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Comparison of Blood Gas and Electrolyte Test Results from the Gem-Premier and the ABL-70 versus a Conventional Laboratory Analyzer

Howard G. Walton, BA, CCP; David M. Boucher, BS, CCP; Rafael Marroquin, MD, CCP

Memorial Medical Center, Modesto, California

Abstract: Blood gas analyzers serve a critical role in providing information that reflects patient homeostasis. This study was undertaken to evaluate the accuracy, reliability, consistency, and bias of the Radiometer ABL-70 point of care blood gas analyzer. Thirty samples were gathered for analysis of pH, pCO_2, pO_2, sodium, potassium, sodium bicarbonate, and base excess. Twenty-nine samples were gathered for hematocrit, 31 for ionized calcium, and 33 for venous pO_2 and saturations. The data were compared with the Gem-Premier point of care analyzer and the hospital blood gas machine and electrolyte analyzer. There was statistical significance between the pH, pCO_2, sodium, potassium, calcium, hematocrit, and venous pO_2 and saturations when comparing the ABL-70 with the Gem-Premier. When comparing the ABL-70 with the Corning 278/270 blood gas machine/Co-Ox, the AVL-9180, and the Dimension XL, there was statistical significance seen between the pH, pCO_2, pO_2, sodium, calcium, hematocrit, and base excess. Although this statistical significance was observed between the ABL-70 and the other analyzers, the significance was not of clinical importance. The ABL-70 demonstrated acceptable accuracy, reliability, consistency, and bias. **Keywords:** cardiopulmonary bypass, blood gas analyzer, point of care testing. *JECT. 2003;35:24–27*

There has been much study into the area of blood gas management during cardiopulmonary bypass (CPB). Recently, the emphasis has been on the use of inline, continuous blood gas monitoring. Many authors have reported the reliability and clinical outcome of using such devices (1–8). There are two main reasons for the use of these devices: 1) trending the patient's blood gas status continuously; and 2) timely data. Yet, no one is advocating the use of these monitors without the intermittent draw of a blood gas for analysis on a blood gas machine. In fact, every monitor is compared to and correlated with a blood gas analyzer (7, 9, 10).

Laboratory blood gas analyzers have always been the gold standard in cardiac surgery when reliable results are needed to treat the patient on CPB. Point of care analyzers have become very popular because of the main advantage of timely results. Often times the perfusionist must wait 20 to 30 minutes for the blood gas and electrolyte results from the main hospital laboratory. With the point of care instrument in the operating room, or close by in the surgery department, the perfusionist can get timely and accurate results (7, 10).

Radiometer bought SenDx Medical, Inc. and is marketing the SenDx 100 blood gas analyzer as the ABL-70 (Radiometer America Inc., Westlake, OH. 44145) with no changes other than improving the sensor electrodes in the cassettes. The SenDx 100 has demonstrated excellent precision and acceptable performance when compared with a reference analyzer (11, 12, 13). Our study was undertaken to evaluate the accuracy, reliability, consistency, and bias of the ABL-70 blood gas machine marketed by Radiometer.

MATERIALS AND METHODS

The Institutional Review Committee of Memorial Medical Center, Modesto, CA, approved this study. The ABL-70 analyzer was compared to our current point of care analyzer, the Instrumentation Laboratory Gem-Premier (Instrument Laboratory, Lexington, MA. 02173), and with the hospital's Ciba-Corning 278 blood gas ma-

Address correspondence to: H.G. Walton, BA, CCP, Memorial Medical Center, Department of Surgery, 1700 Coffee Road, Modesto, CA 95355. E-mail: hwalton@pc-intouch.com
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chine (Corning 278) and Ciba-Corning 270 Co-Ox (Corning 270) (Bayer Corp., Norwood, MA. 02062). The electrolytes were analyzed in the hospital laboratory using the AVL-9180 (AVL Scientific Corp., Roswell, Georgia 30079) for the ionized calcium (iCa) and the Dimension XL (Dale International Inc., Newark, Delaware 19714) for the potassium (K) and sodium (Na).

Initially, 30 samples were gathered for analysis of pH, pCO_2, pO_2, sodium, potassium, sodium bicarbonate, and base excess. Twenty-nine samples were gathered for hematocrit, 31 for ionized calcium, and 33 for venous pO_2 (PVO_2) and venous saturations (SVO_2). A single sample was collected and immediately aspirated into both the Gem-Premier and ABL-70. From that same sample, a portion was injected into a laboratory test tube for the electrolyte analysis. The remainder was iced and sent for analysis on the Corning 278/270 blood gas machine/Co-Ox. Samples were taken during all aspects of CPB (i.e., cool, warming, and warm samples). The results reported are uncorrected for temperature.

The parameters used for comparison were pH, pCO_2, pO_2, sodium, potassium, ionized calcium, sodium bicarbonate, base excess, hematocrit, PVO_2, and SVO_2. The data were analyzed using a statistical package developed for microcomputers (Number Cruncher Statistical System, Kaysville, UT. 84037). Agreement between blood gas values and laboratory-measured samples has been described by the method of Bland and Altman (14). This method allows comparison between two methods of measurement in terms of accuracy (bias—the mean difference between values) and precision (expressed as limits of agreement—two times the standard deviation (SD) of the difference between values).

In consultation with a statistician, we were advised to use the *p* value (a paired *t* test) and SD to compare the ABL-70 with the Gem-Premier and the Corning 278/270 blood gas machine/Co-Ox, AVL-9180, and the Dimension XL. This procedure tests the difference between the means of populations taken in pairs for statistical significance. If there was statistical significance, we used the limits of confidence to determine if this difference was of clinical significance. We used a 99% confidence limit of the estimated mean to make this determination. The correlation (R2) was used to determine weather the data points tracked in the same direction between the two instruments, and how close was this tracking. A stronger linear relationship is indicated, as the correlation gets closer to plus one (100% correlation).

RESULTS

Table 1 shows the results of the comparisons between the Gem-Premier and the ABL-70. There was statistical significance between the pH, pCO_2, sodium, potassium, iCa, Hct., PVO_2, and SVO_2. There was no statistical significance between the pO_2, HCO_3, and BE. The correlation were all 88% and above with the exception of the PVO_2, SVO_2, and hematocrit. The hematocrit had statistical significance ($p < .001$), poor correlation (60%), and large confidence limits (from a lower limit of 0.51 to an upper limit of 4.11).

Table 2 shows the results of the comparisons between the ABL-70 and the laboratory analyzers. Again, statistical significance is seen between the pH, pCO_2, pO_2, sodium, iCa, Hct, and BE. There was no statistical significance between the potassium, HCO_3, PVO_2, and SVO_2. The correlations were all 80% and above with the exception, again, of the PVO_2, SVO_2, and hematocrit. The hematocrit had statistical significance ($p < .001$), poor correlation (62%), and large confidence limits (from a lower limit of –5.8 to an upper limit of –2.15).

The ABL-70 measured the hematocrits consistently and significantly lower when compared with the Gem-Premier and the laboratory analyzers. This is the bias of the instrument. From this data it was decided to adjust the offset of the ABL-70 to be more in line with the measured values of

Table 1. Comparison of the ABL-70 and the Gem-Premier.

Variable	ABL-70	Gem-Premier	Correlation	*p*-value	99% Confidence Limits of Difference		Sample Size n
					Lower	Upper	
pH	7.434 ± .058	7.403 ± .049	0.9193	$p < .001$	.043	.012	30
pCO_2	33.5 ± 4.5	35.7 ± 4.3	0.8853	$p < .001$	1.13	3.25	30
pO_2	286.3 ± 79	282.9 ± 87.6	0.9902	NS	−10.6	3.9	30
Sodium	138.7 ± 4.1	139.4 ± 4.3	0.9542	$p < .004$	.087	1.38	30
Potassium	4.86 ± .98	4.93 ± .92	0.9974	$p < .001$	.04	0.11	30
Ionized Ca	1.13 ± .084	1.08 ± .099	0.9167	$p < .001$	−.073	−.033	31
HCO_3	22.5 ± 2.0	22.1 ± 2.2	0.8931	NS	−.82	.16	30
BE	−1.73 ± 2.49	−1.73 ± 2.36	0.8946	NS	−.56	.56	30
Hematocrit	19.8 ± 4.4	22.1 ± 2.4	0.6014	$p < .001$	.51	4.11	29
Venous pO_2	43.5 ± 8.28	38.9 ± 6.23	0.5999	$p < .001$	−7.8	−1.38	33
Venous Sat.	78.7 ± 8.33	70.7 ± 8.6	0.6093	$p < .001$	−11.5	4.41	33

Note: Where applicable, all data are shown as the mean ± standard deviation (SD).

Table 2. Comparison of the ABL-70 and the IL/Co-Ox/electrolyte analyzer.

Variable	ABL-70	Lab	Correlation	*p*-value	99% Confidence Limits of Difference		Sample Size n
					Lower	Upper	
pH	7.434 ± .058	7.408 ± .049	0.9330	$p < .001$	.015	.036	30
pCO_2	33.5 ± 4.5	35.5 ± 4.6	0.8032	$p < .001$	−3.46	−.604	30
pO_2	286.3 ± 79	264.3 ± 64	0.8753	$p < .004$	2.57	41.33	30
Sodium	138.7 ± 4.1	142.1 ± 4.9	0.9232	$p < .001$	−4.4	2.4	30
Potassium	4.86 ± .98	4.94 ± 1.08	0.8966	NS	−3.2	.16	30
Ionized Ca	1.13 ± .084	1.08 ± .088	0.9572	$p < .001$	.039	.064	31
HCO_3	22.5 ± 2.0	22.6 ± 2.0	0.9556	NS	−.43	.18	30
BE	−1.73 ± 2.49	−1.32 ± 2.17	0.9369	$p < .015$	−.85	.03	30
Hematocrit	19.8 ± 4.4	23.8 ± 2.6	0.6181	$p < .001$	−5.81	−2.15	29
Venous pO_2	43.5 ± 8.28	49.0 ± 13.93	0.5689	NS	−10.9	.027	33
Venous Sat.	78.7 ± 8.33	82.3 ± 9.53	0.5048	NS	−7.9	.64	33
Adjusted Hct.	25.5 ± 3.0	25.5 ± 3.3	0.8596	NS	−.89	.81	30

Note: Where applicable, all data are shown as the mean ± standard deviation (SD).

the Corning 278/270 blood gas machine/Co-Ox, and to correspond with the Laboratory standard. After the offset was adjusted, another 30 samples were taken and the results compared. From the data at the bottom of Table 2 (adjusted Hct.), one can see that the correlation is better (85%), the confidence limits are smaller (from a lower limit of −0.89 to an upper limit of 0.81), and there is no significant difference.

We also ran one sample 24 times to determine the precision of the ABL. This data is presented in Table 3. From this data, it was observed that the coefficient of variation was in agreement with the upper limits of confidence.

DISCUSSION

The accuracy of the equipment measuring blood gases and electrolytes has always been a concern of the perfusionist. Are the results accurate and can the perfusionist depend on the results from these machines? With a point of care instrument in the operating room (OR), the perfusionist can monitor and treat the patient in a timely and precise manner.

Table 3. Precision of ABL-70.

Variable	ABL-70	Coefficient of Variation	99% Confidence Limits	
			Lower	Upper
pH	7.403 ± .016	.0022	7.394	7.413
pCO_2	38.5 ± 1.47	.0383	37.7	39.4
pO_2	184.1 ± 7.8	.0427	179.7	188.7
Sodium	135.6 ± 0.6	.0045	135.3	136.0
Potassium	3.82 ± 0.03	.0093	3.80	3.84
Ionized Ca	1.07 ± 0.014	.0132	1.06	1.07
HCO_3	24.3 ± 0.16	.0066	24.2	24.4
BE	−0.46 ± 0.3	−.6621	−.63	−.28
Hematocrit	24.2 ± 0.19	.0078	24.1	24.3
Saturation	99.6 ± 0.05	.0005	99.6	99.6

Note: Where applicable, all data are shown as the mean ± standard deviation (SD).

The greatest advantage to having a point of care analyzer is to get accurate and consistent results in a timely manner. From the data presented, we found the ABL-70 to be both accurate and consistent. The point of care blood gas and electrolyte analyzer can help the perfusionist make appropriate decisions regarding patient management. The good correlation and limits of confidence demonstrated the accuracy of the ABL-70 when compared with the Corning 278/270 blood gas machine/Co-Ox, AVL, and Dimension analyzers. Although the ABL-70 results reached a significant level when compared with the Corning 278/270 blood gas machine/Co-Ox, AVL, and Dimension, this was clinically of little importance. For example, the pH confidence limits of difference tell us that 99% of the time the true mean is within the interval of .043 and .012 (Table 1). So, if the patient's true mean pH varied by .043 to .012, we would not treat the patient's acid/base balance and the difference becomes of no clinical importance. These data show there is a true difference between the machines, but this is not of clinical significance as demonstrated by the 99% confidence limits of difference. Although the venous samples had no statistical significance (Table 2) when the ABL-70 was compared with the laboratory analyzers, one could argue that the PVO_2 has some clinical significance based on the large negative lower confidence limit.

The ABL-70 was consistent when data was compared with the Corning 278/270 blood gas machine/Co-Ox, AVL, and Dimension analyzers. For example, the pH of the ABL-70 was consistently higher than that of the Corning 278/270 blood gas analyzer through the course of this study. Even when the data demonstrated no statistical significance, as with the K, if the results were different the ABL was consistent. In this case, the K was slightly lower every time it was compared with the Dimension analyzer. This is what we would call the bias of the machine.

The reliability of the ABL-70 was good. We only experienced one bad cassette that prevented us from sampling during a case. When it was changed and quality control (QC) samples were performed, the machine functioned as specified by the manufacture. There was a short learning curve that each perfusionist went through to become familiar with the analyzer, but overall it is easy to use and maintain. The cartridge system allows for easy daily maintenance, QC performance, and blood gas analysis. The ABL-70 fulfills the requirement of a portable blood gas/electrolyte analyzer with acceptable accuracy, reliability, consistency, and bias. It gives fast results and is easy to use. We would recommend the ABL-70 for point of care use in the operating room during cardiac surgery.

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