compared 3 POC testing devices—the Radical-7 pulse oximeter (Radical-7, Neuchtel, Switzerland), the i-STAT (Abbott Point of Care, Princeton, NJ), and the GEM 4000 (Instrumentation Laboratory, Bedford, MA)—to the hospital reference device, the UniCel DxH 800 (Beckman Coulter, Brea, CA) in cardiac surgery patients.**

Design: **Prospective study.**

Setting: **Tertiary care cardiovascular center.**

Participants: **Twenty-four consecutive elective adult cardiac surgery patients.**

Interventions: **Hgb and Hct values were measured using 3 POC devices (the Radical-7, i-STAT, and GEM 4000) and a reference laboratory device (UniCel DxH 800). Data were collected simultaneously before surgery, after heparin administration, after heparin reversal with protamine, and after sternal closure. Data were analyzed using bias analyses. POC testing data were compared with that of the reference laboratory device.**

Measurements and Main Results: **Hgb levels ranged from 6.8 to 15.1 g/dL, and Hct levels ranged from 20.1% to 43.8%. The overall mean bias was lowest with the i-STAT (Hct, 0.22%; Hgb 0.05 g/dL) compared with the GEM 4000 (Hct, 2.15%; Hgb, 0.63 g/dL) and the Radical-7 (Hgb 1.16 g/dL). The range of data for the i-STAT and Radical-7 was larger than that with the GEM 4000, and the pattern or slopes changed significantly with the i-STAT and Radical-7, whereas that of the GEM 4000 remained relatively stable. The GEM 4000 demonstrated a consistent overestimation of laboratory data, which tended to improve after bypass and at lower Hct/Hgb levels. The i-STAT bias changed from overestimation to underestimation, the latter in the post-cardiopulmonary bypass period and at lower Hct/Hgb levels. By contrast, the Radical-7 biases increased during the surgical procedure and in the lower ranges of Hgb.**

Conclusion: **Important clinical differences and limitations were found among the 3 POC testing devices that should caution clinicians from relying on these data as sole determinants of when or when not to perform transfusion in patients. Even though a low bias might support the use of POC data, further analysis of the bias plots demonstrates pattern changes during the surgical procedure and across the range of Hct/Hgb data.**

KEY WORDS: hematocrit, hemodilution, cardiac surgery, hemoglobin, point-of-care tests

POINT-OF-CARE (POC) testing allows for rapid assessment of critical physiologic variables and functions. Given the concerns with transfusion-related risks and the risks of delayed transfusion, an accurate measurement of hemoglobin (Hgb) and hematocrit (Hct) levels is essential for clinical decision making.[1]

Most POC devices require blood samples, and the samples are obtained periodically when indicated. More recently, advances in pulse oximetry (Masimo Radical-7; Masimo, Neuchtel, Switzerland) offer continuous assessment of hemoglobin based on co-oximetry/spectrophotometry.[2–6] In the authors' hospital, clinicians have access to 3 POC instruments, 2 of which require blood sampling—the GEM 4000 (Instrumentation Laboratories, Bedford, MA) and the i-STAT (Abbott Point of Care, Princeton, NJ)—and 1 device that does not require blood sampling, the Radical-7.

Cardiac surgery patients experience significant changes in physiology and hemodynamic functions. Management of these patients involves combinations of vasoactive medications, intravenous fluids, and hemotherapy. This study compared 3 POC devices to the hospital reference laboratory device to assess the accuracy of Hgb and Hct data at baseline and during changes in physiology. The authors hypothesized that point-of-care tests (POCT) for hemoglobin and hematocrit were accurate when compared with the hospital reference device (UniCel DxH 800 (Beckman Coulter, Brea, CA).

METHODS

The cases of 24 consecutive, elective adult cardiac surgery patients were analyzed as part of a quality assurance (QA) assessment of 3 different POC systems after the recent introduction of the i-STAT device into the authors' clinical practice and access to the Radical-7 device. Patients with known or suspected red blood cell dyscrasias or abnormal indices (except for low Hgb or low Hct levels) were excluded.

The collection and reporting of the QA data were approved by the hospital's ethics committee. Written consent was not necessary.

Demographic data collected included age, surgical procedure, and use of vasoactive medications. All patients underwent general anesthesia with standard noninvasive monitors, including pulse oximetry (Radical-7). The systemic and pulmonary vascular pressures were monitored via an intra-arterial catheter and a pulmonary artery catheter, respectively. Hemodynamic management was at the discretion of the attending cardiac anesthesiologist but was based on a general divisional protocol and set of goals.

Data were recorded from 3 POC hemoglobin/hematocrit tests and compared with hospital reference laboratory values. Data were collected from the Radical-7 pulse oximeter, the i-STAT device, and the GEM 4000 device.

The Radical-7 is a noninvasive measure of oxygen saturation and hemoglobin, using co-oximetry that does not require blood sampling. In addition, the Radical-7 records a perfusion index (PI) and pulse variation index (PVI), each yielding a measure of tissue perfusion. The Radical-7 uses a spectrophotometric (co-oximetry) adhesive sensor (rainbow R1 25 and R1

*From the Departments of *Anesthesiology; †Surgery (Division of Cardiac Surgery), Rhode Island Hospital, Providence, RI; and ‡Medicine (Division of Hematology), Rhode Island Hospital, Providence, RI.*

Address reprint requests to Andrew Maslow, MD, 63 Prince St., Needham, MA 02492. E-mail: amaslow@rcn.com

1053-0770/2601-0001$36.00/0

http://dx.doi.org/10.1053/j.jvca.2015.11.010

25L; Masimo) that uses multiple wavelengths of light for analysis of hemoglobin absorption, allowing for measurement of hemoglobin (version 7.6.1.1). The sensor is covered with a black plastic shield to minimize optical interference.

The i-STAT device measures the hematocrit value conductometrically, in which the electrical conductivity is inversely related to the hematocrit level. Higher Hct values reduce conductivity. Hemoglobin is measured indirectly as a function of the hematocrit (hematocrit × 0.34 = hemoglobin).

The GEM 4000 POC analyzer measures hemoglobin by co-oximetry (GEM OPL CO-Oximeter; Instrumentation Laboratory) using multi-wavelength spectrophotometry. The hematocrit value is derived using the following formula: hematocrit = hemoglobin × 3.

Data from these 3 POC devices were compared with that of the hospital reference device. For Hgb assessment, whole blood was aspirated, the red cells lysed, and Hgb was released; the Hgb was linked to a coloring agent (Drabkin's solution), and using spectrophotometry (co-oximetry), the Hgb concentration, based on absorption of light, was measured. The hematocrit value was calculated from the red cell count and the mean cellular volume (MCV) (Hct = red cell count × MCV [fL]/[10E12/L]). The red cell count was determined by the passage of particles through the sensing zone aperture (number of particles per microsecond counted as single events) and the MCV by the displacement of the fluid and effects on electrical conductivity. The UniCel DXH 800 has daily internal quality checks and also runs external quality testing for proficiency.

Data were collected at the following 4 time points:

T = 0 Baseline: before the start of surgery (presurgery)

T = 1 After administration of heparin and before cardiopulmonary bypass (postheparin)

T = 2 After administration of protamine and before sternal closure (postprotamine)

T = 3 After sternal closure (poststernal closure)

Blood samples used for the i-STAT, GEM 4000, and UniCel DXH 800 devices were taken from the same blood aspiration, which was obtained after removal of 7.5 × the dead-space of the sampling line (approximately 20 mL). Radical-7 data were recorded at the same time blood sampling occurred.

Statistical Analysis

The goal of this study was to assess the similarity of hematocrit and hemoglobin estimates obtained from 3 different POC devices (the GEM 4000, i-STAT, and Radical-7) to those obtained using the reference laboratory device (UniCel DxH 800).

The analytic approach was based on a modification of the Bland-Altman graphic analysis, which focuses on the consistency of the differences between 2 devices (bias) and how these may vary depending on the magnitudes estimated (means of estimates). In this study, the authors substituted the hospital's reference laboratory values from the UniCel DxH 800 for the mean. Differences from the UniCel DxH 800 and the POC devices were calculated by subtracting the references values from the POC devices' values. In this way, positive values represented POC overestimates relative to laboratory-obtained values and negative values represented underestimates.

Estimates were gathered in the same patients during 4 phases of their surgeries. General linear models were constructed to estimate the ways in which POC estimates differed from laboratory values (difference scores): (1) overall relative to laboratory values, (2) as a function of the laboratory values and the phase of surgery, and (3) as a function of other covariates and the phase of surgery. Repeated observations were nested within the patient using a correlated error approach. Slopes and bias parameters were tested against zero without alpha adjustment because the alternative could be considered liberal.

RESULTS

The study included 24 cardiac surgery patients. Table 1 reports demographic and intraoperative data. Data were collected at 96 time points. Of these 96, there were 18 time periods in which at least 1 laboratory test was not obtained, yielding 78 time periods when all 4 tests were performed. Of these 18 time periods, there were 13 in which a reference laboratory sample was not obtained, 4 in which a GEM test was not obtained, and 5 in which an i-STAT sample was not performed. The missing data for each technology overlap. In all, there was only 1 sampling time that Radical-7 data were not recorded. At this time, the PVI was 0.228, the lowest value during the entire study collection.

The following analysis included 78 time periods when all devices recorded simultaneous data. Based on the hospital laboratory, the range of Hgb was 6.8 to 15.1 g/dL and the range of Hct data was 20.1% to 43.8%. Of the 78 samples, the Beckman Coulter machine recorded a Hgb >10 g/dL in 47 samples, and a Hgb <10 g/dL in 31.

Correlation

Correlations between the POC devices and the laboratory device data were all significant ($p < 0.0001$). The level of significance was not different before or after CPB. The Radical-7 data correlated less well compared with the GEM 4000 and i-STAT devices ($r^2 = 0.71$ $v > 0.94$) (Fig 1).

Table 1. Demographic and intraoperative data. Included are age, surgical procedure, use of vasoactive medications prior to and after cardiopulmonary bypass (CPB).

Variable	Number
Age (mean (SD)	79.9 (7.0) years
Surgical Procedure (n)	
CABG	17
CABG Valve	16
Valve	40
Aortic Procedure	5
Vasopressors (Norepi/Vaso) (n)	
Pre CPB (yes/no)	30/5
Post CBP (yes/no)	37/6
Inotropes (Epi/Dopa) (n)	
Pre CPB (yes/no)	1/34
Post CPB (yes/no)	19/24
Vasodilators (NTG/NTP) (n)	
Pre CPB (yes/no)	6/29
Post CPB (yes/no)	3/40

CABG-Coronary artery bypass grafting; CPB- Cardiopulmonary bypass; Norepi- Norepinephrine; Vaso- Vasopressin; Epi-Epinephrine; Dopa- Dopamine; NTG- Nitroglycerin; NTP- Nitroprusside; SD- standard deviation