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ORIGINAL RESEARCH

Clinical Performance of a Novel Portable epoc™ Analyzer for Arterial Blood Gas and Electrolyte Testing in Operating Rooms

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Abstract

Background: A new blood gas analyzer (epoc™, Epocal Inc.) has recently been developed for the ambulatory monitoring of respiration and electrolyte balance. However, the accuracy of this instrument has not been fully elucidated. The present study compares the performance of the epoc™ analyzer and a conventional bench-top analyzer in operating rooms.

Materials and Methods: Fifty blood samples were collected from anesthetized surgical patients and three samples were collected from volunteers into syringes containing lithium heparin. pH, pCO_2, pO_2, Na^+, K^+ Ca^{2+}, glucose, lactate and hemoglobin levels were measured using both the epoc™ and calibrated ABL700™ analyzers (Radiometer). Data were statistically analyzed using Pearson correlation coefficients and Bland-Altman plots.

Results: Results showed excellent agreement between the values measured using the epoc™ analyzer and those obtained using the ABL700™ analyzer, except for Na^+.

Conclusions: The epoc™ analyzer is useful in clinical settings, including operating rooms.

Keywords: arterial blood gas, electrolyte, point-of-care, portable gas analyzer

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Introduction

Arterial blood gas and electrolyte testing are essential for the evaluation of a patient's general condition in clinical settings.[1,2] However, most bench-top analyzers for clinical use are large and untransportable. Therefore, medical staff must take blood samples to the analyzer in the laboratory, increasing turn-around time.[3] In addition, clinical physicians need to respond rapidly to changes in a patient's status. Short analysis time is preferable in an emergency situation.

Several portable analyzers are commercially available and are useful for point-of-care testing.[4–7] Previous studies demonstrated high correlations between values measured using portable and bench-top analyzers in various clinical settings, such as in an operating room,[4] in critical care,[5] in an emergency department,[6] and out of hospital.[7] However, these analyzers are stand-alone types, and simultaneous monitoring of more than one patient, such as in operating rooms, is difficult.

A new point-of-care analyzer (epoc™, Epocal Inc., Ottawa, ON, Canada) has been developed for the ambulatory monitoring of respiration and electrolyte balance.[8] This device has a modular design that permits the same hardware to be used simultaneously on more than one patient. Therefore, the epoc™ analyzer may be useful for patients who have undergone surgery in multiple operating rooms at a large hospital. However, the accuracy of this instrument in operating rooms has not been determined. This report compares the performance of the epoc™ analyzer to that of a conventional bench-top analyzer using blood samples from surgical patients.

Materials and Methods

Approval from the Institutional Review Board was obtained before the study. Calibration of the epoc™ analyzer was performed in triplicate 24 hr before the study in accordance with the Clinical and Laboratory Standards Institute (CLSI) Approved Guidelines.[9] Two calibration fluids (RNA Medical Calibration Verification Controls 123 and RNA Medical Hematocrit Calibration Verification Controls 9005) were used for calibration verification at five concentration levels. The between-run precision was also determined daily using 20 replicate analyses of two concentration levels for 2 days. The ABL700™ analyzer (Radiometer, Brønshøj, Denmark) was used as a reference. The ABL700™ analyzer was automatically calibrated at two concentration levels every 4 hr, and checked before use by a medical engineer in accordance with the manufacturer's standard procedures every week.

Fifty blood samples were drawn from the radial arteries of anesthetized surgical patients into 1-mL syringes (BD A-Line™, Becton Dickinson Co., Plymouth, UK) containing 30 I.U. of calcium-balanced lithium heparin. All samples were drawn by an anesthesiologist. A few drops of blood were eliminated from the syringe to prevent air contamination. Each sample was analyzed in duplicate by the epoc™ analyzer and ABL700™ analyzer. Analysis using the ABL700™ analyzer was conducted first while the epoc™ analyzer was being calibrated automatically through the insertion of an epoc™ card. Analysis using the epoc™ analyzer was then conducted. The sample was introduced into the epoc™ analyzer within 60 sec after calibration was completed. The drawing of blood to the introduction of the four analytes was performed within 10 min.

Next, venous blood samples from three healthy volunteers were investigated. These samples were drawn from the left forearm of volunteers by one examiner. One milliliter of blood from each sample was transferred to a 1-mL syringe containing lithium heparin. The analytes were introduced in duplicate to the epoc™ analyzer and ABL700™ analyzers as described above.

pH, pCO_2, pO_2, Na^+, K^+ and Ca^{2+}, glucose, lactate, and hemoglobin levels were measured for all samples. All measurements were performed at the Sapporo Medical University Hospital, Sapporo, Japan. All data were collected by three technologists who received training before the study. Misread data or data from samples with insufficient volumes were excluded. The data from arterial blood samples were statistically analyzed using Pearson correlation coefficients and Bland-Altman plots.

Results

A total of 50 arterial blood samples were analyzed using the epoc™ analyzer. Six samples were not done in duplicate due to insufficient volumes. Six samples analyzed using the ABL700™ analyzer were not done in duplicate due to insufficient volumes. The pO_2 value of one sample was omitted from the analysis

due to air contamination. pO_2 and pCO_2 values of another sample were omitted from the analysis due to sampling error of the ABL700™ analyzer. The lactate values for two samples could not be measured because of the use of old-type cards.

Figure 1 shows the results of correlation statistics. Almost all R values were greater than 0.9, except for Na^+. Although the R value of Na^+ was 0.842, there were strong correlations between all the values measured using the epoc™ analyzer and those measured using the ABL700™ analyzer. Figure 2 shows the results of Bland-Altman plots, revealing that there is nearly no bias in pH, pCO_2, pO_2, K^+, Ca^{2+}, and hemoglobin values. The bias of Na^+ was 3.52 mmol/L with 95% limits of agreement of 7.37/–0.32 mmol/L.

However, a strong bias of Na^+ was not observed in the volunteer samples. The Bland-Altman plots show a bias of 0.37 mmol/L with 95% limits of agreement of 2.1/–1.4 mmol/L for Na^+ in the volunteers.

Discussion

The values measured using the epoc™ analyzer were strongly correlated to the values measured using the ABL700™ analyzer, except for Na^+, as shown in Figures 1 and 2. The bias averaged 3.52 mmol/L higher than the ABL700™ analyzer. However, the reason for the disagreement in the values for Na^+ for both analyzers is unclear. There are no differences between the two analyzers in the measurement principles using electrodes. It may be due to differences in blood sampling procedures, which were done by different anesthesiologists. In fact, the Na^+ measurement in venous blood drawn by one anesthesiologist did not exhibit a bias between the epoc™ and ABL700™ analyzers. Thus, the anesthesiologist sampling procedures may be heterogeneous.

Another possible explanation for the disagreement in Na^+ results is that heparin remaining in the syringe may have affected Na^+ measurements obtained using

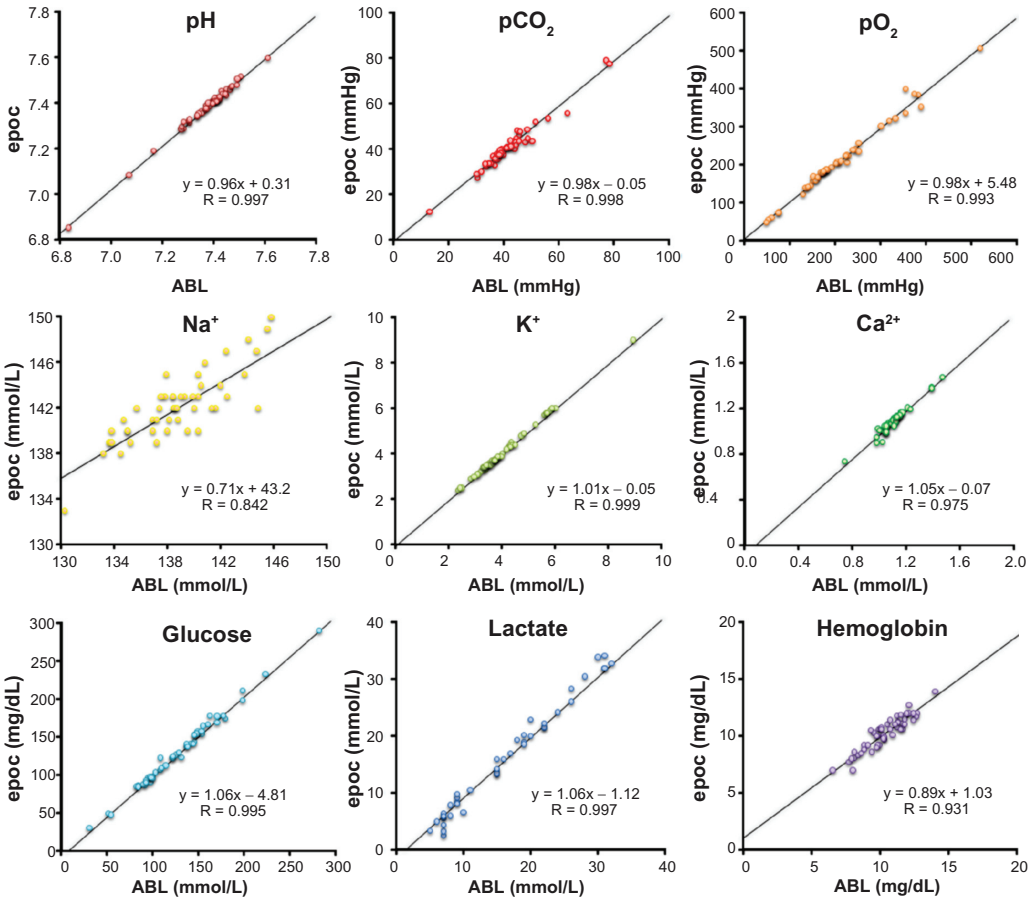

Figure 1. Pearson's correlations for values measured using the epoc™ and ABL700™ analyzers.
Notes: Solid lines represent linear regression. These data demonstrate excellent correlations between the values measured using both analyzers, except for Na^+. R = correlation coefficient.

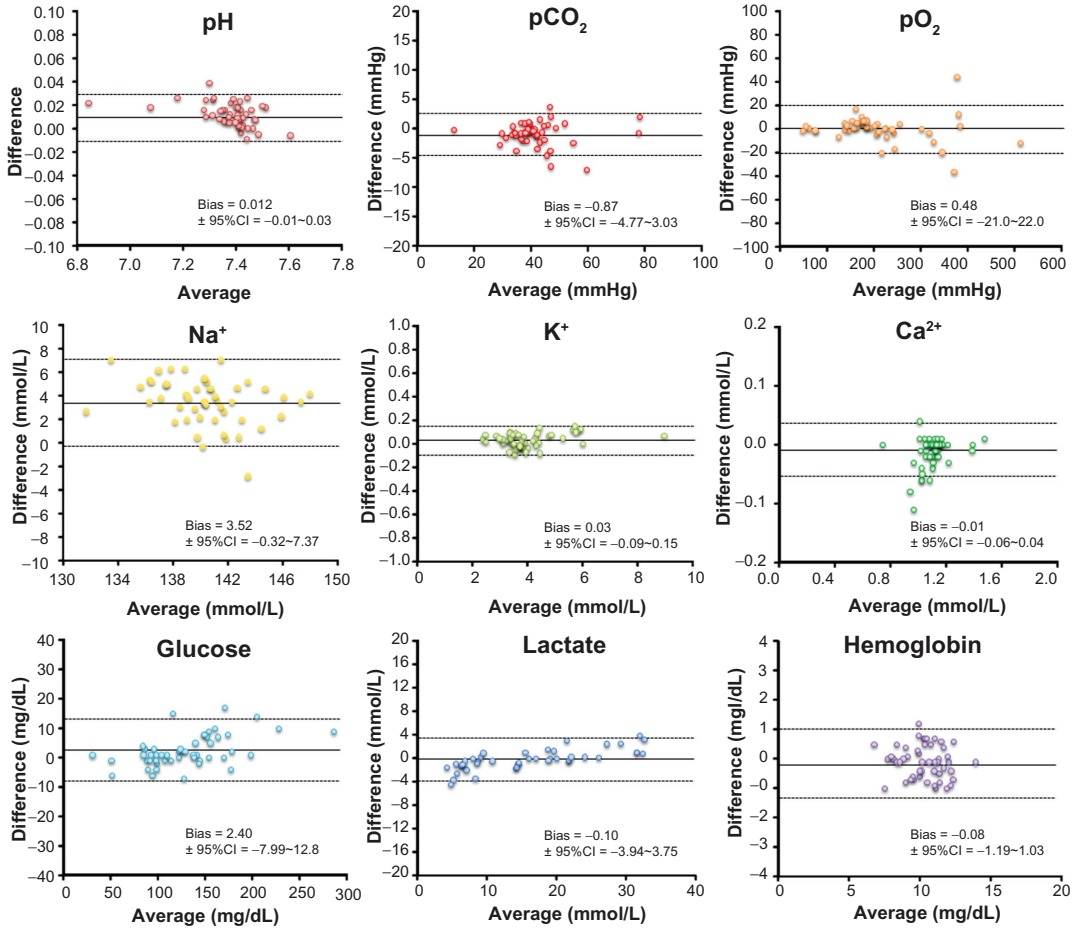

Figure 2. Bland-Altman plots for the values measured using the epoc™ and ABL700™ analyzers.
Notes: Solid lines represent the bias value. Upper and lower dashed lines represent the upper and lower 95% limits of agreement, respectively. These data demonstrate that no differences existed between the values measured using both analyzers, except for Na^+. 95%CI = 95% limit of agreement.

both the epoc™ and ABL700™ analyzers. Heparin forms a stable chelation complex with cations that can reduce measured Na^+ and Ca^{2+} values.[10,11] Traces of Ca^{2+} were added to the syringes containing lithium heparin to adjust the measurements, but no adjustments were made for Na^+. Thus, the measured Na^+ values could be lower than the actual values. In a separate preliminary study, Na^+ concentrations of the normal saline solution were measured by use of the BD A-Line™ (BD, Franklin Lakes, NJ, USA), filled with 1 mL of normal saline (154 mmol/L). Each sample was analyzed in duplicate using the epoc™ and ABL700™ analyzers. This pilot study showed Na^+ concentrations of 157 ± 0.6 and 152 ± 0.3 (mean ± S.D., n = 6, unpublished data) as measured using the epoc™ and ABL700™ analyzers, respectively. Next, the Na^+ concentrations of the normal saline solution were also measured by the use of disposable syringe (Nipro Co., Tokyo, Japan), filled with 1 mL of normal saline using the epoc™ and ABL700™ analyzers. The Na^+ concentrations were 158 ± 0.6 and 153 ± 0.3 (means ± S.D., n = 6 each, unpublished data) as measured using the epoc™ and ABL700™ analyzers, respectively. For each instrument, the Na^+ concentrations from the syringe containing heparin were approximately 1 mmol/L lower than those from the disposable syringe. However, these results cannot explain why the concentrations of Na^+ measured using the epoc™ analyzer were approximately 5 mmol/L higher than those measured using the ABL700™ analyzer.

Another possible explanation is the difference in calibration fluids used for the epoc™ and ABL700™ analyzers. Because samples were measured in duplicate for the two analyzers, the measured Na^+ concentrations should be similar. Moreover, calibrations

were performed frequently for each instrument and thus they exhibited high precision. The content of the calibration fluids is not available. Therefore, the concentration of Na^+ in the fluids may vary. The same calibration fluid should be used in future studies to resolve this problem. Real differences in the measured Na^+ concentration using the two analyzers would be surprising. However, this result could not be verified because the ABL700™ analyzer requires a large amount of calibration fluid that must be stored in a built-in reservoir on the instrument.

Despite these findings, an approximate difference of 3.5 to 5 mmol/L in Na^+ concentration is not clinically significant. Normal Na^+ concentration in blood ranges from 135 to 145 mmol/L, which can vary depending on the laboratory performing the analysis. In addition, symptoms of hyponatremia appear when Na^+ concentration drops abruptly below 130 mmol/L.[12] Symptoms of hypernatremia appear when Na^+ concentration increase abruptly above 158 mmol/L.[12] The concentration of Na^+ in blood has a greater margin of safety compared to other ions. Therefore, the error measurement in Na^+ concentration would not result in a missed diagnosis of electrolyte disturbance, and the bias between the two analyzers can be utilized by clinical physicians.

In conclusion, the bias in Na^+ values might be due to sampling procedures and/or differences in the content of calibration fluids, but the underlying mechanism remains unknown. Although the clinical utility of Na^+ values measured by the epoc™ analyzer is limited, the epoc™ analyzer is useful for both clinical arterial blood gas and electrolyte testing in surgical patients.

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Author Contributions

Conceived and designed the experiments: SS, MY. Analysed the data: SS. Wrote the first draft of the manuscript: SS. Contributed to the writing of the manuscript: YI, ST. Agree with manuscript results and conclusions: YI, ST. Jointly developed the structure and arguments for the paper: TH. Made critical revisions and approved final version: MY. All authors reviewed and approved of the final manuscript.

Disclosures and Ethics

As a requirement of publication author(s) have provided to the publisher signed confirmation of compliance with legal and ethical obligations including but not limited to the following: authorship and contributorship, conflicts of interest, privacy and confidentiality and (where applicable) protection of human and animal research subjects. The authors have read and confirmed their agreement with the ICMJE authorship and conflict of interest criteria. The authors have also confirmed that this article is unique and not under consideration or published in any other publication, and that they have permission from rights holders to reproduce any copyrighted material. Any disclosures are made in this section. The external blind peer reviewers report no conflicts of interest.

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