ORIGINAL ARTICLE

Evaluation of analytical performance of blood gases, electrolytes, and metabolites in critical care using the blood gas analyzer cartridge-electrochemical principle

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ABSTRACT

Introduction: Rapid assessment of blood gases, electrolytes, and metabolites is crucial in critical care settings. This study evaluates the performance and interchangeability of a portable blood gas analyser that operates on the cartridge-electrochemical principle.

Materials and Methods: This prospective study evaluates the precision of this analyser, which uses an electrochemical sensor within single-use cartridges. We compare its performance to that of a cartridge-based sandwich sensor cassette; the blood gas analyser used in intensive care units (ICU). A total of forty arterial blood samples were collected between July and November 2024. Performance was statistically assessed using Passing-Bablok regression, Bland-Altman plots, and the Intraclass Correlation Coefficient (ICC).

Results: The blood gas analysis using the electrochemical sensor method demonstrated excellent within-run imprecision (CV%<5%) across all evaluated analytes, with total imprecision consistent with the manufacturer's specifications. Method comparison revealed a strong correlation (ICC>0.9) and agreement for most parameters between the two methods, including pH, partial pressure of carbon dioxide (pCO_2), sodium (Na^+), potassium (K^+), chloride (Cl^-), glucose, and lactate. However, Bland Altman showed a systematic bias of 9 mmHg in partial pressure of oxygen (pO_2) and 0.02mmol/L in ionised calcium (iCa^{2+}).

Conclusion: The analyser using the electrochemical sensor provides reliable performance for blood gases and biochemical analytes, with strong agreement with the cartridge-based sandwich sensor cassette principle. Nonetheless, caution is advised for pO_2 and iCa^0 measurements due to observed bias, highlighting the importance of awareness of method-specific differences between analysers in clinical interpretation.

KEYWORDS:
Arterial blood gas, cartridge-electrochemical, point-of-care testing, precision, bias, agreement

INTRODUCTION

Blood gas analysis offers insights into acid-base status and assesses and monitors ventilation across various medical conditions.[1-2] Technological improvements in point-of-care testing (POCT) have revolutionised patient care in recent years. POCT is not only easy to use but also enhances patient satisfaction and reduces comorbidities by improving rapid clinical decision-making and earlier focused management of patients.[3] Integrating sensor cassettes designed for potentiometric, amperometric, or optical sensors, the development of dry cartridge electrochemistry and microfluidic technology significantly transforms blood gas analysis. These advancements facilitate the creation of portable and compact medical devices, enhancing the accessibility and efficiency of diagnostic processes.

The contemporary blood gas analyser is manufactured to quantitatively evaluate various blood gas parameters, including the pH of whole blood, the partial pressure of carbon dioxide (pCO_2), and partial pressure of oxygen (pO_2). Furthermore, it provides measurements for various electrolytes, such as sodium (Na^+), potassium (K^+), chloride (Cl^-), and ionised calcium (iCa^{2+}), in addition to glucose and relevant metabolites, including lactate and total bilirubin.[4] In contrast, the Henderson-Hasselbalch equation estimates the bicarbonate (HCO_3-) level and base excess (BE).[5] POCT blood gas analyses with the availability of rapid results enable earlier diagnosis and management of critically unwell patients, especially when biochemical values surpass the clinical reference range, requiring prompt and efficient therapy. Thus, POCT analysers are appealing therapeutic tools in acute patient care.

In many institutions, different blood gas POCT analysers are employed in multiple locations. The performance of these devices differs due to variations in their foundational technologies, reagents, and quality control materials.[6] Addressing blood gas analysis is often complicated by discrepancies in methodological changes over time, leading to debates that may influence the interpretation of results. It is essential to ascertain whether different analysers can yield clinically significant variation and interchangeability of

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results.[7] Besides the pre-analytical steps and established results on accuracy, blood gas analysis is susceptible to inter- and intra-instrumental variation.[8] Given that, the Clinical Laboratory Improvement Amendments (CLIA) require a clinical instrument to undergo strict analytical method verification, including accuracy, precision, reportable range, analytical sensitivity and specificity, limit of detection and reference intervals. Consequently, it must ensure that the analytical performance's representative characteristics fulfil the testing implementation standards.[9]

A notable gap exists in the literature regarding the comparative performance of electrochemical single-use cartridges versus cartridge-based sandwich sensor cassette systems, particularly in blood gas analysers. The conventional blood gas analyser, which employs a cartridge-based sandwich sensor cassette, is recognised for its high accuracy and reliability in clinical settings, demonstrating excellent correlation coefficients across various parameters.[6] Nonetheless, it encounters challenges associated with preanalytical errors, such as the presence of blood clots, which can introduce significant measurement inaccuracies. Emerging sensor technologies, such as electrochemical sensor cartridges, present potential advancements in sensitivity and capabilities for long-term monitoring. A prospective study could evaluate whether the Wondfo BGA-102 offers comparable or superior analytical performance in terms of accuracy and precision relative to established blood gas analysers. Specifically, it remains unclear whether these new cartridges can deliver analytical performance that is non-inferior to existing systems, particularly with respect to parameters such as pH, pO_2, pCO_2, electrolytes, glucose, and lactate levels. Furthermore, the potential advantages of single-use cartridges regarding within-run and between-lot precision, as well as their susceptibility to interfering with substances and environmental factors like temperature and humidity, have yet to be thoroughly investigated. A deeper understanding of these aspects is vital to establish their real-world suitability in point-of-care settings. Yet, to date, there has been a lack of peer-reviewed research that independently assesses the analytical performance of the Wondfo BGA-102, particularly in comparison to gold-standard laboratory or existing blood gas analysers.

The study focused on two platforms based on distinct sensing technologies; the Wondfo BGA-102 employs an electrochemical sensor within single-use cartridges, while the ABL90 FLEX utilises a cartridge-based sandwich sensor cassette[10] in the ICU as a reference standard. This study aims to evaluate whether it may impact measurement reproducibility, analytical bias, and agreement, ultimately assessing the interchangeability of results in clinical practice regarding key blood gas and electrolyte parameters in critical care settings

MATERIALS AND METHODS

Subjects/Materials

The analytical performance study of the electrochemical sensor within single-use cartridges (Wondfo BGA-102) analyser in comparison with the cartridge-based sandwich sensor cassette (Radiometer ABL-90 FLEX) blood gas analyser in the Intensive Care Unit (ICU) Hospital Pakar Universiti Sains Malaysia (HPUSM) was conducted between July 2024 and November 2024.

Residual arterial blood gas samples from the routine ICU of patients 18 years and older admitted to the intensive care unit (ICU) within the study period were utilised for testing. Samples were collected using 1ml heparinised syringes, either through direct arterial puncture or existing arterial lines. Notably, the leftover residual samples from routine analyses are utilised for comparative purposes. Exclusion criteria included patients below 18 years old, individuals with severe coagulation disorders, blood samples containing visible clots or air bubbles, and venous samples. Additionally, samples analysed more than five minutes apart were excluded to minimise the influence of time-dependent changes in blood gas parameters. Quality control measurements were performed on all analysers using standardised control solutions, with three-level QC in accordance with the Malaysian Standards International Organization for Standardization (MS ISO) 15189 standards for accreditation. The study participants' data were acquired from hospital records and the laboratory information system.

Precision study

A precision study was conducted on the electrochemical sensor within a single-use cartridge analyser (Wondfo BGA-102), specifically focusing on its repeatability (within-run imprecision) and reproducibility (total imprecision), in accordance with the CLSI EP15-A2 protocol.[11] The study utilised QC materials at three different concentration levels (Lot No. W84812) to cover the analytical measurement range for multiple parameters. The parameters included were pH, pCO_2, pO_2, iCa^{2+}, Na^+, K^+, Cl^-, glucose, and lactate. The study focused exclusively on just one QC lot. This is to ensure that the analyser measures a stable material consistently under identical conditions, rather than due to differences between QC lots. Utilising multiple lots could confound precision estimates due to inter-lot variability, encompassing discrepancies in matrix consistency and target values throughout the precision study. This QC material is liquified externally to the analytical system and introduced by the operator. For each QC level, triplicate measurements were performed daily over five consecutive days, resulting in 15 replicates per parameter per level. This approach ensured sufficient data to evaluate both within-run (intra-batch) and between-day (inter-batch) variability. The standard deviation (SD) and coefficient of variation (CV) were calculated for each parameter at each QC level to assess the analyser's consistency. Within-run imprecision is the variation observed when the same sample is repeatedly tested in a single analytical run. At the same time, total imprecision captures the combined effects of within-run and between-run variability across multiple days. The calculated data were then compared to the manufacturer's claimed performance specifications to verify whether the analyser met acceptable precision standards. This comprehensive evaluation allowed for a robust assessment of the analyser's reliability under routine laboratory conditions, helping to determine its suitability for clinical use in measuring critical parameters in patient blood samples.

Table I: Characteristics of study participants (N=40)

Variable	n(%)
Gender	
Female	12 (30.0)
Male	28 (70.0)
Ethnic group	
Malay	37 (92.5)
Chinese	3 (7.5)
Ventilation	
Yes	33 (82.5)
No	7 (17.5)
Indication for blood gas analysis	
Respiratory failure	35 (87.5)
Altered mental status	2 (5.0)
Elective intubation	3 (7.5)

Table II: Imprecision study results for the electrochemical sensor within single-use cartridges (Wondfo BGA-102) analyser

Analytes	Level	Control	Mean	SD	Total imprecision, CV (%)	Wondfo CV (%)	Analytical Performance Specification, CV Goals (%)	
							Ricos et al (desirable/minimum)	SFBC/RIliBak
pH	level 1	7.135	7.054	0.010	0.135	-	0.1/-	-/0.4
	level 2	7.414	7.373	0.007	0.098	-	0.1/-	-/0.4
	level 3	7.626	7.608	0.007	0.089	-	0.1/-	-/0.4
pO_2 (mmHg)	level 1	99	93	11.33	12.14	15	-/-	1.5/7
	level 2	125	131	10.38	7.92	15	-/-	1.5/5.5
	level 3	155	165	4.84	2.93	15	-/-	1.5/5.5
pCO_2 (mmHg)	level 1	65	70	2.56	3.66	8	2.4/3	3.8/6.5
	level 2	35.8	40.2	1.47	3.64	8	2.4/3	4.5/6.5
	level 3	19.5	21.8	0.88	4.06	8	2.4/3	4.5/7.5
iCa^{2+} (mmol/L)	level 1	1.38	1.30	0.03	2.22	5	0.9/1.3	1.2/7.5
	level 2	1.18	1.11	0.024	2.16	5	0.9/1.3	1.2/7.5
	level 3	0.58	0.56	0.028	4.81	5	0.9/1.3	1.2/14.5
Na^+ (mmol/L)	level 1	113	109	0.88	0.81	3	0.3/0.5	1/3
	level 2	133	129	1.20	0.93	3	0.3/0.5	1/3
	level 3	157	153	1.68	1.10	3	0.3/0.5	0.7/3
K^+ (mmol/L)	level 1	1.8	1.9	0.05	2.60	3	2.3/3.5	1.5/4.5
	level 2	4.3	4.2	0.06	1.38	3	2.3/3.5	1.2/4.5
	level 3	6.4	5.9	0.08	1.34	3	2.3/3.5	1.2/4.5
Cl^- (mmol/L)	level 1	79	71	0.64	0.91	4	0.6/0.9	1.2/4.5
	level 2	96	89	0.94	1.06	4	0.6/0.9	1.2/4.5
	level 3	119	119	0.91	0.76	4	0.6/0.9	1.2/4.5
Glucose (mmol/L)	level 1	5.1	4.5	0.1	2.23	10	2.3/-	2.4/5
	level 2	10.3	11.8	0.74	6.28	10	2.3/-	1.2/5
	level 3	15.2	17.6	1.17	6.66	10	2.3/-	1.2/5
Lactate (mmol/L)	level 1	0.88	0.83	0.09	11.25	15	13.6/-	-/-
	level 2	2.75	2.29	0.16	7.02	15	13.6/-	-/-
	level 3	6.69	6.32	0.34	5.44	15	13.6/-	-/-

SD= standard deviation, CV= coefficient of variation, SFBC= French Society of Clinical Biology, pO2= partial pressure of oxygen, pCO2= partial pressure of carbon dioxide

Method comparison study

We performed a prospective method-comparison study to evaluate the electrochemical single-use cartridges (Wondfo BGA-102) point-of-care blood gas analyser versus the cartridge-based sandwich sensor cassette (Radiometer ABL-90 FLEX) blood gas analyser in the ICU as a reference analyser. The study includes a total of 40 random arterial whole blood samples from 1ml of heparinised syringe, which were tested for pH, pCO_2, pO_2, iCa^{2+}, Na^+, K^+, Cl^-, glucose, and lactate on both blood gas analysers. The minimum sample size of 40 was required for this study according to Clinical and Laboratory Standards Institute (CLSI) EP9-A2 guidelines.[12] Upon placing the blood sample in the first analyser, any air bubbles that may have formed during the aspiration process were promptly removed from the remaining sample. Subsequently, the sample was sealed with an airtight cap and mixed thoroughly by hand before being analysed in the second analyser. The time interval for measuring samples in both analysers is under five minutes. The interval between the two assays was negligible, as the analysers were initially placed close to one another. The samples were randomly tested across the two blood gas analysers without any predetermined sequence to reduce potential bias.

Table III: Comparative analysis of analyte measurements: electrochemical single-use cartridges (Wondfo BGA-102) vs. Cartridge-Based Sandwich Sensor Cassette Radiometer ABL-90 FLEX)

Analyte	Passing-Bablok regression			Bland-Altman			ICC (95% CI)
	Y Intercept (95% CI)	Slope (95% CI)	R^2	Mean difference (95% CI)	Lower limit of agreement	Upper limit of agreement	
pH	-0.034 (-0.883 to 0.700)	1.004 (0.904 to 1.112)	0.932	-0.006 (-0.042 to 0.030)	-0.226	0.215	0.982 (0.966-0.991)
pCO_2 (mmHg)	-4.526 (-7.517 to -1.695)	1.070 (1.010 to 1.161)	0.973	-1.2 (-4.7 to 2.3)	-22.4	19.9	0.989 (0.966-0.995)
pO_2 (mmHg)	14.745 (10.233 to 18.636)	0.947 (0.901 to 0.996)	0.961	9 (-3 to 21)	-64	83	0.977 (0.605-0.994)
iCa^{2+} (mmol/L)	0.020 (-0.230 to 0.197)	1.000 (0.836 to 1.231)	0.820	0.02 (-0.01 to 0.05)	-0.19	0.23	0.945 (0.889-0.972)
Na^+ (mmol/L)	-2.000 (-25.833 to 5.631)	1.000 (0.947 to 1.167)	0.904	-2 (-4 to 0.04)	-14	11	0.957 (0.777-0.985)
K^+ (mmol/L)	0.000 (0.000 to 0.203)	1.000 (0.947 to 1.000)	0.970	0.03 (-0.14 to 0.20)	-1.0	1.1	0.992 (0.984-0.996)
Cl^- (mmol/L)	0.500 (-6.767 to 15.182)	1.000 (0.864 to 1.067)	0.922	0.4 (-2.13 to 2.93)	-15	16	0.979 (0.961-0.989)
Glucose (mmol/L)	-0.223 (-0.843 to 0.241)	1.050 (0.984 to 1.135)	0.964	0.2 (-0.8 to 1.2)	-5.9	6.3	0.99 (0.981-0.995)
Lactate (mmol/L)	0.440 (0.329 to 0.547)	0.795 (0.716 to 0.886)	0.976	0.12 (-0.59 to 0.83)	-4.25	4.49	0.985 (0.971-0.992)

pCO_2= partial pressure of carbon dioxide, pO_2= partial pressure of oxygen, iCa^{2+} = ionised calcium, Na^+ = sodium, K^+ = potassium, Cl^- = chloride, R^2= coefficient of correlation, ICC= intraclass coefficient

Statistical analyses

The means, SD and CV for each level of control were determined in the imprecision study. Between-day imprecision, bias and total error (TE) were determined for each analyte on each analyser as follows:

CV = (SD/Mean) x 100; CV% is the coefficient of variation for measuring between-day imprecision, SD is the standard deviation.

$$\text{Bias\%} = \frac{\text{Average absolute deviation from the target value}}{\text{Target}} \times 100$$

TE (%) was calculated as 1.65 x CV (%) + Bias (%).

Considering a Gaussian distribution, the factor 1.65 indicates that 95 % of the outcomes will lie within the TE limit.[13]

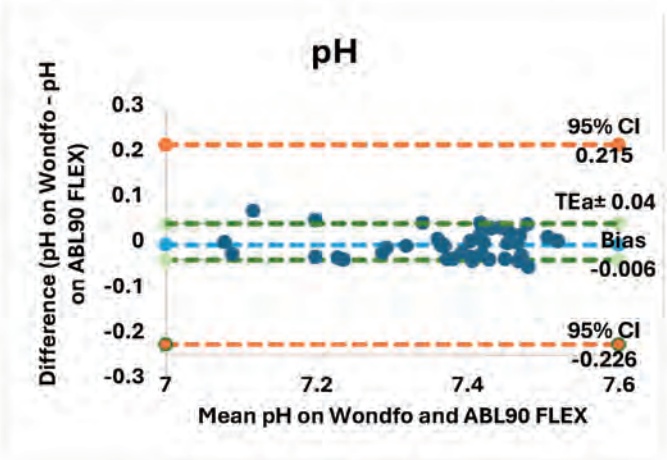
According to the guidelines outlined in EP15-A2, imprecision results should be compared against the manufacturer's claims. When the repeatability and within-laboratory SD are lower than those specified by the manufacturer, the user has successfully demonstrated precision, aligning with these claims and requiring no further calculations. Conversely, if the obtained values exceed those reported by the manufacturer, a statistical test must be conducted to determine whether the observed difference is statistically significant.[14]

Various sources of analytical performance goals were considered for comparison in this study. Preference was given to the database compiled by Ricos et al[15-16], however, certain parameters were either not included (such as pO_2) or were based on outdated evaluations (such as pH) in that database. In such cases, alternative benchmarks were used, including the total allowable error (TEa) criteria from the Royal College of Pathologists of Australasia (RCPA)[17], imprecision goals from the French Society of Clinical Biology (SFBC – Société Française de Biologie Clinique)[18], and the German RiliBÄK guidelines.[19]

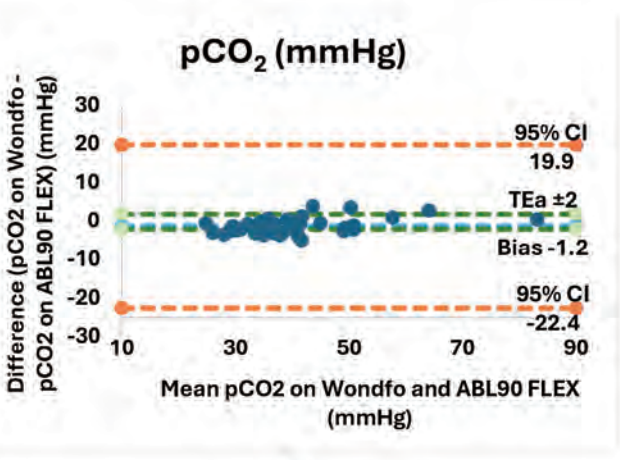
The assumption of normality for the difference data was tested using the Shapiro-Wilk test and visually assessed using a histogram. Data for all the analytes shows sufficient normality for the subsequent application of Bland-Altman analysis. Patient sample-based method comparisons were evaluated by calculating Spearman rank correlation coefficients and the slope and intercept using Passing-Bablok regression analysis with two-sided 95% confidence intervals (CI) calculated for each slope and intercept. An intercept of zero or close to zero indicates no systematic difference between the methods, while a slope close to 1 indicates a strong relationship between them. Intraclass coefficient (ICC) was calculated using a two-way mixed effects model for absolute agreement to assess the correlation between both analysers for different analytes. The relative mean differences, or biases, between the methods were visualised using Bland-Altman difference plots. These plots effectively depict the upper and lower limits of agreement and are derived using the mean difference ± 1.96 multiplied by the standard deviation of the differences. The TEa is used to assess whether the mean difference was clinically relevant. SPSS version 21.0 is utilised in all statistical analyses.

Ethics approval

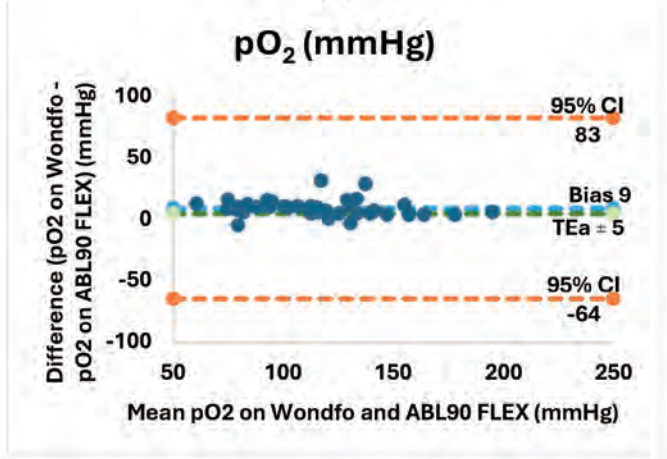
This study was approved by the Human Research Ethics Committee (JEPeM) of Universiti Sains Malaysia, with JEPeM code USM/JEPeM/KK/24040299.


pH
Difference (pH on Wondfo - pH on ABL90 FLEX)
0.3
0.2
0.1
0
-0.1
-0.2
-0.3
95% CI
0.215
TEa± 0.04
Bias
-0.006
95% CI
-0.226
7
7.2
7.4
7.6
Mean pH on Wondfo and ABL90 FLEX

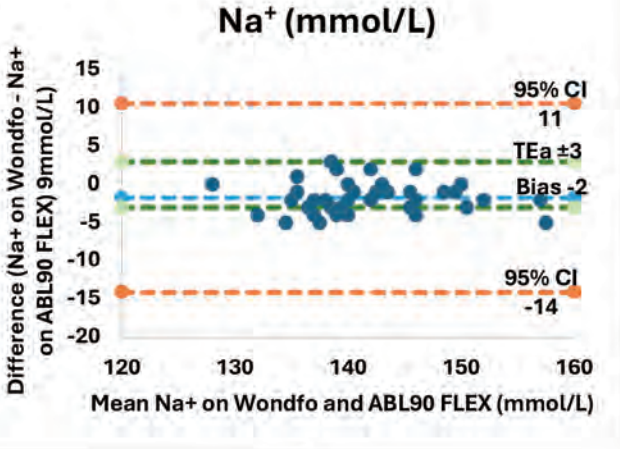
A


pCO2 (mmHg)
Difference (pCO2 on Wondfo - pCO2 on ABL90 FLEX) (mmHg)
30
20
10
0
-10
-20
-30
95% CI
19.9
TEa ±2
Bias -1.2
95% CI
-22.4
10
30
50
70
90
Mean pCO2 on Wondfo and ABL90 FLEX (mmHg)

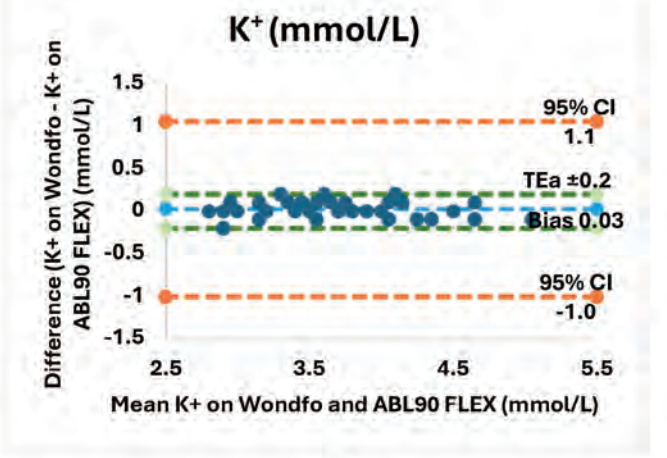
B


pO2 (mmHg)
Difference (pO2 on Wondfo - pO2 on ABL90 FLEX) (mmHg)
100
50
0
-50
-100
95% CI
83
Bias 9
TEa ± 5
95% CI
-64
50
100
150
200
250
Mean pO2 on Wondfo and ABL90 FLEX (mmHg)

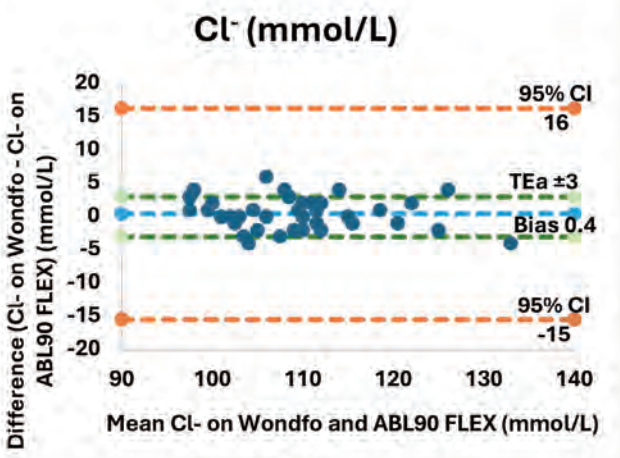
C


Na+ (mmol/L)
Difference (Na+ on Wondfo - Na+ on ABL90 FLEX) 9mmol/L)
15
10
5
0
-5
-10
-15
-20
95% CI
11
TEa ±3
Bias -2
95% CI
-14
120
130
140
150
160
Mean Na+ on Wondfo and ABL90 FLEX (mmol/L)

D


K+ (mmol/L)
Difference (K+ on Wondfo - K+ on ABL90 FLEX) (mmol/L)
1.5
1
0.5
0
-0.5
-1
-1.5
95% CI
1.1
TEa ±0.2
Bias 0.03
95% CI
-1.0
2.5
3.5
4.5
5.5
Mean K+ on Wondfo and ABL90 FLEX (mmol/L)

E


Cl- (mmol/L)
Difference (Cl- on Wondfo - Cl- on ABL90 FLEX) (mmol/L)
20
15
10
5
0
-5
-10
-15
-20
95% CI
16
TEa ±3
Bias 0.4
95% CI
-15
90
100
110
120
130
140
Mean Cl- on Wondfo and ABL90 FLEX (mmol/L)

F

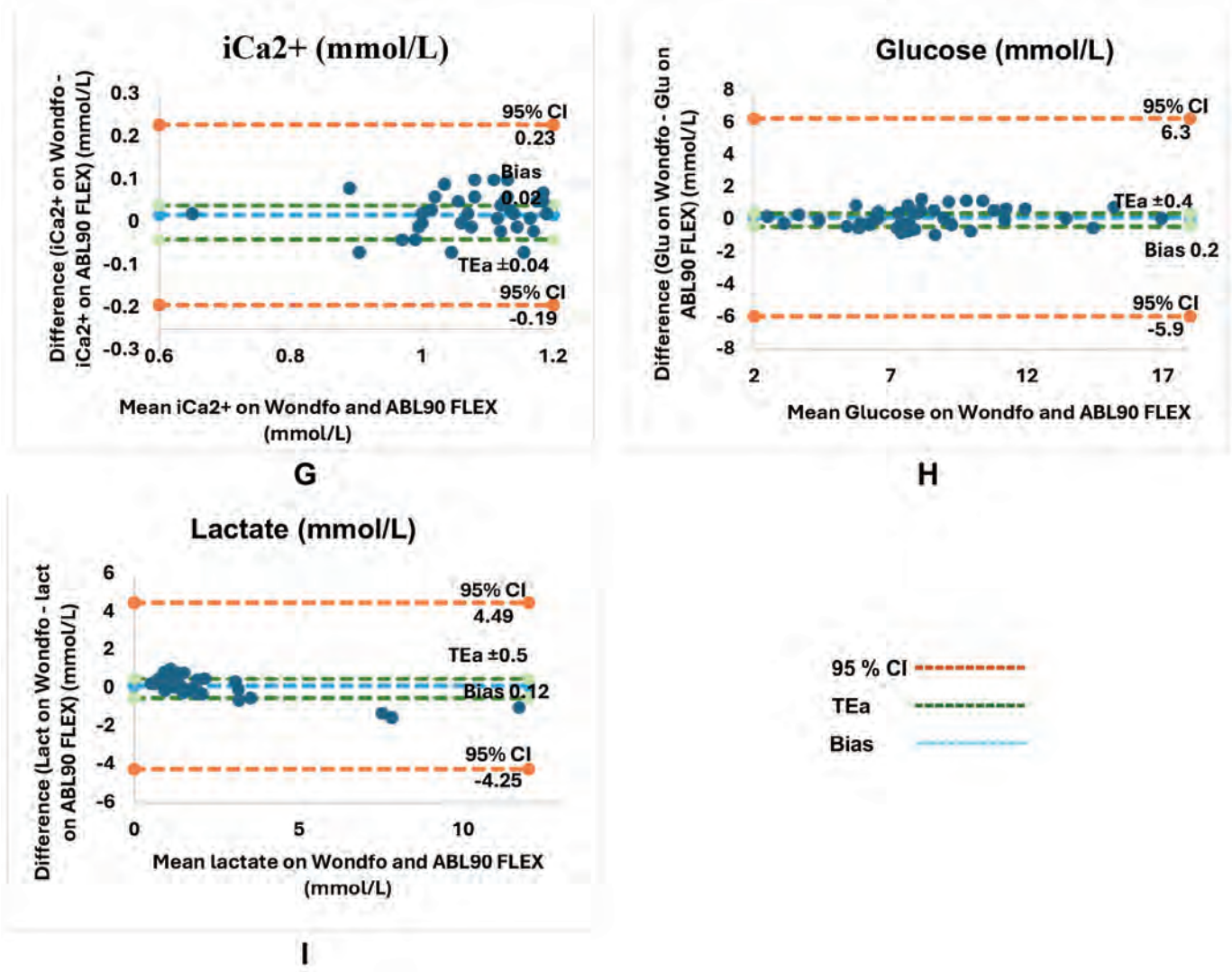


Fig. 1: Bland–Altman plot for agreement between using Wondfo BGA and Radiometer ABL90 FLEX for various parameters: pH (A), pCO2 (B), pO2 (C), sodium (D), potassium (E), chloride (F), ionized calcium (G), glucose (H) and lactate (I)

RESULTS

A total of 40 patients were recruited for the study. The patients' median (25th, 75th percentile) age is 59.0 (43.6-74.4) years. Table I displays the characteristics of the participants involved in the study.

Analysis of precision

Our research showed that the electrochemical sensor within single-use cartridges (Wondfo BGA-102) analyser exhibited a within-run CV of under 5% for all measured analytes, including pH, pCO_2, pO_2, iCa^{2+}, Na^+, K^+, Cl^-, glucose, and lactate. The total imprecision of all the analytes aligns with the manufacturer's claim, indicating that the precision study meets the required standards, as shown in Table II.

Analysis of method comparison study

Forty samples of whole blood in a heparinised syringe were subjected to the method comparison study. The electrochemical sensor within single-use cartridges (Wondfo BGA-102) analyser demonstrates high correlation and agreement with the cartridge-based sandwich sensor cassette (ABL90 FLEX Radiometer) for most analytes. Significant results were observed for pH, K^+, Cl^-, and glucose, showing near-perfect slopes, high coefficient of correlation (R^2) values, narrow Bland–Altman limits, and ICC exceeding 0.98. The analyser showed slightly lower performance for pO_2 and iCa^{2+}, with wider limits of agreement and lower R^2 for iCa^{2+}, though still within acceptable clinical limits. These findings confirm that the analyser provides reliable and accurate measurements for most critical care parameters. Generally, all the parameters measured showed an excellent correlation between both analysers (ICC > 0.9), as shown in Table III and Figure 1.

The mean difference (bias) between both analysers was less than 2, except for the parameter pO_2. The pO_2 showed a bias of 9 mmHg with a limit of agreement between -64 and 83. At the medical decision point (MDP) of different levels, i.e., 99mmHg, 125mmHg and 155mmHg, TE measured exceeded the TEa of 6% based on RCPA. For ionised calcium, at MDP of

1.30mmol/L, 1.05mmol/L and 0.45mmol/L with a bias of 0.02mmol/L, the calculated TE exceeded TEa (± 0.04 if ≤1.00mmol/L, ± 4% if >1.00mmol/L based on RCPA).

DISCUSSION

This study revealed that most patients experiencing respiratory failure and ventilation in the ICU require frequent and particular monitoring of their acid-base status and oxygenation. Accurate blood gas measurements are essential for making immediate clinical decisions and ensuring patient safety.

The precision study conducted according to CLSI EP15-A2 guidelines demonstrated that most parameters for the electrochemical sensor within single-use cartridges (Wondfo BGA-102) analyser met the manufacturer's claim and the desirable CV goals outlined in performance databases such as Ricos et al., RiliBÄK, SFBC, and the RCPA. The results suggest that the analyser delivers consistent performance across a range of critical parameters including pH, pO_2, pCO_2, electrolytes (Na^+, K^+, Cl^-, iCa^{2+}), glucose, and lactate. Nevertheless, in our precision study, the CV for pO_2 at levels 1 and 2 and for glucose at levels 2 and 3 surpassed the permissible limits established by RiliBÄK. This observation is consistent with previously published research, which indicated variability in pO_2 measurements across different POCT platforms.[18] The limitations in precision for pO_2 suggest that this parameter may be more vulnerable to instrument-specific variability or pre-analytical factors. The use of QC materials for precision studies, particularly those prepared externally for the analytical system, poses a risk of introducing temperature fluctuations or air exposure during manual handling. Such variabilities may contribute to the imprecision observed, especially when dealing with highly volatile analytes, such as pO_2.[20-21]

Moreover, the comparative analysis of the electrochemical single-use cartridges (Wondfo BGA-102) versus the cartridge-based sandwich sensor cassette (Radiometer ABL-90 FLEX) blood gas analysers revealed that the results for pH, pCO_2, Na^+, K^+, Cl^-, glucose, and lactate were statistically comparable within a 95% confidence interval, signifying a high degree of analytical agreement. This was supported by strong correlation coefficients and ICC, which support the interchangeability of results for these parameters in clinical settings. These results are comparable to other contemporary POCT validation studies such as those conducted on Abbott i-STAT Alinity[20] and GEM Premier 5000[22], which also demonstrated strong agreement for most core analytes against a core laboratory or established POCT platform. However, the mean difference for pO_2 was 9mmHg suggesting a systematic bias between the two analysers. The pO_2 is widely acknowledged as the most sensitive parameter in blood gas analysis, particularly in relation to pre-analytical factors that can compromise its accuracy and reliability. Various issues can introduce bias into pO_2 measurements. These include the possibility of air bubbles within the syringe barrel or needle hub, air contamination, and insufficient mixing of the sample. Furthermore, delays in analysis, inadequate sample volumes, and calibration discrepancies among different blood gas analysers can negatively affect study outcomes.[23-24]

Another factor that could account for the differences in pO_2 readings is the difference in measurement principles. The Wondfo BGA-102 utilises amperometry for the measurement of 0, whereas the ABL90 FLEX uses an optical system for pO_2. These methodological differences could inherently affect the bias, particularly under varying clinical or environmental conditions. A 9mmHg positive bias in pO_2 is clinically significant. It may lead to a misinterpretation of oxygenation status, especially within the low-to-normal pO_2 range, where even small changes can influence clinical decisions, such as decisions on oxygen therapy or ventilatory adjustments, that are sensitive to relatively small deviations. Therefore, when conducting serial measurements, it is advisable to use the same analyser, as this approach helps minimise analytical variability. Additionally, rigorous adherence to standardised collection protocols, including the immediate expulsion of air bubbles and prompt analysis, is of utmost importance for preserving the integrity of pO_2 measurements.[24-25]

Similar concerns apply to iCa^{2+} measurements, as ABL 90 FLEX uses a potentiometric measuring principle, whereas Wondfo BGA-102 utilises a multi-sensor in one cartridge, which contributes to bias between analysers. Although the mean bias between the two analysers was minimal (0.02 mmol/L) and CV remained within acceptable ranges (2.16%–4.81%), the calculated TE at multiple medical decision points exceeded TEa (± 0.04). This suggests that while the overall performance of iCa^{2+} measurements is deemed satisfactory, the results may not be interchangeable between the two analysers at certain decision thresholds. Clinically, even minor iCa^{2+} biases between blood gas analysers can significantly impact the classification of hypo- or hypercalcemia, which subsequently affects calcium replacement protocols and the care of critically ill and neonatal patients. Supported by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) recommendation in 1991, several pre-analytical variables can influence discrepancies in iCa^{2+} levels. These factors are primarily related to sample handling and processing since iCa^{2+} is highly sensitive to changes in pH. Important considerations include the type and concentration of heparin used, the extent of sample dilution, and any delays in analysis. These variables can lead to altered iCa^{2+} values and create apparent biases between different analysers.[26]

The evaluation of acid-base status is incomplete without considering the estimated HCO_3- and BE, which provide further information on the metabolic component. While these parameters are not directly measured by either the Wondfo BGA-102 or the ABL90 FLEX, they are mathematically derived from measured values (pH and pCO_2) using the Henderson-Hasselbalch equation and standard algorithms5. Since our study found a high correlation and agreement for both pH (ICC = 0.982) and pCO_2 (ICC = 0.989) between the two analysers, it can be inferred that the derived values of HCO_3- and BE would also exhibit a high degree of interchangeability between the two platforms. Nevertheless, it is important to note that any

systematic bias in the measured pH or pCO_2, even if statistically small, could propagate into the calculated values, potentially affecting the precise metabolic interpretation at medical decision points.

Another significant limitation of this study is related to the sample size. Although the CLSI EP9-A2 guidelines recommend a minimum sample size of 40, this may restrict the ability to detect bias across the entire analytical range. As a result, the limited sample size could impact the generalisability of the findings and hinder the identification of subtle biases in measurement accuracy at different concentrations, especially in extreme acidotic and alkalotic conditions. A larger sample size would strengthen the findings and allow for a more comprehensive evaluation of the performance characteristics between the blood gas analysers. Furthermore, the diverse clinical scenarios in the ICU, including conditions like sepsis, trauma, and cardiac arrest represent a spectrum of clinical illnesses. This broad range of patient conditions, particularly those requiring aggressive respiratory or metabolic management can introduce a potential bias of measurement due to extreme physiological values and complex clinical interventions.

CONCLUSION

In conclusion, the Wondfo BGA-102 offers reliable performance for a wide range of blood gas and biochemical analytes, showing strong agreement with the Radiometer ABL90 FLEX for most parameters. Nonetheless, certain biases, especially in pO_2 and iCa^{2+} measurements, highlight the importance of cautious interpretation of the results. The systematic biases observed necessitate the implementation of inter-analyser verification protocols and potentially the need for harmonisation across different POCT platforms within the same clinical setting to ensure patient safety and consistency in care. Clinicians must remain vigilant and well-informed when evaluating patient data from different devices, reinforcing the need to assess the performance of each analyser before its use.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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