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Comparison of point-of-care versus central laboratory measurement of hematocrit, hemoglobin, and electrolyte concentrations

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ABSTRACT

Objectives: We aimed to investigate the accuracy of certain laboratory examinations obtained by the ABG analyzer (ROCHE AVL OMNI *S*) as compared to hospital central laboratory (CL).

Methods: We prospectively collected data obtained from the same arterial blood sample regarding hematocrit, hemoglobin, potassium, and sodium.

Results: ABG analyzer results were significantly lower (p < 0.0001) compared to CL values thus values between the two methods are not interchangeable. The mean bias for Hb, Na⁺ and K⁺ were within accepted by US Clinical Laboratory Improvement Amendment (USCLIA) differences (cut-off points) but not for Ht. In 8.0%, 17.5%, 37.5% and 56.0% of Hb, Na⁺, K⁺ and Ht measurements respectively and 29.75% in sum the differences were over the USCLIA accepted limits. ABG analyzer significantly underestimate the values of Hb, Ht, Na⁺ and K⁺, compared to CL and almost 30% of all examined parameters were beyond USCLIA accepted biases.

Conclusions: ABG analyzer significantly underestimates the values of Hb, Ht, Na⁺ and K⁺ compared to CL and almost 30% for all examined parameters are beyond USCLIA accepted biases. These data do not support widespread or even careful use of POCT for making diagnostic and treatment decisions until technology improves and results in improved outcomes.

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Introduction

Laboratory test results are always important for critical care decisions providing physicians with valuable information about the condition of the patient so that diagnosis and appropriate therapeutic interventions can be applied without delay.¹

There has been significant interest regarding point-of-care testing (POCT) in a critical care setting (e.g. ICU) where rapid therapeutic interventions are needed.^{2,3} POCT is defined as "testing at or near the site of patient care whenever the medical care is needed".⁴ The purpose of POCT is to provide immediate

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information to physicians about the patient's condition, so that this information can be integrated into appropriate treatment decisions that improve patient outcomes, that is, reduce patients' criticality, morbidity, and mortality. Also, POCT may be useful for patient monitoring during critical illness.⁵ ICUs are increasingly using POCT as a routine element of patient management and especially for blood gas analysis on every day basis. However, POCT is still trying to find its place in the ICU because of costs and accuracy issues.^{6–10}

The main advantages of POCT are the availability of the results by the patient within several seconds to minutes and the potential reduction of preanalytic and postanalytic errors.^{9,10} POCT significantly reduces turn-around-time (TAT-time between sample taking and result availability) providing immediate laboratory results and shorter door-to-clinical decision time. Also, current POCT instruments simplify repeated measurements, are user friendly and easy to use and require a very small sample volume (usually blood) to perform a test.^{1,6}

However, conflicting results from various studies, probably due to the use of different devices, add to accuracy, costs and performance concerns.^{10–12} While some studies concluded that results differed significantly for plasma sodium and chloride concentrations, others found also significant differences in potassium values. Thus, it is not uncommon to find clinicians using the POCT results to

Abbreviations: POCT, point-of-care testing; TAT, turn-around-time; ABG, arterial blood gases; CBC, complete blood count; CL, central laboratory; Ht, hematocrit; Hb, hemoglobin; Na⁺, Sodium; K⁺, Potassium; USCLIA, US Clinical Laboratory Improvement Amendment; SD, standard deviation; ICU, intensive care unit.

Ethical Approval: The research protocol was evaluated and approved by the local Institutional Review Board of the Hospital (Scientific Committee). No informed consent was required due to the naturalistic nature of the study.

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2

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act in an emergent situation (particularly where extreme electrolyte values are obtained) while sending an additional sample to the central laboratory (CL) to "confirm" the POCT values.⁷ The differences in the values obtained have been attributed to the use of different devices, the effect of transport of samples through a pneumatic system as well as the type of sample used.⁷

The purpose of the study was to investigate the feasibility of POCT in an acute setting by examining the accuracy of POCT results for common laboratory tests including hematocrit (Ht), hemoglobin (Hb), and electrolytes (Sodium – Na⁺, and Potassium – K⁺) as compared to those of CL.

Materials and methods

Study design and setting

In this pilot observational study we prospectively recorded laboratory values for Ht, Hb, Na⁺, and K⁺ obtained by an ABG analyzer (ROCHE AVL OMNI *S*, Switzerland) located in the ICU and the CL automatic analyzers of our hospital. Hematology equipment is Sysmex XE 2100TM (Automated Hematology System, Roche) and biochemistry equipment is Ilab 600 (chemistry analyzer, Biochem Diagnostics). The study protocol was approved by the hospital ethics committee. The ABG analyzer is calibrated every day following the manufacturers' instructions and used by one experienced technician for the study purposes to avoid handling variability and related possible user errors.

Data collection

Arterial blood was obtained via an arterial line in the morning (07.00-08.00) by the same technician as ordered by the attending physician in charge and according to patients needs as medically indicated. In the study we included patients having an arterial line, requiring at the same time ABG analysis, complete blood count (CBC) and electrolyte measurement and this was done by the same technician during weekdays by a single blood draw. After eliminating tubing dead space, blood was drawn in 20 ml syringe according volume needed. Part of the blood was placed in a 2.5 ml heparinized syringe and immediately analyzed to our ICU ABG analyzer. The remaining blood was placed in appropriate tubes for CBC containing EDTA and biochemistry tubes suitable for serum analysis and sent to CL for analysis. Thus, the same sample of blood obtained by only one blood suction via the arterial line was used for both measurements. Results from the ABG analyzer and CL were recorded in a database for comparisons.

Statistical analysis

Numerical data are expressed as mean \pm standard deviation (SD). Measured values from CL were compared to those obtained from the AVL OMNI *S* ABG analyzer using a paired sample *t*-test. Statistical significance was considered at the level of p < 0.05. The difference between measured values of CL and ABG analyzer were analyzed by the Bland–Altman plots as difference *vs.* average. Bland and Altman analysis compares paired data to assess the agreement between two different methods of clinical measurement.¹³ Also, the differences between the two methods for Ht and Hb were expressed as percentages (%). Spearman's rho correlation coefficient was also calculated as most appropriate due to the small sample size.

Results

Patients' characteristics are shown in Table 1. Patients had an arterial line, required blood sampling for CBC and electrolytes send to CL but also ABGs measurement according to the attending physician on charge decision for the clinical management of the patients. Also, sampling was performed by the same technician during weekdays and not weekends.

We totally had 200 paired observations regarding Ht, Hb, Na⁺, and K⁺ over a period of 55 weekdays (3.6 per day). Mean (\pm SD) number of specimens per patient was 6.5 \pm 5.1 (95% Cl of mean 4,6 to 8,3; median 5; 25–75% percentile, 4 to 7; range 3–11). Mean time for printed results availability was <2 min from the ABG analyzer, >1 h for CBC and >2 h for electrolytes. Table 2 shows that ABG analyzer results were significantly lower (p < 0.0001) for Ht, Hb, Na⁺ and K⁺ as compared to CL. Mean Hb measured by the ABG analyzer was lower by 0,29 g/dl (3.2%), the Ht by 2,1% (7.7%), Na⁺ by 2,2 mmol/L and K⁺ by 0,43 mmol/L.

Table 3 shows the values of mean bias, the SD and 95% limits of agreement (LoA) between the two methods according to Bland–Altman analysis. Mean bias for Hb was 3,1% and for Ht 7,2%. Also, Table 3 shows the Spearman's rho correlation coefficient and the significance of the correlation.

In 8.0% (16/200), 17.5% (35/200), 37.5% (75/200) and 56.0% (112/200) of Hb, Na⁺, K⁺ and Ht measurements respectively and 30.0% (238/800) in sum the differences were over the US Clinical Laboratory Improvement Amendment (USCLIA) accepted limits that are within \pm 7.0%, \pm 4.0 mmol/L, \pm 0.5 mmol/L, and \pm 6.0% respectively.¹¹

Bland–Altman plots of the difference *vs.* average separately for Ht, Hb Na⁺ and K⁺ are shown in Fig. 1 along with the bias and the 95% limits of agreement. The variability for Ht, Hb Na⁺, and K⁺ was not consistent and the magnitude of difference ranged significantly (Table 3) which could be clinically significant. The scatter around the bias line was larger as the average was higher or lower for all parameters.

Fig. 2 shows the Spearman's rho correlation (scatter plot with best fit values - slope) between values obtained from ABG analyzer (AVL) and CL separately for Ht, Hb Na⁺ and K⁺.

Discussion

The main finding of this study is that the ABG analyzer significantly underestimates Ht, Hb, K^+ , and Na^+ values and thus values

Table 1

Basic characteristics of the patients	. Data are expressed in mean \pm SD.
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ICU	Eight bed, general multidisciplinary ICU
N	31 patients
Men/women	18/13
Age, years	67.5 ± 16.2
APACHE II score	22.2 ± 1.4
SOFA score	9.0 ± 0.9
ICU stay, days	$\textbf{22.8} \pm \textbf{4.9}$
Total arterial-catheter days	273
Admission diagnosis was	
Postoperative monitoring;	15/31
Pneumonia/respiratory failure;	7/31
Shock;	2/31
Stroke;	2/31
Coma;	1/31
CHF/pulmonary edema;	1/31
Cardiac arrest;	1/31
Status epilepticus;	1/31
Cardiac tamponade;	1/31
Outcome	
Survivors; 19/31	61.3%
Mortality; 12/31	38.7%
Predicted mortality (APACHE II)	43.9%

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