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Test Retest Reproducibility of a Hand-Held Lactate Analyzer in Healthy Men

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Abstract

The objective of the present study was to evaluate the test-retest reliability and day-to-day precision of a hand-held Blood Lactate Analyzer. Blood lactate levels were evaluated on 12 samples of human beings and blood was collected from both ring and middle finger for test-retest reliability. Day-to-day precision was determined by known concentration of two aqueous lactate control solutions once a day for 10 consecutive days. Results showed high test-retest reliability (r = 0.948; mean 2.41±0.86 in ring and 2.45±0.76 in middle finger) and high day-to-day reliability (r = 0.998; mean 1.1±0.08 in low control and 4.28±0.24 in high control solution). The results were similar to those previously reported. The results of this study support the use of the hand-held device in healthy human beings.

Key Words: Test-Retest, Reliability, Blood Lactate, Portable Analyzer

Introduction

Measurement of blood lactate has many important applications. In clinical setting, it helps to identify the disease severity (*Planche et al., 2001; Saunders et al., 2005; Tennent-Brown et al., 2007; Thorneloe et al., 2007*), prognosis *(Coghe et al., 2000),* and treatment efficacy *(Ivers and Mukherjee, 2006)* in many conditions. In sports settings, it also helps to identify an optimal training intensity *(Bishop, 2001)* and proper recovery to reduce chances of injury occurrence, as the increased lactate level seems to inhibit certain enzymes so as to create fatigue.

Traditionally, measurements of lactate have been made by using large laboratory based analyzers that are expensive and cumbersome – need of lactate transportation, centrifugation, storage in ice (refrigeration) etc, all of which requires higher technical knowledge from user *(Thorneloe et al., 2007).* In sports, ideally the lactate concentrations should be measured during a training session and reported immediately to the athlete to ensure the desired training intensity *(Bishop, 2001).* But the above said limitations of the large laboratory based equipments tend to limit their usage in the field during training. The essential qualities of any tool are that they provide accurate and reliable results in a rapid and simple manner. With the advent of less expensive, rapid hand- held lactate analyzers that have proved accurate in animals *(Coghe et al., 2000; Tennent-Brown et al., 2007; Thorneloe et al., 2007),* critically ill human beings *(Planche et al., 2001; Ivers and Mukherjee, 2006),* even in sportsmen *(Bucklay et al., 2003; Pyne et al, 2005),* lactate measurement is likely to increase in sports community in order to improve performance, facilitate recovery and reduce the chances of injury.

Thus, the purpose of the present study was to see test-retest reliability of Lactate Plus hand held analyzer in healthy

human beings and day-to-day precision of the same in two control solutions.

Material and Methods

Twelve healthy male subjects (age 17-24 yrs, height 163-178 cms and weight 58-75 kgs) were used for the present study.

A hand-held portable lactate analyzer (Lactate Plus, Nova Biomedical, Waltham, MA, USA) was used to determine blood lactate level. It determines plasma lactate levels quantitatively (in mmol/L) on 0.6µl of whole blood by the use of a single use reagent strip of an enzyme-coated electrode and a small meter within 15 sec. The hand-held device's measuring range is between 0.3 and 25.0 mmol/L for human. It has high reliability (test-retest and day-to-day) and validity (as per user's manual).

After getting their informed consent, all the subjects were asked to sit for 30 minutes after washing their hands with soap. Tip of either middle or ring finger was used as a puncture site for the first time. A Lancet BD was used to puncture the site without pain and even awareness of the subject. Then both sides of the puncture sites were pressed gently to develop a drop of blood, care was taken not to squeeze vigorously as it causes wrong lactate value. The first blood drop was wiped off using sterile cotton swab as it may contain interstitial fluid. When the second drop developed, test strip with Lactate Plus meter was touched to the blood drop until it filled up with blood and meter beeped. Plasma blood lactate value was available within next 20 sec. The whole procedure was repeated in the other site again.

Blood lactate measurements were performed on two sites (tip of either middle or ring finger) in twelve healthy human beings and on two control solutions (low and high lactate control solutions, 1.0-1.6 and 4.0-5.6 mmol/L respectively) for ten consecutive days for test-retest reliability, day-to-day precision of Lactate Plus (hand-held) analyzer respectively.

Lactate values obtained from both sites (ring and middle finger) and both control solutions (high and low) were presented by descriptive statistics (mean, standard deviation (SD), standard error of mean (SEM), coefficient of variance (CV)), alpha correlation model using SPSS 10 version.

Results

Descriptive statistics of blood lactate values from two sites is presented in Table 1, where as descriptive statistics of control solutions is presented in Table 2.

Table 1: Descriptive statistics of blood lactate values in mmol/L from two sites using Lactate Plus (hand-held) analyzer (n=12)

	Mean	Median	Range	SD	SEM
Ring	2.41	2.30	1.40-4.50	0.86	0.25
Middle	2.45	2.35	1.60-4.10	0.76	0.22

Table 2: Descriptive statistics of lactate values in mmol/L from two control solutions using Lactate Plus (hand-held) Analyzer (n=10)

	Mean	Median	Range	SD	SEM	CV
Low	1.10	1.10	1.0-1.2	0.08	0.03	7.27
High	4.28	4.30	3.9-4.6	0.24	0.09	5.60

Blood lactate concentrations obtained in healthy human beings ranged from 1.4 to 4.5 mmol/L with mean ± SD values of 2.41 ± 0.86 and 2.45 ± 0.76 mmol/L for ring and middle finger respectively (Table 1). Lactate values with low control solution ranged from 1.0

to 1.2 mmol/L (mean 1.1 mmol/L) and with high control solution ranged between 3.9 - 4.6 mmol/L (mean 4.28 mmol/L).

The Lactate Plus was found to have moderate to high test-retest reliability (r = 0.948; SEM = 0.25 mmol/L) with 95% confidence interval ranging from 0.693 to 0.970 (Table 3). In addition 95% of repeated measurements on the Lactate Plus were within 0.4 mmol/L of the initial measurement. Figure 1 shows the correlation between the two site's lactate values from Lactate Plus (r = 0.908; p < 0.01), with regression line.

Table 3: Test-retest reliability of the Lactate Plus (hand-held) analyzer evaluated on two sites at the same time (n=12)

	Pearson correlation	Alpha model reliability	ICC (Inter class correlation)	95% CI	Error Variance
Middle & Ring	**0.908****	**0.948**	**0.901**	**0.693–0.970**	**6.59**

****-p<0.01-highly significant**

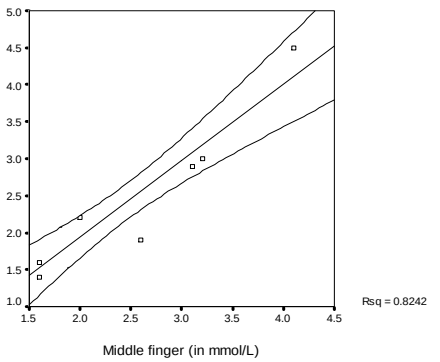

Figure 1:- Correlation between the blood lactate concentrations obtained from two sites

Table 4: Day-to-day precision of the Lactate Plus (hand-held) analyzer evaluated on two control solutions in ten consecutive days (n=10)

	Alpha model	ICC (Inter Class Correlation)	Error Variance (in %)
High & Low	**r = 0.999**	**r = 0.993**	**5.50**

The Lactate Plus was found to have very high day-to-day precision when using the same standard lactate control solutions each day for ten days (r = 0.999; SEM = 0.03 mmol/L for low, 0.09 mmol/L for high control solutions) (Table 4). The differences between two sites lactate values ranged from -0.35 to +0.20. These values along with difference between mean value of each control solution and each day values represented in Figure 2 along with 95% limits of agreement (shown in dotted line).

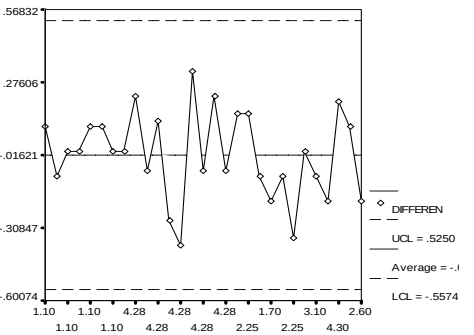

Figure 2:- Bland-Altman plot showing relationship between mean lactate concentration determined at both sites, mean control solution (high & low) (x-axis) and the difference between two sites (ring & middle finger), mean control value and each day value (y-axis) showing the mean bias (solid line) with the 95% limits of agreement (dotted lines) (n=32)

DISCUSSION:

The results of the present study demonstrated moderate to high test-retest reliability in healthy human being's resting blood lactate values and very high day-to-day precision on control solution.

Consistent with a previous study *(Bishop, 2001)*, there was strong correlation (p = 0.908; p < 0.01) between the two sites of measurements. Repeated measurements of lactate concentration with Lactate Plus on two samples drawn at the same time showed high reliability (r = 0.9477, n = 12) and low SEM (0.23) which were similar to previous studies *(Bishop, 2001; Pinnington and Dawson, 2001 and Poscia et al, 2005)*. It was also found to have very high day-to-day reliability when using the same standard

lactate solutions each day for ten days, our value r = 0.998 ± 0.04 (n=10) is in agreement with *Bishop (2001)* that showed r = 0.993 ± 0.4. Low values of coefficients of variance (CV) in low and high control solution in the present study also support the values reported by *Fell et al (1998)*.

Conclusion

Our results support the use of Lactate Plus hand-held device in field environment. Its ease of use and rapid turn around time (15 Sec) allow for prompt decision making in training and recovery adjustments, and relative low cost for sample processing, all of which recommends its use in athletic setting.

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