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Clinical Evaluation of the ABL-77 for Point-of-Care Analysis in the Cardiovascular Operating Room

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Abstract: As a small portable instrument, which can be dedicated to the perfusionist, the Radiometer model ABL-77 point-of-care blood gas, electrolyte, and hematocrit analyzer has come to provide an alternative to in-line monitoring of such parameters. This is not to say that it can necessarily replace the utility of in-line monitoring. However, point of care instruments, such as the ABL-77, can provide faster results than a more remote lab. This study was done as part of an ongoing quality assurance program in conjunction with the main lab department to maintain accreditation. The hypothesis being tested is that during cardiopulmonary bypass (CPB) the ABL-77 is in agreement with alternative instruments used outside the cardiovascular operating room. With the appropriate institutional approval, a total of 20 blood samples were randomly gathered among five patients after initiation of CPB. This was done over a five-day period for pH, pCO2, pO2, potassium, sodium, and hematocrit determinations. Analysis results from the ABL-77 were compared to those made by three other bench top models. These included a Radiometer model ABL-720 analyzer, a Dale Dimension model RxL analyzer, and a Beckerman model LH 750 Coulter Counter. A statistically significant difference is demonstrated for all parameters when each of these instruments is compared to the ABL-77. However, the observed mean differences are only judged to be clinically significant in the case of hematocrit. The ABL-77 is found to demonstrate a negative bias with respect to the different methodologies used by the ABL-720 and the Coulter Counter. This bias may be due to the hemodilution of plasma with crystalloid solution during CPB. This causes error in hematocrit results as the methodology of many point of care instruments is based on the electrical conductivity of whole blood. This may be corrected by using a relationship determined from linear regression analysis. This error adjustment has been implemented as part of a concerted blood conservation effort. Otherwise, the ABL-77 has been found to be reliable and consistent for point of care blood analysis. **Keywords:** cardiopulmonary bypass, point-of-care analysis, blood gases, electrolytes, hematocrit. *JECT. 2006;38:128–133*

The post-second world war decade of the 1950s saw the beginning of rapid developments in clinical instrumentation technology. These included the Sanz electrode for pH measurement, the Severinghaus electrode for pCO_2 measurement, and the Clark electrode for pO_2 measurement (1,2). Other methods and clinical instruments for measuring electrolytes, hemoglobin, and counting blood cells soon followed. Vacuum tubes gave way to transistors, and transistors to integrated circuits using operational amplifiers. With this, instruments became smaller, more automated, and easier to maintain and operate. Along with the supporting electronics, the sensor electrodes have been miniaturized to allow for testing on very small sample volumes. Many instruments have evolved from large discreet bench top analyzers into small portable devices that determine multiple parameters and can be operated in a variety of areas where space is a premium. This close proximity to the patient includes the operating room, the catheterization laboratory, or the patient's bedside. In reference to laboratory analysis, the term "point-of-care" was coined. This concept began in the early 1980s when critical care areas began to demand rapid turnaround (<2 minutes) of blood analysis results (3).

In contrast to intermittent sampling, continues in-line blood monitoring has offered the advantage of real-time results. For blood gases, this technology was based on chemical fluorescence transmitted through fiber optic cables. Intensity of fluorescence will be proportional to the concentration of molecules diffused across a membrane in contact with the blood (4). This method allows the clinician more precise control of the monitored parameters. Improvements in cardiopulmonary bypass patient outcomes using continuous in-line blood gas, potassium, and hematocrit monitoring vs. intermittent blood gas monitoring have been shown (5). Despite this, continuous in-line blood gas monitoring has been slow to catch on. This may be because of preconceived prejudice of drawbacks and problems with early versions (6,7). Such a situ-

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ation is unfortunate because over the past decade, in-line monitoring technology has matured to provide reliable data compared with more established bench top methods (8–10).

Having a point-of-care blood analyzer in the cardiac operating room offers an alternative and adjunct to in-line monitoring. Although still not real time, a compromise is made in getting results back quickly. When using a laboratory in a remote location, the time lag may be variable and will depend on the availability of personnel to transport and the backlog of samples being tested. Also, with an analyzer in the operating room, the perfusionist can provide expedient measurements before and after cardiopulmonary bypass, during off-pump procedures, postoperative explorations, and for noncardiac procedures if needed. In some institutions, the perfusionist must pay the price for this added convenience by helping maintain the plethora of documentation required for the clinical laboratory accreditation process.

This study was done as part of ongoing quality assurance to comply with the Clinical Laboratory Improvement Amendments (CLIAs) (11). The hypothesis being tested is that, during cardiopulmonary bypass, the ABL-77 provides results comparable with other bench top methods outside the cardiovascular operating room. A single ABL-77 Series analyzer (Radiometer America Inc., Westlake, OH) is currently used as the cardiovascular operating room point-of-care instrument for measurement of hematocrit (HCT), pH, pCO_2, pO_2, Na^+, K^+, and Ca^{2+}. Every 6 months, results from corresponding blood samples, run on the appropriate backup analyzer, were obtained and compared. This data analysis is used to determine the degree of agreement between different analyzers and methodologies. Also, it is used to determine what if any correction factors would be needed if an outside laboratory instrument is considered a standard reference.

The ABL-77 analyzer uses a disposable sensor or test cartridge that contains small potentiometric electrodes, a reference electrode, and a thermostat. The sample pathway is a low volume single pass flow through area. As ion or red cell concentrations change, so do currents and potentials between specifically designed electrodes. The hardware functions basically as a modified electrical meter with microprocessors that convert different electrical potentials and currents into the appropriate display readings (1,2).

MATERIALS AND METHODS

This study was conducted with the appropriate institutional approval. Before testing patient samples, five levels of aqueous controls were run on the ABL-77. The manufacturer provides controls with specified ranges. Three levels each are used for pH, blood gases, and electrolytes. Two levels are used for hematocrit quality assurance. These controls are stored in an area with a monitored temperature of 21–22°C. Over a period of 5 days, a total of 20 arterial blood samples were drawn among five randomly selected patients during elective coronary artery bypass surgery with cardiopulmonary bypass. The first sample for study was drawn within 10 minutes after initiation of cardiopulmonary bypass. Subsequent samples were drawn at 30-minute intervals and analyzed without temperature correction. All cardiopulmonary bypass samples were taken from the arterial side of a continuous flow though sampling manifold after flushing the luer connection with 2 mL of blood. A post-cardiopulmonary bypass sample was drawn within 10 minutes after administration of protamine. This sample was taken from the radial artery monitoring line after drawing back 10 mL of waste.

All patients were allowed to drift to a systemic temperature of approximately 34°C during the cross-clamp period and warmed to 38°C before termination of cardiopulmonary bypass. Systemic temperature was monitored by a Foley probe. Priming solution for the cardiopulmonary bypass circuit consisted of 1800 mL of Normosol-R and 10,000 units of porcine heparin. None of the patients received blood or colloid solution in the prime during cardiopulmonary bypass.

For each sample, a new 10-mL syringe was used for collection. In the case of postprotamine samples, blood was collected using a heparinized syringe. The syringe was immediately aspirated by the ABL-77 using the same sensor cassette for all testing. Approximately 4 mL of blood was introduced into a 4-mL Becton Dickinson Vacutainer (Becton Dickinson and Company, Franklin Lakes, NJ) containing tri-potassium salt of ethylenediaminetetraacetic acid (K3-EDTA) as an anticoagulant. These Vacutainer tubes were sent to the main laboratory for hematocrit testing. Next, approximately 3 mL was introduced into a 3-mL Becton Dickinson Plasma Separation Vacutainer tube (PST) containing a polymer barrier gel and lithium heparin. These were also sent to the main laboratory, but used for sodium and potassium testing. The main laboratory currently uses a Beckman model LH 750 Coulter Counter (Beckman Coulter Inc., Miami, FL) for hematocrit testing. Electrolyte testing by the main laboratory is done on the Dade Behring Dimension model RxL (Dale International Inc., Newark, DE). After evacuating any air bubbles, the remaining contents of each syringe was placed on ice and immediately sent to the intensive care unit laboratory for testing on the ABL-720 bench top analyzer (Radiometer America Inc.). The cardiopulmonary department maintains this instrument. Blood gas results were uncorrected for temperature. With each blood gas analysis, the ABL-720 also determines total hemoglobin. Hematocrit was calculated as approximately three times the total hemoglobin (12,13).

All data were collected from the intensive care unit blood gas laboratory and main laboratory department into paired sample data points with the ABL-77 data. Statistical results were calculated using Microsoft Excel 2000 (Microsoft Corp., Redmond, WA). A paired *t* test was used to test for statistically significant differences between the means of the sample results from the ABL-77 vs. the means of the sample results from the alternative analyzer for each parameter. Confidence intervals were next calculated to help distinguish differences that may be clinically significant as well. Clinical significance was defined as a magnitude of deviation that, in the clinician's judgment, may have prompted an intervention during routine use (14–16).

When comparing two methods of clinical measurement, Bland and Altman (17) advocate a graphical plot of the differences between instruments against their mean values. Agreement is shown if data points fall close to the mean bias line or at least within 2 SD. This analysis has the advantage of potentially showing bias to be uniform over the entire range of measured values. Use is best shown in larger studies, provided data are evenly distributed over a broad range (3,8). The ABL-77 includes correlation adjustment software that allows the user to mathematically align the analytical results of the ABL-77 with results from a reference analyzer. This can only be done using linear regression analysis between the two analyzers. Thus, directly measured parameters were studied in this way because they are available for correlation adjustment by the ABL-77 software. Ionized calcium was excluded from this study, because there currently is no other in-house instrument for direct measure of ionized calcium.

To confirm reproducibility of results, aqueous quality controls were chosen at random and analyzed. These included a total of 20 normal level tests for blood gases and electrolytes and 20 level two tests for hematocrit. Four such same level control tests, for each parameter, were done on each day of the study. This was in addition to the routine single control testing at different levels for all parameters. Hedlund et al. (3) described a similar methodology to confirm point-of-care laboratory instrument reproducibility. Opening a new mid range pO_2 control vial for each analysis minimizes the concern of high gas tensions equilibrating with ambient air. This could occur during the repeated testing of a sign control vial with high pO_2. All control solutions were of the same lot number to avoid any lot variability. Means values, SD, and coefficients of variance were determined from this data. The coefficient of variance was calculated as the percentage of variability about the mean. Generally, a value of less than 20% is desirable (18).

RESULTS

Table 1 shows the results of the comparisons between the ABL-77 point-of-care analyzer and the ABL-720 bench top analyzer. At $p < .05$, there was a statistically significant difference for pH, pCO_2, pO_2, and HCT measurements between the two instruments. On the other hand, correlation between the ABL-77 and ABL-720 was excellent for all parameters. Correlation coefficients were all greater than 95%.

Confidence intervals in Table 1 show the points within which 95% of the differences are observed to occur between the ABL-77 and ABL-720.

Table 2 shows the comparisons between the ABL-77 and main laboratory department analyzer used for the electrolytes sodium and potassium. Here again, statistically significant differences are shown for each parameter. However, correlation coefficients are both excellent at greater than 95%. Confidence intervals between the ABL-77 and Dimension Model RxL are quantified in the far right columns of Table 2.

Table 3 shows the comparison of the ABL-77 with the Coulter Counter. The correlation coefficient is excellent; however, the data show a statistically significant differ-

Table 1. Comparison of the ABL-77 and the ABL-720 ($n = 20$).

Parameter	ABL-77 (Mean ± SD)	ABL-720 (Mean ± SD)	Correlation Coefficient	*p* Value	95% CI Limits of Difference	
					Lower	Upper
pH	7.365 ± 0.126	7.381 ± 0.140	0.9950	<.05	–0.024	–0.008
pCO_2	39.7 ± 12.27	38.42 ± 11.13	0.9976	<.05	0.63	1.94
pO_2	272.65 ± 74.4	240.35 ± 56.3	0.9850	<.05	23.3	42.3
Hematocrit	19.84 ± 5.91	24.12 ± 5.64	0.9590	<.05	–5.07	–3.49

Table 2. Comparison of the ABL-77 and the Dimension RxL ($n = 20$).

Paramerter	ABL-77 (Mean ± SD)	Dimension RxL (Mean ± SD)	Correlation Coefficient	*p* Value	95% CI Limits of Difference	
					Lower	Upper
Sodium	135.3 ± 3.83	136.3 ± 4.46	0.9563	<.05	–1.71	–0.29
Potassium	5.09 ± 0.82	5.46 ± 0.91	0.9843	<.05	–0.48	–0.28

Table 3. Comparison of the ABL-77 and the LH 750 Coulter Counter ($n = 20$).

Parameter	ABL-77 (Mean ± SD)	Coulter Counter (Mean ± SD)	Correlation Coefficient	p Value	95% CI Limits of Difference	
					Lower	Upper
Hematocrit	19.84 ± 5.91	23.82 ± 5.56	0.9832	<.05	–4.50	–3.45

ence. In comparing Table 1 and Table 3, the mean hematocrit values are approximately the same for results from the ABL-720 and the Coulter Counter (24.12 vs. 23.82). Confidence intervals in each case, for the limits of difference shown by the ABL-77, are similar as well (with a lower limit of –5.07 and upper limit of –3.49 vs. a lower limit of –4.50 and upper limit of –3.45, respectively).

Table 4 shows the repeatability of the ABL-77 in terms of all parameters measured. These data were not generated by blood measurements. The first column lists mean values obtain by repeated testing of an aqueous control solution control. One control solution was used to assess blood gas and electrolyte measurements, and a second was used to assess hematocrit measurements only. The second column is the SD of the 20 repeated tests about the mean. This is listed as the precision for each parameter. The last column of Table 4 is the percentage coefficient of variance about the mean.

DISCUSSION

The overall results of this study support the primary hypothesis with one exception. That is to say that, during cardiopulmonary bypass, the ABL-77 compares acceptably with all parameters evaluated by alternative instruments with the exception of hematocrit. Correlation was excellent in all cases, but this alone is inadequate in assessing agreement between two instruments (17). When p values were calculated, a statistically significant difference was observed in the case of all parameters. However, in further calculating confidence intervals, these differences were judged not to be of clinical significance except in the case of hematocrit. A case could be made for the observed pO_2 limits of difference in Table 1 being of clinically significance at a pO_2 level approaching 100 mmHg. It has been our experience from data observations with previous quality assurance studies that deviation from equality becomes less significant as pO_2 decreases. Walton et al. (19) observed a pO_2 upper limit difference of 41.33 mmHg in a similar comparison and data range. This approximates our finding in Table 1 and Walton et al. does not make a case for pO_2 correction.

Table 4. ABL-77 reproducibility study, normal level controls, level 2 hematocrit ($n = 20$).

Parameter	Mean	Precision (SD)	COV (%)
pH	7.429	0.003	0.04
pCO_2	39.26	0.806	2.05
pO_2	102.5	1.541	1.50
Hct	19.9	0.229	1.15
Na+	135.4	0.507	0.37
K+	3.78	0.037	0.99

Of greatest concern are the data in Table 1 and Table 3 showing that, between the three instruments, the ABL-77 does have a consistent tendency to measure hematocrit as lower. This can be described as the bias of the instrument. Bias is the mean difference between the study analyzer and the reference method used (3,17,19). Although the ABL-720 and Coulter Counter use different methodologies to determine hematocrit, the comparisons of each with the ABL-77 are remarkably similar. In the case of the comparison to the ABL-720, the bias for ABL-77 hematocrit was –4.28. In the case of comparison with the Coulter Counter, the bias for ABL-77 hematocrit was –3.98.

Such differences in hematocrit measurements could make a difference in the decision to give blood. For example, from Table 3, ABL-77 hematocrit values show a difference of as much as –4.5. Thus, if the ABL-77 reads a hematocrit of 17%, the actual value may be closer to 22%. Blood use could be unnecessarily increased. Assuring the accuracy of hematocrit point-of-care testing may be regarded as an integral part of a blood conservation effort.

Because the ABL-77 does allow for correction of hematocrit, based on linear regression analysis, doing so assumes a reference analyzer is correct, and the ABL-77 is in error. Methodology used by point-of-care devices is based on absolute values of conductivity as being indicative of hematocrit. This relationship can be determined experimentally using a microcentrifuge as a reference method. This method assumes that the plasma protein concentration is constant (20,21). In patients being treated with plasma expanders, blood diluents, or massive infusion therapy, this is no longer the case, and hematocrit determination has been found to give falsely low values (22,23). Data listed in Table 1 and Table 3 confirm this be the case with the hemodilution of cardiopulmonary bypass.

In Table 1, the ABL-720 results appear consistent with optical spectroscopy of hemoglobin being used to calculate a hematocrit value. Walton et al. (19) found a hematocrit bias of –3.98 when comparing conductivity to optical methodology during cardiopulmonary bypass. This is similar to the observation of bias for hematocrit listed in Table 1. They calculated a 99% confidence interval that was wider, at –5.81 to –2.15. This may be because of their larger sample size ($n = 30$).

In Table 3, the Coulter Counter uses the Coulter principle to determine hematocrit. This methodology is based on relative impedance drops as individual red blood cells pass through a micro-orifice in a given blood volume (2). McNulty et al. (23) compared conductivity based hematocrit measurements and the Coulter method using centrifuge determinations as a standard of reference during cardiopulmonary bypass. The Coulter method showed a bias of only –0.26 (±1.7%) compared with centrifuge determinations. Single regression analysis indicated that a 1-g/dL decrease in total plasma protein results in an absolute decrease in measure by 1 hematocrit% unit from a conductivity instrument. In vitro blood dilution studies by Hopfer et al. (20) found a lower limit difference of –4.0 for point-of-care conductive hematocrit determinations compared with a bench top hematology analyzer. This is similar to the observations of bias shown in Table 3.

Cha et al. (24) have been able to significantly reduce error introduced by plasma dilution when using conductivity to measure hematocrit. By using alternating current, they found that reactive impedance at a frequency of 1 MHz was a better parameter for predicting hematocrit than resistance. This would seem to imply that plasma has a dielectric property, as do cell membranes, and there is a capacitive reactance at work (25–27). This finding suggests a refinement may be engineered to the conductivity methodology.

The current recourse taken, as a result of the data in Table 1 and Table 3, was to correct the hematocrit values reported by the instrument. Slope and offset values are established using linear regression analysis with a reference laboratory that does not use conductivity methodology for hematocrit determination. In doing so, ABL-77 values, from a paired data set collected after hemodilution, are plotted on the *x*-axis vs. each corresponding reference analyzer value on the *y*-axis. Once the correction values are entered under the manager setup menu, the ABL-77 will prompt the user each time with the option to apply them. The instrument will measure a value "*x*" and use the linear regression equation to solve for "*y*," the corrected value. Correction is applied after initiation of cardiopulmonary bypass and just after termination.

Walton et al. (19) showed adjustment for conductivity hematocrit determinations to be effective in narrowing their observed difference range down to only –0.89 to 0.81. The comparison was to optical methodology only and did not include the Coulter method during cardiopulmonary bypass. McNulty et al. (28) showed correlation between photometric and Coulter measurements of hemoglobin to demonstrate a correlation coefficient of 0.97 at $p < .0001$. This is consistent with comparing the hematocrit results of Table 1 to Table 3. The mean hematocrit values for the ABL-720 and Coulter Counter are very similar, as are the limits of difference. McNulty et al. (28) also showed correcting conductivity-based hemoglobin values for changes in total protein significantly improved correlation with Coulter methodology.

The data in Table 4 are representative of the consistency of results experienced with the ABL-77. This shows, at least over the course of the 5-day study period, that no clinically significant variation was shown. Note that all coefficients of variance are very low (<3%). This was the acceptable level adopted by Hedlund et al. (3) in their reproducibility studies using aqueous controls as a test subject.

In conclusion, the ABL-77 provides reliable results during cardiopulmonary bypass for all parameters with the exception of hematocrit. This can and should be corrected by periodic comparison with instrumentation that does not rely on conductivity methodology. Further study of the ABL-77 could include evaluating variability between different sensor cassette lot numbers for all parameters. This was eliminated in this study because all data were collected using the same sensor cassette. A comparative study of one sensor cassette lot number to a series of others could be used to verify the accuracy of hematocrit adjustment established by the first. If no significant lot variability can be found, a constant correction formula should be justified for sensor cassettes manufactured under other lot numbers. Such confirmation testing has not been required under the current laboratory department. This may be because of the fact that the ABL-77 of this study only allows for 50 blood tests from each sensor cassette, and lot numbers tend to change frequently. This does not make the process of establishing a new correction with each cassette change-out seem very practical in a busy clinical setting. However, correlation study of all parameters is required to be repeated every 6 months. Previous quality assurance data show the results have been very consistent. Corrected hematocrit results from the ABL-77 during cardiopulmonary bypass have also been observed to be consistent with in-line monitored values.

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