

Original Article

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Point-of-care Hemoglobin Measurement in Comparison with Hematology Analyzer: A Cross-sectional Study in Emergency Department

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Abstract

Introduction: Point-of-care hemoglobin testing devices can help emergency physicians to make their clinical decisions in a timelier manner. They can also improve the patient care process by decreasing the length of stay and costs. Although different devices are available now, their diagnostic accuracy remains still uncertain.

Objective: This study compares the results of hemoglobin levels measured by a point-of-care hemoglobin testing device and central lab auto-analyzer.

Methods: Hemoglobin level was measured both by a point-of-care device (Mission® Plus Hb) and the central laboratory auto-analyzer (Sysmex KX-21N™) in medical cases presenting to emergency department (ED) and requiring hemoglobin (Hb)/hematocrit (Hct) level measurement. The agreement of Hb and Hct between the two methods was assessed based on intraclass correlation coefficient (ICC), Bland-Altman analysis and the Mountain plots. Also, time gap between point-of-care testing and preparation of central lab results was measured.

Results: Hb and Hct were measured in 86 cases mostly presented because of gastrointestinal bleeding. We found a good agreement between the two methods for hemoglobin (ICC=0.985) and hematocrit levels (ICC=0.991). The bias was 0.09 and 95% limits of agreement (LoA) were -0.89 to 1.07 for Hb level. Mean of time delay between point-of-care testing and preparation of central lab results was 207.31 minutes (SD=93.66) and this delay was clinically significant ($p=0.001$).

Conclusion: Point-of-care measurement of Hb level provides proper quantitative results in ED patients. It significantly decreases laboratory turnaround time and may be used to improve the patient throughput by decreasing the length of stay in most clinical settings.

Key words: Emergency Service, Hospital; Hemoglobin; Laboratory Proficiency Testing; Point-of-Care Testing

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INTRODUCTION

Laboratory data is used in between 40% to 70% of all medical decision makings (1, 2). Hemoglobin level measurement is the most common hematologic test used both in emergency department (ED) patients and a variety of other patients in outpatient and inpatient settings (3, 4). Hemoglobin is conventionally measured with central lab hematology auto-analyzers via a time-consuming process. Currently, small portable point-of-care testing (POCT) devices, which are readily available in some countries (even in pre-hospital settings), have provided the ability of continuous and spot-check measurement of hemoglobin level by different minimally invasive or noninvasive methods in a timelier manner (5-7). POCT has become more popular in routine medical practice and if it can provide consistent reliable bedside test results, it may help physicians to make more accurate decisions in a timelier manner.

Controlled use of POCT devices in patients with clearly defined indications has the potential to spare the time of diagnostic procedures, decrease the length of stay in ED, decrease the costs for patient and hospital, increase the patient and personnel satisfaction and improve the overall patient care process (8). Although there are different POCT devices available now, the reliability of their test results is still a conflicting area. This study evaluated the agreement of a point-of-care Hb measurement device in comparison with automated central laboratory hematology analyzer in ED patients.

Methods

Study design and setting

This single-center cross-sectional study was performed in an ED of a tertiary level referral teaching hospital with annual censuses of about

50,000 in Tehran, Iran. This hospital is a referral center for adult hematology/oncology cases older than 18 years old. We enrolled cases from May to December 2018 by convenience sampling. Institutional ethics committee approved the study (Code: IR.SBMU.MSP.REC.1396.315). Informed consent was obtained from all patients or their legal guardians.

Participants and intervention

We included patients with acute or chronic gastrointestinal/vaginal bleeding, chronic anemia with different indications for blood transfusion (like known cases of hematologic and oncologic disorders, chronic renal failure cases, etc.), patients presenting to the ED with chief complaints of weakness and syncope, any other cases that were admitted to the ED that required Hb level measurement. Because of the importance of the spot check and serial Hb level in decision making for trauma patients, they were included in another study conducted in a trauma center. Patients with hemoglobinopathies which affect the results of Hb level assessment and pregnant women were excluded from the study.

Study protocol

For all included patients, a point-of-care Hb measurement was performed by a single research assistant after taking a history and conducting a physical exam. Then a venous sample was sent to central lab for measuring the Hb level. Demographic data, patient's chief complaint, point-of-care and central lab test results and time gap between reading the POCT results and preparing the central lab ones were documented.

Measurements

All POCT measurements were carried out with Mission® Plus Hb (ACON Laboratories, Inc. USA). This is a small portable handheld device which measures a wide range of Hb (4.5 to 25.6 g/dl) and Hct (13% to 75%). The device is turned on and a test strip is inserted in. One of the fingers is punctured to collect 10 µL capillary blood via a tiny tube and transferred to the test strip. Hb level is first measured in this fixed pre-determined volume of blood and then the whole capillary blood Hb and Hct level is calculated automatically and displayed within 15 seconds.

All central lab measurements were done by Sysmex KX-21N™ (Sysmex, Norderstedt, Germany) on venous blood samples.

The Mission® Plus was checked every day using the control cuvette and a standard known concentration of Hb. Sysmex KX-21N™ was controlled in central lab in a daily basis by using 3 standard control sets.

Data analysis

Variables were described with mean, minimum, maximum, frequency and percent. The Hb/Hct level values were described as mean ± standard deviation (SD). Mean difference of Hb/Hct was assessed with paired samples t-test. We assessed absolute agreement of Hb and Hct levels measured by POCT device and central lab automated analyzer with intraclass correlation coefficient (ICC). Also, we assessed of agreement between the two methods with Bland-Altman analysis and presented bias and 95% limits of agreement (Mean of differences ± 2 SD) with 95% CI for each. The Bland-Altman plot was drawn based on mean of both methods and differences in X and Y axes, respectively. Also, the mountain plot was generated to visualize the distribution of difference better. If the two methods are unbiased with respect to each other, the scatter plots should be centered over zero. P-value < 0.05 was considered statistically significant.

RESULTS

Baseline data

Ninety patients were enrolled in the study. Four patients were excluded because of a failure in POCT. Hb level was very low (2.3, 3.4 and 3.5 g/dl) in three of these four patients and very high (27 g/dl) in one of them as measured by automated hematology analyzer. Therefore, eighty-six cases were finally analyzed. Mean age of study patients was 60.37±16.9 years old with a minimum of 16 and a maximum of 94. Other demographic data is summarized in table 1.

Main results

The mean (SD) of Hb-POCT and Hb-LAB was 10.12 (2.89) and 10.03 (2.91), respectively and this difference was not significant (p=0.093). However, mean difference of Hct between the two methods (-0.44) was statistically significant (p=0.001). The absolute agreement based on ICC was 0.98 and

Table 1: Baseline data of study patients

Variable	Number (%)
Sex	
Female	31 (36.0)
Male	55 (64.0)
Chief complaint	
Gastrointestinal bleeding	42 (48.8)
Weakness	43 (50.0)
• Known cases of cancer	13 (15.1)
• Chronic anemia	28 (32.5)
• Chronic renal failure	1 (1.1)
• Cor pulmonale	1 (1.1)
Vaginal bleeding	2 (2.2)
Syncope	1 (1.1)

Table 2: Distribution, mean differences and ICC of Hb and Hct levels measured by POCT device and central lab automated analyzer (n=86)

Variable	Min, Max	Mean (SD)	P-value	ICC (95% CI)
Hb-POCT	4.50, 6.80	10.12 (2.89)	-	0.985
Hb-LAB	4.70, 17.40	10.03 (2.91)	-	(0.977 to 0.990)
Two Hb levels difference	0.00, 1.70	0.092 (0.50)	0.093	-
Hct-POCT	15.00, 54.00	30.87 (8.66)	-	0.991
Hct-LAB	14.20, 56.00	31.30 (8.52)	-	(0.983 to 0.994)
Two Hct levels difference	0.00, 3.60	0.44 (1.11)	0.001	-

CI: Confidence interval; Hb: hemoglobin; Hct: hematocrit; ICC: Intraclass correlation coefficient

0.99 for Hb and Hct, respectively; which shows a high agreement between the two methods (Table 2).

Based on Bland-Altman analysis, bias of Hb levels was 0.09 (95% CI: -0.02 to 0.20) and 95% limits of agreement (LoA) was -0.89 to 1.07. Therefore, a very good agreement existed between Hb levels measured by POCT device and those by central lab automated analyzer and the bias was not significant (Figure 1). The bias of Hct levels was -0.44 (95% CI: -0.68 to -0.20) and 95% limits of agreement was -2.6 to 1.70, and only four cases (4.65%) were out of 95% LoA (Figure 2).

Therefore, the agreement of Hb between the two methods was a little better than that of Hct level. The Mountain Plot showed that the difference between the two methods was lower for Hb levels than that for Hct levels, and as the plot was centered over zero, it presented lower differences (Figures 1, 2).

Mean of time delay between obtaining POC and central lab test results was 207.31±93.66 minutes (range: 64-571 minutes). By considering 60 minutes as a limit for clinical importance and the difference in preparing the Hb level measurement by lab, the two methods used in this study were

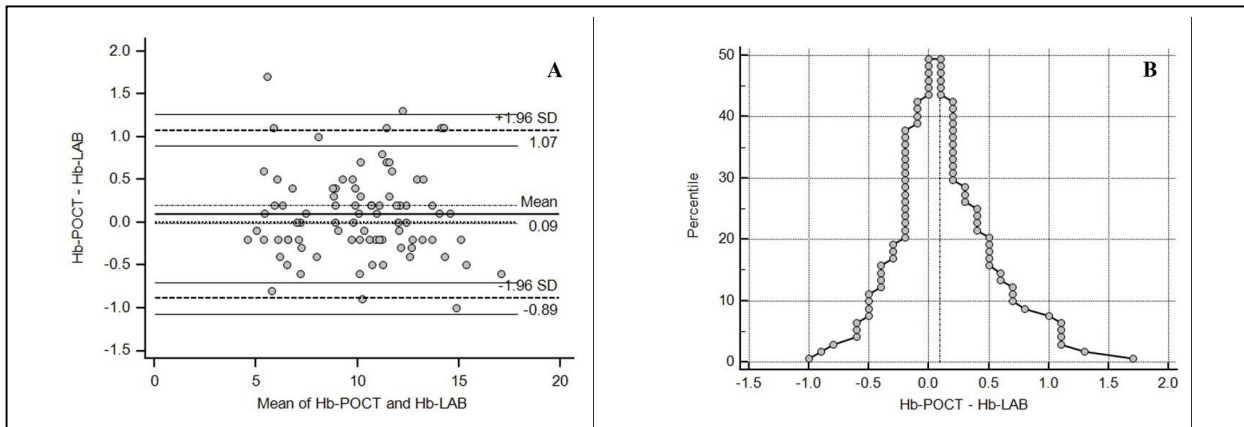


Figure 1: Bland-Altman plot (A) and the Mountain plots (B) of hemoglobin (Hb) levels measured by POCT device and central lab automated analyzer

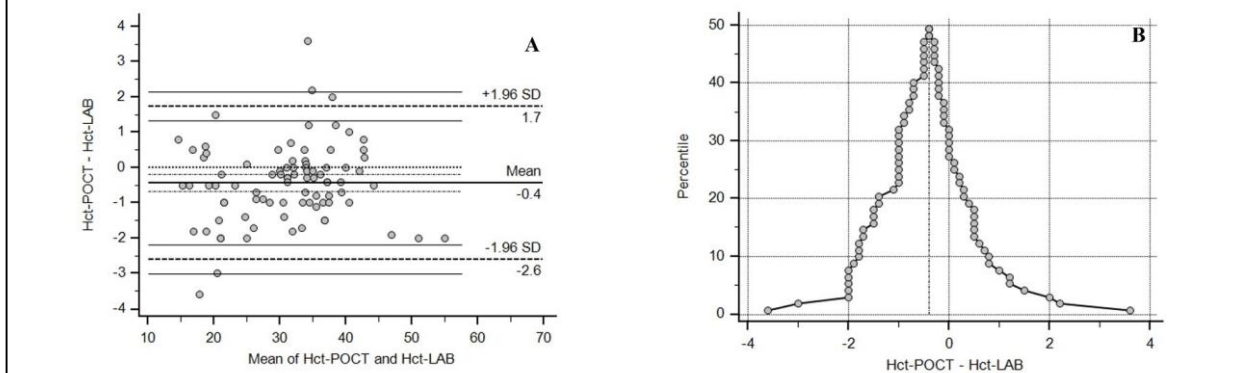


Figure 2: Bland-Altman plot (A) and the Mountain plots (B) of hematocrit (Hct) levels measured by POCT device and central lab automated analyzer

significantly different in preparing the results of Hb measurements ($P=0.001$). This means that the delays of central lab in measuring the Hb level may yield a negative impact on patients' clinical course and outcome.

DISCUSSION

Our study showed that the Hb concentrations measured by Mission® Plus Hb using a fingerstick blood sample are comparable with results of central lab auto-analyzer. While an intraclass correlation coefficient of 1 indicates a perfect agreement between the two methods, coefficient between POCT and central lab Hb levels in our study was 0.985 and coefficient was even higher between POCT and central lab Hct levels (0.991). Our results revealed that time was dramatically saved by performing bedside tests with Mission® Plus Hb.

Our results are similar to those of Raikhel et al. who studied 152 adult patients presenting to an outpatient research clinic. These patients were tested for Hb measurement by 3 methods: noninvasive pulse co-oximetry, a POCT device (HemoCue201+®), and hematology analyzer of central lab. They showed that both noninvasive pulse co-oximetry and HemoCue 201+® provide accurate results in comparison with hematology auto-analyzer. The mechanism of action in HemoCue 201+® is similar to the device we used in our study. Both of them use finger-tip blood sample and use strips to collect and transfer the blood into the device, just like regular glucometers. Noninvasive SpHb® testing had bias and SD similar to those of HemoCue 201+®. In this study noninvasive pulse co-oximetry measurements were as accurate as central lab and POCT device and they may offer additional benefits for patient and providers, but there were also 4 cases of measurement failure in pulse co-oximetry group while all attempts were successful in measuring the Hb level by POCT device (9).

In another study, Dolscheid-Pommerich et al. retrospectively compared the values of Hb measured by POCT device (System Rapidlab™1265) and central laboratory auto-analyzer in 2548 patients in an emergency department. Point-of-care Hb measurement had been a common practice at this level I trauma center for years. They observed a highly significant ($r=0.96$, $p<0.001$) overall correlation between Hb levels measured by System Rapidlab™1265 and central lab auto-analyzer with a mean difference of -0.44 g/dl. In samples with $Hb<8$ g/dl and also in very old patients (>85 years old), the difference

between results of central lab and POCT device was not statistically significant (10). In a study on neonates, Rechner et al. showed that with adequate training and monitoring, the HemoCue which works like the device we used in our study can be used directly on the neonatal unit for rapid determination of Hb levels while it uses much less blood by collecting capillary blood sample from heel prick compared with that of the central laboratory (11). Bernard et al. also compared Hb levels measured by HemoCue and hematology analyzer in 398 cases. Comparing HemoCue to auto-analyzer in terms of Hb levels revealed a correlation coefficient of 0.99 and limit of agreement of -0.38 to -0.64 g/dl verifying that the results of Hb level assessments using HemoCue® device were comparable to those of automated hematology analyzer (12).

In a study with 500 blood donors, venous Hb concentrations were measured by hematology analyzer and capillary Hb level was measured by fingertip or earstick blood sample. This study showed that hemoglobin levels measured by HemoCue and finger-tip blood were higher than those measured by central lab in venous samples as their differences exceed the limit of 1g/dl in 9% of samples tested by HemoCue. Accordingly, Hb levels measured by HemoCue and ear-stick samples were significantly higher than the actual hemoglobin concentration (13).

HemoCue POCT device was also used in another study by Adam et al. in Sudan. They measured Hb level by HemoCue in 108 pregnant women with 2 methods of blood sampling (venous blood, capillary blood). Venous blood samples were collected by special vacutainer tubes and capillary blood samples were obtained from middle fingertip of left hand. In this study, there was no agreement between Hb levels measured by HemoCue® and automated hematology analyzer. The mean±SD of hemoglobin levels were 12.70 ± 1.77 measured by HemoCue® with venous blood samples, 12.87 ± 2.04 measured by HemoCue® and 11.53 ± 1.63 measured by hematology analyzer (14). In another study by Seguin et al., Hb values were determined using the portable HemoCue system and central lab analyzer. In their study, 150 samples were obtained from 79 adult patients hospitalized in surgical intensive care unit. Hb level was measured by HemoCue and compared to the results of central lab assessments done on the simultaneously obtained sample. The mean absolute differences between Hb-Lab and HemoCue were 1.1 g/dl (95%CI, -3.6 to $+5.8$ g/dl). They concluded that HemoCue could not determine

the level of Hb accurately in critically ill patients and suggested that peripheral edema may affect the accuracy of results predominantly (15).

Several other studies found some limitations in using POCT devices in general daily practice. Kim SH et al. evaluated a total of 32 studies in a meta-analysis and reported that although the mean difference between noninvasive and central laboratory measurements was small, the limits of agreement were wide, which means that clinicians should cautiously make clinical decisions based on POCT devices. In their meta-analysis, mean difference and SD were 0.10 ± 1.37 g/dl while we had a mean difference of 0.09 and SD of 0.33 in our study (16). Hiscock R. et al. assessed the agreement between POCT hemoglobin measurements with laboratory-based one in 39 studies. They found also wide limits of agreement (-1.3 to 1.4 g/dl) and concluded that clinicians should carefully consider these limits of agreement before making clinical decisions about transfusion on point-of-care measurements alone (17).

Some studies emphasize general disadvantages of POCT like the lack of universal standard training for obtaining blood samples and/or calibration of the devices and insufficient internal and external quality assessments. These studies show that POCT should be used with certain indications under clear and tight institutional regulations to ensure patient safety and oversee other disadvantages (18-20).

Limitations

Hb measurement by fingertip capillary blood collection is still an invasive method. It provides just a spot check intermittent monitoring of Hb level. Our study showed POCT device significantly saved time, but it is not determined if this decrease

in time improved patient outcomes or not. Complementary outcome studies are needed to assess the true impact of POCT on patient care. Small sample size was another limitation in our study, so studies with larger sample sizes will be beneficial in determining the agreement and accuracy of POCT measurements in emergency department. We had just one operator in our study that performed all 90 measurements; it is recommended that studies with a larger sample size employ multiple operators to improve the generalization of results.

CONCLUSIONS

Point of care measurement of Hb level by Mission® Plus Hb provides proper quantitative results in emergency department patients. It decreases laboratory turnaround time significantly and may be used to improve the patient throughput by decreasing the length of stay in most clinical settings.

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AUTHORS' CONTRIBUTION

All the authors met the standards of authorship based on the recommendations of the International Committee of Medical Journal Editors.

CONFLICT OF INTEREST

None declared.

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