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Comparison of the Lactate Pro and the YSI 1500 Sport Blood Lactate Analyzers

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To determine the agreement, reliability, and linearity of the Lactate Pro with the YSI 1500 Sport lactate analyzer, seven male and five female volunteers performed a discontinuous incremental exercise test at discrete percentages of their maximum aerobic power on a cycle ergometer. Five blood samples were collected for each subject; one after each of five increasing workloads. Agreement was evaluated by comparing, in parallel, measurements from the Lactate Pro and the YSI 1500 using Bland-Altman plots. Reliability was determined by performing 10 repeated assays on blood collected at 160 W and 370 W in a randomly selected subject. Strength of association was determined by performing linear regression analysis of the measures obtained from both analyzers. Bland-Altman analysis revealed that blood lactate concentrations from the Lactate Pro were 0.5 ± 1.0 mM (mean ± SD) higher than the YSI 1500 with the limits of agreement being 0.2 to 0.7 mM. Coefficients of variation from blood collected at 80 W and 370 W were 7.1% and 8.9%, respectively. The linear regression equation was Lactate Pro = 1.067(YSI 1500) + 0.036 (R^2 = 0.967). In conclusion, the Lactate Pro is reliable and has sufficient agreement and linearity with the YSI 1500 for use in submaximal research and athletic testing.

key words : *comparison, testing, lactate, bicycling*

Introduction

In 1886, the measurement of blood lactate (BLa) concentrations by Gaglio required up to 200 mL of blood and several days for analysis (Aduen et al., 1994; Noordally & Vincent, 1999; Slomovitz et al., 1998). The advances in technology since then have resulted in improvement in both the time and the volume of blood required to analyze lactate concentrations. The development of completely portable, hand-held lactate analyzers has allowed for lactate testing to escape the domain of the laboratory and enter into training and competition venues. The Lactate Pro is an example of one of these new generation lactate analyzers.

The use of BLa as a parameter for testing in coaching and research settings requires an instrument that is both valid and reliable (Bishop & Martino, 1993). A portable, battery-powered, and user-friendly BLa analyzer allows for the immediate testing of BLa concentrations both at training and competition venues (Fell et al., 1998). Prior to being incorporated into use, any new measurement technique needs to be validated in order to determine whether the instrument is actually measuring what it was designed to measure.

The KDK Corporation (Kyoto, Japan) has recently introduced the Lactate Pro blood lactate test meter, which is a completely portable whole BLa analyzer. Several hand-held and/or portable blood

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lactate analyzers have been evaluated and deemed accurate and reliable for use in sport testing laboratories, training and competition venues, hospital emergency departments, and intensive care units (Aduen et al., 1994; Bishop & Martino, 1993; Brinkert et al., 1999; Noordally & Vincent, 1999; Slomovitz et al., 1998; Weil et al., 1986).

There have been three recent studies that have evaluated the Lactate Pro. Medbo, Mamen, Holt Olsen, and Evertsen (2000) examined the Lactate Pro versus two YSI 1500s and found moderate agreement (slopes of the regression lines were equal to 0.668 and 0.758) between both models. Neither of the two other studies (McNaughton et al., 2002; Pyne et al., 2000) compared the Lactate Pro to the YSI 1500, although Pyne et al. (2000) used another YSI model (2300 Stat) in their comparison. The YSI 1500 has been used extensively over several years in this laboratory having been previously and repeatedly examined in comparison with established methodologies (i.e., Sigma colorimetric L-lactate method, Kit 735) with regression analyses results always greater than 0.95 (r^2). However, it was felt that further study into the reliability of the Lactate Pro and its agreement and linearity with the YSI 1500 was warranted. Therefore, the purpose of this study was to determine the reliability of the Lactate Pro and its strength of association with the YSI 1500 Sport lactate analyzer. It was hypothesized that there would be no significant differences between the BLa concentrations obtained from both analyzers.

Methods

Subjects

Measurements were made in seven male (age 27.9 ± 4.3 (mean ± SD) years, body mass 76.9 ± 7.5 kg, height 177.4 ± 3.4 cm, VO_2max 54.4 ± 7.0 $mL \cdot kg^{-1} \cdot min^{-1}$) and five female (age 25.0 ± 6.7 years, body mass 69.3 ± 2.5 kg, height 172.8 ± 3.1 cm, VO_2max 46.9 ± 3.4 $mL \cdot kg^{-1} \cdot min^{-1}$) trained volunteers after reading and providing written informed consent that was approved by the Ethics Committee of the Faculty of Kinesiology at the University of Calgary.

Apparatus

The Lactate Pro is a hand-held, battery powered test meter with a liquid crystal display, a built-in thermo-sensor, and a strip inlet for insertion of check strips, calibration strips, and test strips. The check strips are inserted prior to use to ensure that the test meter is operating properly. The thermo-sensor automatically compensates for temperature and the test meter can be calibrated automatically by inserting a calibration strip. Chemical test strips that analyze BLa concentrations ranging from 0.8 to 23.3 mM are used following calibration and require only 5 μL of whole blood, which can be analyzed in 60 seconds. The reaction principle of the chemical strips has been described elsewhere (Shimojo et al., 1993).

The reference analyzer used for this evaluation was the YSI 1500 Sport (YSI Incorporated,

Yellow Springs, OH), which uses a membrane sensor containing immobilized L-lactate oxidase that is placed between two membrane layers of polycarbonate and cellulose acetate. Most assay techniques initially convert lactate to pyruvate enzymatically and a more easily detectable substance that is produced or consumed in the reaction is measured (Fell et al., 1998). In this instrument, hydrogen peroxide is produced and oxidized on a platinum electrode resulting in an electrical current proportional to the concentration of lactate in the sample of whole blood. This sensor technology has been previously validated through a measurement range of 0 to 30 mM (Aduen et al., 1994; Bishop et al., 1992; Weil et al., 1986).

Experimental Protocol

Prior to testing, subjects were familiarized with the equipment and experimental protocols and all testing was performed on an electronically-braked cycle ergometer (Ergo-metrics 800S, SensorMedics, Anaheim, CA). After a 10 min warm-up at 100 W (males) or 75 W (females), the subjects rode a progressive exercise test starting at 110 W and increasing by 30 W every 2 min until volitional exhaustion. VO_2max was considered the highest 30 sec measure of VO_2. Subjects breathed through a non-rebreathing valve (model 2700, Hans-Rudolph, Kansas City, MO). Expired gas was sampled continuously using a MMC Horizon System (SensorMedics, Anaheim, CA) metabolic cart. Maximal aerobic power (MAP) was recorded and used to set the workloads for the BLa testing.

A discontinuous incremental exercise test was used to elicit increasing concentrations of BLa. Subjects had a minimum of 48 hours rest between this test and the VO_2max test in order to ensure adequate recovery. The subjects exercised at power outputs corresponding to 25%, 50%, 75%, 100%, and 115% of their individual MAP. Each power output was three minutes in duration followed by a two-minute passive rest interval, except for the rest interval between 100% and 115% MAP which was five minutes. For the 115% MAP work interval, the subject rode for three minutes or until volitional exhaustion, whichever came first. These power outputs were chosen in order to elicit a substantial physiological range of BLa concentration. Strong verbal encouragement was given to each subject during both the VO_2max and discontinuous incremental tests.

Prior to each use, the Lactate Pro was calibrated with a calibration strip supplied by the manufacturer. With five seconds left in each work interval, a finger tip was wiped clean using an alcohol pad and dried to prevent contamination of the sample with sweat (Ament et al., 1997). Five blood samples were obtained from each subject: one immediately following each work interval. An automatic blood sampler (Penlet II, LifeScan Canada Ltd., Burnaby, BC) with a sterile lancet (LifeScan Canada Ltd.) was used to break the skin and draw the blood sample. Each blood sample was collected in a 100-μL capillary tube (VWR Micropets, West Chester, PA) before blood at the puncture site was analyzed with the Lactate Pro.

The collected blood samples were transferred into a preservation tube (YSI 2372), shaken to mix the blood and the preservation agents, and then chilled at 2°C. Prior to operation, the YSI 1500 was calibrated using a 5 mM (YSI 2327) and a 15 mM (YSI 2328) lactate standard according to manufacturer instructions. Approximately 25 μL of each blood sample was injected approximately

45 min later into the YSI 1500 and analyzed after hemolysis (YSI 1515 lysing agent) and stabilization (YSI 2357 buffer).

The temperature and relative humidity in the laboratory during the testing sessions were 20.7 ± 1.1 ℃ and 24.1 ± 0.6%, respectively. The average time lag, defined as the time period from the beginning of blood collection in the capillary tube to analysis by the Lactate Pro, was 23.3 ± 8.0 sec.

Statistical Analyses

Agreement between the two analyzers was assessed using Bland-Altman (Bland & Altman, 1986) plots. Bias was defined as the mean difference between the two analyzers and limits of agreement was the 95% confidence interval of the mean difference, which gave an assessment of precision (Brinkert et al., 1999). Reliability was measured in two samples nominally called low and high and were collected from a randomly selected subject 3 min into a workload of 80 W (low) and 3 min into a workload of 370 W (high). Ten repeated assays were performed on each sample with the Lactate Pro (Fell et al., 1998; Slomovitz et al., 1998) and a coefficient of variation (CV) was calculated to determine the reliability of the Lactate Pro at the low and high BLa concentrations. Linear regression analysis was used to analyze the strength of association between the Lactate Pro and the YSI 1500. Statistical significance was set at $p < .05$ and the SPSS 9.0 (SPSS Incorporated, Chicago, IL) program was used for all statistical analyses.

Results

Agreement

Bland-Altman (Bland & Altman, 1986) analysis with the average of the measurements by both analyzers on the x-axis and the difference in BLa concentrations (Lactate Pro - YSI 1500) between the analyzers on the y-axis is presented in <Figure 1>. The bias ± SD was calculated to be 0.5 ± 1.0 mM and limits of agreement were 0.2 - 0.7 mM. The difference in measurements between the analyzers ranged from 0.0 mM to 2.7 mM. Only 6.7% of the BLa measurements fell outside two SDs of the bias with all instances occurring at an average blood lactate concentration greater than 7.0 mM.

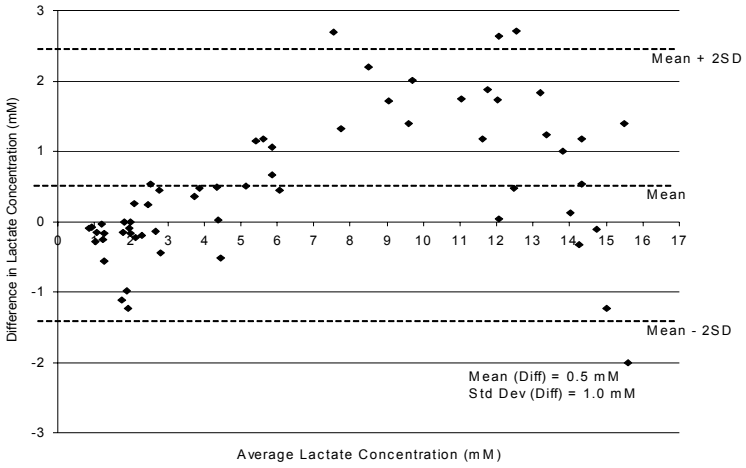

Fig 1. *Bland-Altman (Bland & Altman, 1986) analysis of agreement between the Lactate Pro and the YSI 1500.*

Reliability

The means ± SD of the repeated assays of the low and high BLa concentrations were 1.4 ± 0.1 mM and 12.4 ± 1.1 mM, respectively. The CV for the low BLa concentration was 7.1% while the CV for the high BLa concentration was 8.9% (Figure. 2).

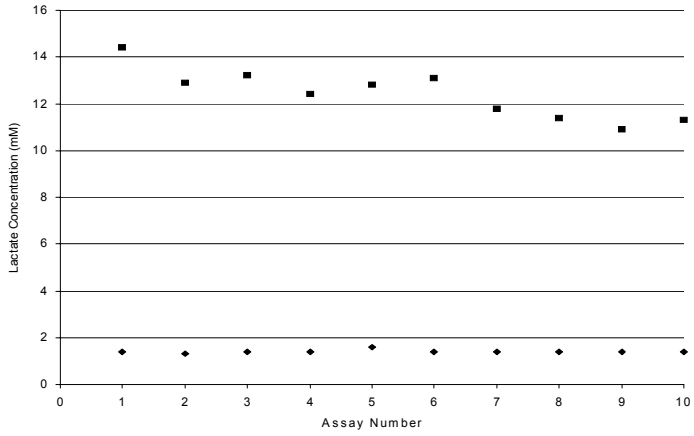

Fig 2. *Repeatability of assays at low and high BLa concentrations as measured by the Lactate Pro.*

Strength of Association

The scatterplot of the BLa concentrations measured by both analyzers, with the line of identity

included for reference, is presented in <Figure 3>. The linear regression equation was Lactate Pro = 1.067(YSI 1500) + 0.036 (R^2 = 0.967). However, upon visual inspection the data appear to display a curvilinear relationship and a 2nd order polynomial equation explained more of the variation (R^2 = 0.985).

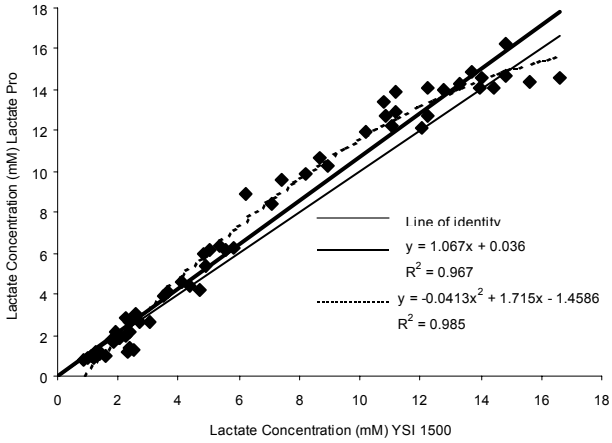

Fig 3. *Linear regression and 2nd order polynomial analysis with reference line of identity of BLa concentrations as measured by the Lactate Pro and the YSI 1500.*

Discussion

This study corroborates the work of McNaughton et al. (2002), Medbo et al. (2000), and Pyne et al. (2000) in showing that the Lactate Pro is accurate, produces reliable results, and is user-friendly in the measurement of BLa concentration. Linear regression analysis of the Lactate Pro measurements against the YSI 1500 measurements (Figure. 3) illustrated that there was a strong association between both analyzers. Perfect association between two analyzers would occur with a slope equal to 1 and a y-intercept of 0 in the regression equation. The association of the Lactate Pro and the YSI 1500 found in this study is stronger than that found by Medbo et al. (2000) but both studies demonstrated that the Lactate Pro overpredicted the BLa concentration compared to the YSI 1500. The overprediction by the Lactate Pro is evident when looking at the Bland-Altman (Bland & Altman, 1986) analysis. There was a small bias with the Lactate Pro measuring an average of 0.5 mM higher throughout the physiological range than the YSI 1500. The bias is physiologically insignificant but as the difference increases at higher concentrations, it could lead to erroneous interpretations of data (Davison et al., 2000).

The data set in this investigation appears to have three groupings: 0.8 - 6 mM, 6 - 11 mM, and greater than 11 mM. Below 6 mM, there is close agreement between the two analyzers, in the middle range (6 - 11 mM) there is a trend for the Lactate Pro to overestimate, and in the upper range (> 11 mM) it could be suggested that the Lactate Pro is less able to discriminate between

different BLa concentrations. In fact, it appears that the present limited data set displays a curvilinear trend (see Figure. 3), which interestingly may be argued to be observed in the findings of Pyne and colleagues (Pyne et al., 2000) who compared the Lactate Pro to the ABL 700, Accusport, and YSI 2300 Stat.

The current investigation and that of several other studies hint at a systematic insensitivity of the Lactate Pro above 6 mM (Medbo et al., 2000; Pyne et al., 2000). Medbo et al. (2000) found there were less systematic errors for BLa concentrations less than 6 mM than for samples that extended above 6 mM. Comparison of BLa measured by the Lactate Pro versus both enzymatic photofluorometry (the reference method) and YSI 1500 showed the trend for increased variability above 6 mM (Medbo et al., 2000). On samples with BLa concentrations greater than 10 mM, Medbo and coworkers (2000) found the Lactate Pro produced values that were 12% higher than the enzymatic photofluorometry method. Our data is in agreement showing the Lactate Pro recorded higher values by 7.2% at concentrations greater than 10 mM.

BLa concentration has prognostic value in clinical states because the severity of lactic acidosis mirrors the degree of tissue hypoxia in critically ill patients and valuable information could be gained by monitoring BLa levels (Brinkert et al., 1999; Mizock, 1987). Minimum blood lactate concentrations for the diagnosis of lactic acidosis has been reported to range from 4 mM to 7 mM (Mizock, 1987). Measurements up to 7 mM would need to be precise by any analyzer to be of clinical value but measurements above this range would still be clinically useful with increasing differences in agreement and precision between analyzers (Slomovitz et al., 1998). The Lactate Pro may have been developed for clinical use, which may explain the good agreement at lactate concentrations up to 6 mM and the decreased agreement above 6 mM.

A specific sport testing application is the measurement of BLa accumulation during incremental tests to detect submaximal lactate breakpoints, which are used to discriminate training effects, set training intensities, and predict performance (Bourdon, 2000). These breakpoints generally occur below 7 mM and high precision of measurement below 7 mM is desirable to avoid erroneous interpretations of data when identifying lactate breakpoints (Bourdon, 2000).

The reliability of the Lactate Pro was lower at the high BLa concentration compared to the low BLa concentration. The present CVs are comparable to those obtained by Shimojo et al. (1993) who evaluated the single-use electrode strip that is used by the Lactate Pro. The assay precision that they calculated from 10 repeated low and 10 repeated high BLa concentrations was 8.4% and 1.7% (CV), respectively. McNaughton et al. (2002) also calculated a higher CV (10%) for the low BLa concentration than for the high BLa concentration (3.1%) However, we found that there was more variation in the high BLa sample and that the Lactate Pro systematically produced decreasing measurements as this sample was repeatedly analyzed. Previous studies have not demonstrated this systematic decrease in repeated measures and it is unclear why the present trend occurred in the high BLa sample only.

Practically, the Lactate Pro was easy to use and successfully performed assays on 100% of the samples tested. Minimal operator training was required, although correctly handling the test strips in their protective foil covering required some practice so that the reagent did not become contaminated. There was no need for pipetting samples because the Lactate Pro automatically

aspirates 5 μL of blood onto the test strip, thus eliminating volume measurement error.

In conclusion, this study supports previous work and has shown the Lactate Pro to be easy to use, require only a small blood sample, allow for rapid BLa measurement, and to be relatively cost efficient. Caution should be exercised when measuring BLa concentrations above 6 mM because of the demonstrated increased variability and when comparing BLa data that has been measured on different analyzers. However, this study demonstrates the Lactate Pro can be used for accurate submaximal sport testing applications.

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