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Blood Gas Measurements Using Point-of-Care Testing Devices in Pediatric Patients

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ABSTRACT

Introduction: There is an increasing use of point-of-care testing (POCT) devices for patients. These portable devices are preferred by healthcare personnel because they are quick and easy to use. The aim of this study was to investigate whether POCT devices can provide rapid and reliable blood gas measurements.

Methods: Blood gas measurements were performed for 30 pediatric patients at the University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital using a POCT device and a fully automatic blood gas analyzer. Eleven parameters (pH, pCO_2, pO_2, sodium, potassium , calcium , glucose, lactate, hematocrit, $cHCO_3$, and cSO_2) were compared. The statistical analyses were performed using the NCSS software. To determine the correlation between the two methods, the intraclass correlation coefficient (ICC) was calculated, and Bland-Altman graphs were used.

Results: The ICC demonstrated an almost strong correlation with pH (ICC=0.889), pCO_2 (ICC=0.968), pO_2 (ICC=0.981), sodium (ICC=0.799), potassium (ICC=0.968), calcium (ICC=0.909), glucose (ICC=0.967), $cHCO_3$ (ICC=0.919) and cSO_2 (ICC=0.988) and moderate correlation with lactate (ICC=0.626) and hematocrit (ICC=0.491). All p-values were all <0.001 for all analytes.

Conclusion: The POCT device was compared with a fully automatic blood gas analyzer. Unjustified postponement of analysis in patients with respiratory failure, shock, or electrolyte disorders can delay the application of appropriate treatment. Not only the benefits of an accurate POCT measurement but also the benefits of clinical practice and process changes should be taken into consideration.

Keywords: Point-of-care testing devices, POCT, blood gas

Introduction

Respiratory disorders, dehydration, and electrolyte disorders are among the most common causes of admission to the pediatric emergency department (ED) for all ages (1). Blood gas analyzers are widely used in modern intensive care units (ICU) and EDs, providing a basic metabolic panel for managing clinical conditions such as respiratory, circulatory, and electrolyte disorders.

Arterial blood gas (ABG) analysis is the traditional method for evaluating the ventilation and acid-base status of patients. Venous blood gas (VBG) has recently been accepted as an alternative analytical method for some clinical conditions. VBG analysis and SpO_2 measurement provide accurate information about the acid-base, ventilation, and oxygenation status of patients with critical disease in the ED and ICU (2). The National Academy of Clinical Biochemistry Laboratory Laboratory Medical Practice Guidelines recommend that ABG results be taken into consideration to improve the outcomes of patients in the ED and ICU (3).

Point-of-care testing (POCT) devices for the analysis of patient samples, which can generally be performed at bedside or in another place outside the clinical laboratory by health professionals without any laboratory training (4). Using POCTs fulfills the need for rapid results and immediate decision to initiate therapy. Sample transfer time to the laboratory can be saved, and clinical decision-making can be performed rapidly (5). However, increased costs for the purchase and maintenance of analyzers, personnel training, laboratory information system, quality control, and external quality assessment procedures are important for ISO 15189:2022 accreditation (6). POCT has shorter turnaround times (TAT) for blood gas analysis results than the central laboratory; therefore, it is a clinically important advantage in decision-making.

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The current study aimed to investigate whether POCT devices can provide rapid and reliable blood gas measurements, which are of critical importance for intensive care patients.

Methods

Approval for the study was granted by the Ethics Committee of University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital (approval number: 2024-02-16, date: 05.02.2024). This observational cohort study included 30 pediatric patients hospitalized. In total, 69 arterial blood samples were collected from the 30 patients in accordance with the Clinical and Laboratory Standards Institute (CLSI) C46-A2 guidelines (7) and antisepsis rules. The samples were withdrawn into a 2 mL volume PICO syringe (Radiometer Medical ApS) and anticoagulated with 80 IU of lyophilized electrolyte-balanced heparin.

The samples were analyzed in accordance with the CLSI EP9-A2 guidelines (8) using POCT (Epoc blood analysis - Epocal Inc., Canada) and a fully automatic blood gas device (Cobas b221, Roche, Germany) in the central laboratory.

Statistical Analysis

Statistical analyses were performed using the NCSS software (Number Cruncher Statistical System, 2007, Kaysville, UT, USA). To determine the level of agreement between the two devices, the intraclass correlation coefficient (ICC) was calculated. The Wilcoxon test was used to determine differences between dependent samples. A value of $p<0.05$ was set as statistically significant.

Results

The two devices were compared in terms of 11 parameters; pH, pCO_2, pO_2, sodium (Na^+), potassium (K^+), calcium (Ca^{++}), glucose, lactate, hematocrit, $cHCO_3$, and cSO_2. The results comparing the blood gas measurements performed using POCT and a fully automatic blood gas analyzer in the central laboratory are shown in Table 1.

The ICC demonstrated almost perfect agreement with pH [ICC (95% confidence interval (CI): 0.889 (0.827, 0.930), $p<0.001$], pO_2 [ICC (95% CI): 0.981 (0.937, 0.991), $p<0.001$], pCO_2 [ICC (95% CI): 0.968 (0.883, 0.987), $p<0.001$], sodium [ICC (95% CI): 0.799 (0.556, 0.897), $p<0.001$], potassium [ICC (95% CI): 0.968 (0.815, 0.988), $p<0.001$], calcium [ICC (95% CI): 0.909 (0.856, 0.943), $p<0.001$], glucose [ICC (95% CI): 0.967 (0.947, 0.979), $p<0.001$], $cHCO_3$ [ICC (95% CI): 0.919 (0.259, 0.976), $p<0.001$] and cSO_2 [ICC (95% CI): 0.988 (0.965, 0.994), $p<0.001$] and moderate agreement with lactate [ICC (95% CI): 0.626 (0.409, 0.767), $p<0.001$] and hematocrit [ICC (95% CI): 0.491 (0.291, 0.650), $p<0.001$].

In the current study, pH, pO_2, sodium, potassium, $cHCO_3$, and cSO_2 levels were slightly higher with POCT than with Cobas, and a statistically significant difference was present ($p<0.001$).

PCO_2 and lactate levels were also slightly lower with POCT than with Cobas, and a statistically significant difference was also present ($p<0.001$).

Calcium ($p=0.066$), glucose ($p=0.141$) and hematocrit ($p=0.226$) levels did not show statistically significant differences, whereas glucose and hematocrit levels were slightly lower but calcium levels were slightly higher with POCT than with Cobas.

Discussion

Blood gas analysis plays an important role in the diagnosis, follow-up, and clinical evaluation of critical patients (9,10). A blood gas analysis device can analyze the pH, partial carbon dioxide pressure (pCO_2), and partial oxygen pressure (pO_2). Moreover, current blood gas analyzers are more sophisticated and, at the same time, electrolyte measurements [sodium (Na^+), potassium (K^+), ionized calcium ($iCa2^+$), chloride (Cl^-)], metabolites (glucose, lactate), hematocrit, and co-oxymetry (total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, and deoxyhemoglobin) are performed.

In critical patients presenting to the ED and patients admitted to the ICU and receiving fluid treatment, all electrolytes are routinely measured with automatic analyzers in the central laboratories of hospitals, but this is time-consuming. The TAT in the emergency laboratory of tertiary-level hospitals is mean 15 minutes (11). This generally delays the decisions that need to be made rapidly regarding electrolyte values.

Table 1. Comparison of blood gas measurements performed using POCT and a fully automated blood gas analyzer in the central laboratory

Parameter	Epoc (mean ± SD)	Roche (mean ± SD)	Difference (95% CI)	p	ICC (95% CI)	p	Reference range
PH	7.45±0.07	7.42±0.07	0.030 (0.027, 0.034)	<0.001**	0.889 (0.827, 0.930)	<0.001**	7.35-7.45
PCO_2	39.46±8.42	40.74±8.49	-1.278 (-1.692, -0.864)	<0.001**	0.968 (0.883, 0.987)	<0.001**	35-45 mmHg
PO_2	85.89±54.70	79.95±51.68	5.941 (3.839, 8.042)	<0.001**	0.981 (0.937, 0.991)	<0.001**	75-100 mmHg
Sodium	139.65±5.02	137.87±5.25	1.786 (1.099, 2.472)	<0.001**	0.799 (0.556, 0.897)	<0.001**	135-145 mmol/L
Potassium	3.78±0.81	3.64±0.84	0.143 (0.105, 0.181)	<0.001**	0.968 (0.815, 0.988)	<0.001**	3.5-5.0 mmol/L
Calsium	1.20±0.12	1.19±0.13	0.012 (-0.001, 0.025)	0.066	0.909 (0.856, 0.943)	<0.001**	2.1-2.6 mmol/L
Glucose	134.83±56.59	137.38±55.41	-2.558 (-5.988, 0.872)	0.141	0.967 (0.947, 0.979)	<0.001**	70-100 mg/dL
Lactate	2.46±1.46	3.34±2.96	-0.876 (-1.336, -0.416)	<0.001**	0.626 (0.409, 0.767)	<0.001**	0.5-2.2 mmol/L
Hematocrit	33.68±6.04	34.55±5.70	-0.871 (-2.292, 0.550)	0.226	0.491 (0.291, 0.650)	<0.001**	38-46% (female), 42-54% (male)
$cHCO_3$	27.21±4.81	25.63±4.70	1.579 (1.293, 1.866)	<0.001**	0.919 (0.259, 0.976)	<0.001**	22-28 mmol/L
cSO_2	82.83±21.68	80.96±23.06	1.871 (1.156, 2.584)	<0.001**	0.988 (0.965, 0.994)	<0.001**	95-100%

**p<0.01, ICC: Intraclass correlation coefficient, CI: Confidence Interval, SD: Standard deviation, POCT: Point-of-care testing, POCT: Point-of-care testing

Blood gas analysis can be performed in central laboratories using conventional devices or in the wards, in inpatient services, operating rooms, and ICUs using a POCT device. These devices are used to support emergency interventions for patients (9,12). POCT provides clinical benefits by allowing clinicians to initiate appropriate treatment for emergency conditions. In central laboratories, where a small number of blood gas analyses are performed, calibrations performed several times a day increase costs. Therefore, POCT is economically more advantageous in these centers (13).

In patients followed-up in the ICU, the ventilation and oxygenation targets determine the treatment plan. Traditionally, arterial oxygen concentration (measured as partial oxygen pressure PaO_2) and pulse oximetry are used in the follow-up of oxygen saturation. The general recommendations for oxygenation are for the PaO_2 values to be 75-100 mmHg (14-16). The harmful effects of hypoxia are well known, and although most physicians tend to give more oxygen "just to be on the safe side" and to avoid hypoxia, hyperoxidation must also be avoided because oxygen can be toxic. Hypoxemia and hyperoxemia are harmful; therefore, oxygen therapy must be titrated (17).

In conditions such as hypoxemia, hypercarbia, and acidosis in ICU, the decision for starting treatment is critically important. Based on the current study findings, the use of a validated POCT device is recommended for the diagnosis and treatment of ABG abnormalities. In a study by Allardet-Servent et al. (18), the data from the central laboratory of 314 paired samples collected from 51 critical patients were reliably consistent with the POCT device results. In the present study, the correlation (ICC) between the two devices was determined to be 0.889 for the pH measurements, 0.981 for the pO_2 measurements, 0.968 for the pCO_2 measurements, and 0.988 for the cSO_2 measurements.

In critical patients, blood electrolytes are often measured, and the anion gap (AG) and strong ion difference (SID) are calculated from electrolyte measurements. These measurements play a role in guiding clinical decisions on improving acid-base status. In the present study, a strong correlation with sodium (ICC=0.799), potassium (ICC=0.968), and calcium (ICC=0.909) was observed.

The guidelines recommend that POCT can be used for ionized calcium analysis in ICU and potassium analysis in ED. However, during the preparation of the guidelines, there was insufficient evidence that POCT electrolyte results can improve clinical outcomes in an ICU setting (3). Several researchers have stated that caution should be exercised when interpreting electrolytes measured using various POCT devices. Correlation of the ionized calcium results for both devices in the guidelines were not observed in the current study. This may be due to the age distribution and pre-analytic problems.

In a study by Morimatsu et al. (19), the plasma sodium and chloride electrolyte concentrations were significantly different in the results obtained from two different measurement technologies, namely, POCT and laboratory devices. These differences in the measurements had a significant effect on the SID value (with similar large variations) calculated from the traditional AG value (large variations up to 15 mEq/L), and the individual electrolyte values (sodium and chloride). These large differences in electrolyte values and basic acid-base variables are clinically important and should be discussed in detail. Statistically significant differences were also found in the pH, potassium, and hematocrit measurements, which were due to differences in the calculated AG and SID (19,20). It has been reported in some studies that these differences are attributable to the automatic analyzers and chemical reactions used in the laboratory (21). It was shown in one study that the concentration of the measured electrolytes was reduced because taking the samples into tubes with heparin increased the volume and because of the binding of heparin to the electrolytes (22).

According to the US Clinical Laboratory Improvement Amendments 2006, deviations from the gold standard calibration measurements of 0.5 mmol/L in potassium and 4 mmol/L in sodium are accepted as normal (23).

There is currently strong evidence that indirect-ion selective electrode (ISE) sodium directly increases ISE measurements up to 4-10 mmol/L due to hypoproteinemia (24,25). Sodium and potassium measurements with direct ISE are recommended for critical patients. José and Preller (26) investigated the opinions of clinicians regarding the use of blood gas analyzers to measure potassium in acute conditions. The questionnaire results demonstrated that 52% of the clinicians preferred to wait for laboratory confirmation before making clinical decisions.

José and Preller (26) retrospectively compared 500 paired ABG samples performed within 1 h from central laboratory samples and found that 95% of the results had fallen to within 0.5 mmol/L difference limits. In a large retrospective study using a database including more than 11,000 matched samples performed within one hour, there was shown to be a strong correlation between the POCT and central laboratory results of sodium, potassium, and ionized calcium to enable clinicians to make clinical decisions immediately (27).

The advantage of POCT use rather than laboratory testing in the monitoring of blood glucose levels is that it allows insulin adjustments to be made more rapidly and more often. In the current study, a strong correlation with glucose (ICC=0.967) was found. The glucose results obtained from the device should be interpreted with caution. Inaccuracy of measurement should not be allowed despite the speed. In a study by Shearer et al. (28), POCT glucose values measured from central catheter or fingertip samples were significantly different from laboratory glucose values. There was observed to be a difference of at least 20 mg/dL between the POCT values and the laboratory glucose values in approximately 20% of the patients, which was clinically significant. Sensitivity of glucose measurement is extremely important. The accuracy of POCT is not sufficiently definitive for insulin management protocols with narrow glucose ranges. Most patient glucose measurement devices are designed to monitor glucose level curves, not based on single glucose values (28). In another study regarding personnel and POCT equipment costs, it was shown that the costs of POCT were higher than those of the laboratory analysis (29).

Normal acid-base homeostasis is a serious problem in ICU. In critical patients with acute kidney damage and lactic acidosis, acid-base disorders can be treated with continuous renal replacemant therapy (CRRT) (30). Urea, lactate, hydrogen (H^+), toxic substances, and drugs are eliminated from the blood following CRRT. In the decision to use CRRT,

pH, bicarbonate, and lactate levels are monitored during the follow-up of acidosis and the efficacy of CRRT. In the current study, a strong correlation with HCO_3 (ICC=0.919) and a moderate correlation with lactate (ICC=0.626) was found.

In conditions requiring emergency intervention, the turn-around time for blood gas analysis is extremely important in the management of critical patients.

In a randomized, controlled study to evaluate the efficacy of POCT in dehydration, anemia, and electrolyte abnormalities in pediatric ED, the time to POCT test results was 65 min, which reduced the decision time by 45 min, and consequently the time spent in ED was reduced by 39 min (31). Using the data from that study, Whitney et al. (32) calculated a cost saving of USD 303.30 per patient. According to another study conducted in pediatric ED, clinicians reported that as the availability of the tests increases, POCT is more advantageous, and its areas of use should be expanded (33).

POCT can provide results in a shorter TAT. There is evidence that, although not always, in many conditions, this provides an advantage in clinical decision-making compared with central laboratory services. A rapid TAT also provides the advantage of more effective time spent on admission or discharge of the patient. When POCT is considered to be generally more expensive than central laboratory testing, tests with higher clinical efficiency are important for preferring POCT (34).

Conclusion

Based on the results of this study, POCT using a validated device can be recommended for the diagnosis and treatment of ABG abnormalities. Unjustified postponement of analysis in patients with respiratory failure, shock, or electrolyte disorders can delay the application of appropriate treatment. Accurate POCT measurements provide high quality data in clinical practice. The definition and application of evidence-based practice guidelines should be encouraged.

Ethics Committee Approval: Approval for the study was granted by the Ethics Committee of University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital (approval number: 2024-02-16, date: 05.02.2024).

Informed Consent: Retrospective study.

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