Clinical Biochemistry 49 (2016) 708–712

Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Analytical evaluation of the epoc® point-of-care blood analysis system in cardiopulmonary bypass patients

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ARTICLE INFO

Article history:
Received 15 September 2015
Received in revised form 14 December 2015
Accepted 15 December 2015
Available online 20 February 2016

Keywords:
Point-of-care testing
Blood gas analysis
epoc®
Method evaluation
Comparison study
Cardiac surgery

ABSTRACT

Objectives: The aim of this study was to evaluate the analytical performance of the new epoc® point-of-care blood analysis system in cardiopulmonary bypass patients.

Design and methods: The precision study was conducted on 3 epoc® blood analysis systems using 5 levels of quality control materials twice per day for 5 days. The blood specimen was collected in blood gas syringes from 40 cardiac perfusion patients for the comparison study on epoc® (all 3 meters), Instrumentation Laboratory GEM4000, Abbott iSTAT, Nova CCX, and Roche Accu-Chek Inform II and Performa glucose meters.

Results: The epoc® blood analysis systems demonstrated clinically acceptable precision for all analytes (from 0.07%, 0.07%, and 0.13% for pH 7.6, 7.4, and 7.0 levels; to 3.87%, 3.74%, and 7.56% for pO_2 197, 103, and 56 mm Hg levels). Comparison studies yielded a correlation coefficient R from 0.9201 (sodium) to 0.9969 (pO_2) with the GEM4000; from 0.9071 (sodium) to 0.9965 (potassium) with the iSTAT; from 0.8793 (sodium) to 0.9957 (pO_2) with the CCX, and 0.9850 and 0.9904 with Roche Inform II and Performa meters respectively. Average biases for all analytes were within the total allowable error limits.

Conclusion: The epoc® blood analysis system is acceptable for point-of-care testing in the cardiovascular surgery setting.

1. Introduction

The availability of point-of-care (POC) analyzers allows for diagnostic and monitoring processes in different clinical settings to become easier and more efficient. Market surveys have consistently demonstrated a significant increase in utilization of point-of-care testing (POCT) in hospitals, physician's offices, and locations as diverse as ambulances or remote community health centers where laboratory testing is not accessible immediately. The US revenue forecast for POCT market is likely to increase from $1500 million to $3800 million in the decade from 2006 to 2016 [1,2]. As oppose to traditional central laboratory blood testing, the POC devices take the advantage of a faster turnaround time of results at the operational convenience with improved quality of medical service, although the cost per test is usually higher.

Laboratory testing is essential for the blood gas, acid/base, and glucose management, as well as making critical decisions on transfusion during cardiopulmonary bypass surgery [3–5]. The use of desktop POC blood gas analyzer in the cardiovascular operating room (CVOR) has been on the rise over the past decade. It eliminates the process of transporting blood specimen to the core laboratory then allows physicians and perfusionists to better manage their bypass patients during surgery. However, the demand on more portable POC blood gas devices still exists for continuous monitoring the critical cardiac patients in other areas such as post-operative intensive care units and catheterization laboratories in addition to the CVORs for the cell salvage, left ventricular assist device and transcatheter aortic valve implantation procedures. Analytically, the cardiopulmonary bypass (CPB) cases can be challenging for POCT devices since (1) analytes such as pO_2 and hematocrit/hemoglobin have bigger ranges than most other clinical situations; (2) hematocrit/calculated hemoglobin based on conductivity may be underestimated compared to that measured by co-oximetry or Coulter counter methods in hemodilution (hematocrit less than 30%) [6].

The epoc® blood analysis system (Epocal Inc., Ottawa, Ontario, Canada) is a newly developed in vitro diagnostic hand-held analyzer (8.5 × 3.4 × 2 inch) smaller than the Abbott iSTAT for testing whole blood samples at POC which provides blood gas, electrolytes, ionized calcium, glucose, lactate, and hematocrit/calculated hemoglobin results in 30 second and is able to communicate wirelessly inside hospital network. Furthermore, the operating cost of epoc® testing is economically

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http://dx.doi.org/10.1016/j.clinbiochem.2015.12.015
0009-9120/

Table 1
Linearity study of three epoc® blood analysis systems. R, correlation coefficient.

Analyte	Range	epoc® no. 1			epoc® no. 2			epoc® no. 3		
		Slope	Intercept	R	Slope	Intercept	R	Slope	Intercept	R
pH (pH unit)	7.029 to 7.903	1.0508	−0.3562	0.9997	1.038	−0.2685	0.9998	1.0459	−0.3229	0.9997
pCO_2 (mmHg)	13.1 to 121.2	1.0611	−2.372	0.9995	1.0652	−1.2034	1	1.0659	−2.16	0.9981
pO_2 (mmHg)	28.1 to 603.2	1.0713	−6.4583	0.9998	1.0983	−8.0461	0.9998	1.0681	−2.0518	0.9999
Sodium (mmol/L)	82 to 186	1.029	−4.1055	0.9999	1.0246	−3.8304	0.9999	1.033	−4.8439	1
Potassium (mmol/L)	2.1 to 12.4	1.0383	−0.1448	0.9999	1.0375	−0.16	1	1.0352	−0.1384	1
Ionized calcium (mmol/L)	0.29 to 3.57	1.0477	−0.0338	0.9999	1.0362	−0.0234	1	1.0425	−0.0343	0.9999
Glucose (mmol/L)	1.0 to 38.6	1.079	−0.3781	0.9999	1.1122	−0.5152	0.9998	1.0498	−0.2103	1
Lactate (mmol/L)	0.59 to 18.53	1.0009	−0.0321	1	0.9761	0.0098	1	1	−0.0326	1
Hematocrit (%)	10 to 64	1.0011	0.7624	0.9998	1	1	1	0.9855	1.107	0.9998

close to that of testings on core laboratory blood gas analyzer. Recently, the epoc analyzer has been demonstrated good correlation with Abbott iSTAT and Nova CCX analyzers [7,8]. However, its performance has not been evaluated in a CVOR setting on CPB patients.

The aim of this study was to evaluate the analytical performance of the new epoc® point-of-care blood analysis system on CPB patients, with a head-to-head comparison against Instrumentation Laboratory GEM4000, Abbott iSTAT, Nova CCX blood gas analyzers, and Roche Accu-Chek Inform II and Performa glucose meters.

2. Materials and method

The epoc® point-of-care blood analysis system was evaluated using several Clinical and Laboratory Standards Institute (CLSI) evaluation protocols for testing precision (EP5) [9], accuracy (EP15) [10], linearity (EP6) [11], and bias (EP9) [12].

2.1. The epoc® analysis system

The epoc® blood analysis system contains a test card, a wireless card reader, and a host mobile computer. Each test card, can be stored at room temperature, contains an array of sensors and calibration fluid to generate electrical signals proportional to analyte concentrations in the sample. The card reader scans the barcode and reads the test card by measuring electrical signals. pH, pCO_2, sodium, potassium, and ionized calcium are measure potentiometrically; pO_2, glucose, and lactate are measured amperometrically, whereas hematocrit is determined conductometrically [13]. Hemoglobin is calculated from the measured hematocrit using the formula: Hemoglobin (g/L) = Hematocrit (decimal fraction) × 340 [14,15]. It communicates the result with the host mobile computer wirelessly via Bluetooth. From the host mobile computer the result displayed can also be wirelessly transmitted to laboratory computers, hospital information systems, or patient electronic

Table 2
Precision study (Each level of quality control material was run on 3 epoc® analyzer twice per day for 5 days.) CV, coefficient of variation.

Analyte	Quality control material	Mean	CV (%)	Manufacturer's specifications for CV at comparable level analyte (%) [13]
pH	Eurotrol GAS level 1	7.012	0.13	0.1
(pH unit)	Eurotrol GAS level 2	7.379	0.07	
	Eurotrol GAS level 3	7.595	0.07	0.1
pCO_2	Eurotrol GAS level 1	71.9	3.27	3.7
(mmHg)	Eurotrol GAS level 2	37.3	1.45	
	Eurotrol GAS level 3	22.7	1.22	3.4
pO_2	Eurotrol GAS level 1	55.7	7.56	6.4
(mmHg)	Eurotrol GAS level 2	102.8	3.74	
	Eurotrol GAS level 3	197.1	3.87	3.4
Sodium	Eurotrol GAS level 1	109.7	1.07	0.7
(mmol/L)	Eurotrol GAS level 2	139.5	0.45	
	Eurotrol GAS level 3	165.3	0.37	0.6
Potassium	Eurotrol GAS level 1	2.0	2.64	1.9
(mmol/L)	Eurotrol GAS level 2	4.0	1.04	
	Eurotrol GAS level 3	6.2	0.29	1.0
Ionized calcium	Eurotrol GAS level 1	1.5	1.54	1.2
(mmol/L)	Eurotrol GAS level 2	1.2	1.85	
	Eurotrol GAS level 3	0.7	1.28	1.7
Glucose	Eurotrol GAS level 1	1.8	3.66	3.4
(mmol/L)	Eurotrol GAS level 2	6.0	1.37	
	Eurotrol GAS level 3	15.0	1.52	2.8
Lactate	Eurotrol GAS level 1	0.9	3.36	6.3
(mmol/L)	Eurotrol GAS level 2	2.6	1.80	
	Eurotrol GAS level 3	6.0	2.00	3.4
Hematocrit	Eurotrol Hct level A	20	1.66	2.2
(%)	Eurotrol Hct level B	50	1.29	1.6