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STOP THE PRICKS: A VALIDATION STUDY OF A NONINVASIVE LACTATE THRESHOLD DEVICE

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STOP THE PRICKS: A VALIDATION STUDY OF A NONINVASIVE LACTATE
THRESHOLD DEVICE

By

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ABSTRACT

Purpose: The aim of this study is to assess the validity of a noninvasive lactate threshold device (NID) to determine lactate threshold heart rate (LTHR) and aerobic threshold heart rate (AeTHR).

Methods: Twenty-one recreational athletes completed a personalized graded exercise test on a treadmill. All participants wore the noninvasive device and blood lactate samples were taken at the end of 3-minute stages. Lactate threshold heart rate and aerobic threshold heart rate were then calculated using four traditional methods and compared against the same heart rate values calculated by the device.

Results: No significant differences were found in lactate threshold heart rate and the aerobic threshold heart rate between the noninvasive device and four traditional lactate methods.

Conclusions: This study provides preliminary support for the validity of the NID for estimation of LTHR (4mmol), but weaker support for validity at AeTHR (2mmol).

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INTRODUCTION

Over the past 50 years the concept and importance of an individual athlete's lactate threshold (LT) has become more common, especially in endurance sports. Lactate is a marker of the metabolic strain being experienced by the body (Davison, et al., 2000; Jacobs, 1986), and the LT can be used to help establish training zones and intensities. For example, when prescribing training for an iron distance triathlete (12+ hour event), the LT helps establish the aerobic zone which is below LT and where the majority of training will take place. Knowing LT also allows the coach to include workouts designed to increase LT and therefore increase overall aerobic pace. In addition, multiple testing sessions can also be utilized to track an athlete's progress over time (Billat, 1996).

Lactate threshold testing is most often performed in a laboratory with bench model analyzers, but these models have the downside of cost and inconvenience for most athletes, trainers, and coaches. However, portable lactate analyzers provide a more cost-efficient and convenient option. Several portable models have been tested and found to be valid in their lactate measurements, such as the Accutrend Lactate and the Lactate Pro (Baldari, Bonavolontà, Emerenziani, Gallotti, Silva & Guidetti, 2009; Tanner, Fuller & Ross, 2010) and The Lactate Scout and Lactate Plus (Hart, Drevets, Alford, Salacinski & Hunt, 2013; Tanner et al., 2010). However, all of these devices

require a sample of blood, such as from a finger stick. Multiple blood samples directly from the finger can increase measurement error (Hart et al., 2013). In order to conduct a blood sample test, the athlete has to have someone to help collect and analyze the sample while they are completing the exercise test. This poses an issue for coaches with large teams or athletes that do not live in the same location as their coach or near a lab facility. Also, while more economical than a bench analyzer, portable blood lactate devices are still expensive, and require the recurring purchase of additional testing and calibrating strips. These issues have spurred the development of new lactate testing technologies that do not require a blood sample, and can be done by an individual athlete anytime and anywhere.

Recently a new device on the market claims to estimate the lactate threshold heart rate (LTHR) and aerobic threshold heart rate (AeTHR) via measurements of oxygen saturation of the muscle. This noninvasive device is marketed to individual athletes as a way to measure and monitor their LT without having the need for blood testing or a laboratory facility. The wearable device uses near-infrared spectroscopy (NIRS) to measure the oxygen saturation levels in the calf muscle during a graded exercise test (GXT), and then applies a proprietary algorithm to determine the point of LT. The NIRS device sends light into the tissue and it is either absorbed or scattered. The amount that is scattered is relative to the oxygen level of the hemoglobin (Hb) and myoglobin (Mb) in the

tissue (Grassi et al, 1999). Using laboratory measures, Belardinelli and colleagues (1995) described a slow decrease in muscle oxygenation over a lower work rate range, followed by a more rapid decrease in the range of the LT and a plateau around VO_{2max} . They determined that NIRS can be used as a noninvasive method of monitoring skeletal muscle changes in oxygenation during incremental exercise. Further, Grassi and colleagues (1999) evaluated whether measurements of muscle oxygenated blood by NIRS were associated with the onset of blood lactate accumulation. They concluded that there was a high correlation ($r = 0.95$) between the onset of muscle deoxygenation and the lactate threshold.

Despite the support for NIRS for determination of LT, limited testing has been performed on novel portable technology that utilizes NIRS, such as the NID. The previously cited studies on NIRS were conducted with laboratory experiments, and utilized a different testing site (vastus lateralis versus the gastrocnemius with the NID). The necessity for a portable lactate-testing device, capable of being used individually, is in high-demand within the endurance community. If valid, the NID would be able to provide athletes and coaches with LT data outside of a laboratory setting, while using a noninvasive method of measurement. However, before wide usage of such technology is endorsed for LT assessment and training prescription, the validity of the NID must first be

determined. Thus, the aim of this study is to assess the validity of a NID for lactate (4mmol) and aerobic (2mmol) threshold points.

METHODS

Participants

Participants were recruited from a triathlon club that serves Nacogdoches and the surrounding area. An email was sent to the triathlon club offering lactate testing to athletes with an explanation of how, when results are applied, LT data can enhance their training. Fourteen female (mean \pm SD; age: 27-51 yr; height: 165.0 ± 5.8 cm; mass: 70.2 ± 11.6 kg; BMI: 25.7 ± 4.1 kg/m²; VO_{2max}: 37.8 ± 6.0 ml/kg/min) and seven male (mean \pm SD; age: 28-53 yr; height: 177.8 ± 7.6 cm; mass: 83.5 ± 8.03 kg; BMI: 26.0 ± 1.4 kg/m²; VO_{2max}: 45.9 ± 6.4 ml/kg/min) participants were tested. For inclusion criteria, participants from the triathlon club were required to be currently training for an endurance event, and were required to have had at least 4 weeks of consistent training. Exclusion criteria included less than 4 weeks of training, medical issues that would prevent the participant from completing the graded exercise test, injuries that would prevent them from running on a treadmill, daily carbohydrate intake of less than 40%, and a fatigue number higher than and including 8 measured with a 1-item scale developed by Van Hooff et al (2007). One participant was eliminated due to holding onto the treadmill which affected HR at the specified workload.

Instruments

BSX Insight

The BSX Insight (Multisport version, BSX Athletics, Austin, TX) is an optical lactate threshold sensor that uses NIRS to measure muscle oxygen saturation for subsequent estimation of LT. Specifically, the BSX provides lactate threshold heart rate (LTHR) and aerobic threshold heart rate (AeTHR) from an individually-prescribed maximum treadmill protocol. The BSX estimates the LTHR to occur at 4mmol of blood lactate, while the AeTHR is estimated to occur at 2mmol. For accurate measurements, NIRS requires a dark environment, so the device is fitted into a compression sleeve that both keeps the light out and the device in place on the lower leg. Details of device placement and protocol details are found in the procedures.

Lactate Plus

The Lactate Plus (Nova Biomedical Corporation, Waltham, MA) is a portable blood lactate analyzer requiring 0.7 microliters of blood and analyzes results in 13 seconds. The Lactate Plus has been shown to be suitable as an alternative to bench-model analyzers (Hart, Drevets, Alford, Salacinski & Hunt, 2013; Tanner et al., 2010).

Indirect Calorimetry

Indirect calorimetry is a method of analyzing energy metabolism and is estimated from measurements of oxygen (O_2) consumption and carbon dioxide (CO_2) production (Ferrannini, 1988). For the present study, the Vista Mini-CPX VO_2 chamber type mixing and measurement system (VacuMed, Ventura, CA) was utilized to assess breath-by-breath VO_2 during the testing protocol. This system has been shown to be valid in assessing cardiorespiratory performance (Paulucio, Nogueira, Velasques, Ribeiro & Pompeu, 2015). The VO_2 and respiratory data provided was used to help determine the standard LT for comparison to the NID system's estimation.

Experimental Design and Procedures

Before the participants arrived at the Human Performance Lab, they were briefed on the testing environment and protocols via an email confirming their scheduled test time. Participants were asked to have abstained from exercise for at least 24 hours before their scheduled test. Although research has shown that diet modifications don't affect LT (McLellan & Gass, 1989; Yoshida, 1984), participants were asked to maintain a normal, well-balanced diet prior to testing and record the three prior days of food intake using the MyFitnessPal app. Upon arrival, any questions about the protocol and environment were answered. Following informed consent, participants completed basic descriptive data. Three prior days' macronutrients were evaluated and the participant was asked to rate

their fatigue on a scale of 1 to 10 as described by Van Hooff, Geurts, Kompier, & Taris (2007) to screen for exclusion criteria. Height was measured to the nearest tenth of a centimeter and weight was measured to the nearest tenth of a kilogram.

NID Preparation

Next, the following information about the participant was entered into the NID app on the iPhone 6: conversational pace (min/mile), 10K pace (min/mile), consecutive months of training, training days per week, and running miles per week. These values were determined ahead of time by the participant, based on recent race and training data. The app then provided a basic outline of the test, which the tester and participant reviewed together (Figure 1). Per NID instructions, the prescribed protocol was checked for length to confirm that each test would last at least 20 minutes to get sufficient data.

The NID was paired with the iPhone via Bluetooth wireless connection, prior to placing it in the compression sleeve, and on the participant's left calf. Appropriate calf sleeve size was determined by measuring the participant's calf at the largest circumference point to the nearest centimeter. The device was then positioned on the back of the left calf at the level of the largest circumference of the calf. The device was also paired with a heart rate monitor capable of transmitting via ANT+ wireless technology [Garmin Heart Rate Monitor 010-10997-00, Garmin Ltd].

Treadmill Test Protocol

Participants were familiarized and fitted with a mask for use with the Vista Mini-CPX. Measurements of VO_2 , VCO_2 , and RER were continuously monitored and recorded during the entire duration of the prescribed protocol. After the test, VO_{2max} was determined by the Turbofit software, and ventilatory threshold (VT) was calculated by the ventilatory equivalent method (Gaskill, Ruby, Walker, Sanchez, Serfass & Leon, 2011).

The test began and followed the paces individually prescribed by the NID protocol. At each stage, the app provided a timer, the current pace/speed, participant's heart rate, and muscle oxygenation percent (Figure 2). Every three minutes a new stage began, and treadmill speed was manually changed according to the speed prescribed on the app until volitional fatigue. Results for LTHR, AeTHR and corresponding paces were then immediately available either through the app or the product website (Figure 3).

Blood Lactate Analysis

Finger prick blood samples were collected before the start of the test, at the end of each 3-minute stage, and immediately following the end of the test. Blood samples were taken from the tip of the middle or ring finger. The finger site was chosen over the earlobe due to the ease of measurement since these sites can be used interchangeably (Moran, Prichard, Ansley, & Howatson, 2012). Aliquots of

each sample were analyzed by the Lactate Plus (LP), which was calibrated and operated in accordance with the manufacturer's instructions.

After graphing the lactate values across the stages, two points on the curve were determined, the aerobic threshold (AeT) at 2mmol and LT at 4mmol. The inflection point where lactate values increased by greater than 1mmol over subsequent stages was also noted. If there wasn't a point at which the graph reached 4mmol then the stage before the clear inflection point was considered the LT point. The corresponding heart rates for AT and LT were then determined at these points.

For application to the consumer, the present study utilized the 3-minute staged protocol individually established by the NID. While some research has shown that longer duration stages are better for the assessment of LT (e.g. Bishop, Jenkins & MacKinnon, 1998), other research has shown that stage durations between 3 and 6 minutes are necessary to obtain precise lactate measurements to determine the desired metabolic inflection points especially in trained participants (Thoden, 1991). Therefore, since there is not a consensus in the research, and 3-minute stages have been shown to be accurate, the present study opted to use the individualized 3-minute staged protocol established by the NID.

Statistical Analysis

Mean values for VO_2 , VCO_2 , lactate, heart rate, and speed were calculated along with the heart rates at calculated LT, AeT, and VT. Three methods were used to examine the validity of the NID for the two dependent variables, LTHR and AeTHR. First, mean differences of LTHR were examined between the NID and three standard methods using repeated measures ANOVA. The AeTHR determined by the NID and the standard method was analyzed with a dependent T-test. Pearson correlations were used to examine linear relationships between the NID and three standard methods for LTHR and one standard method for AeTHR. Finally, Bland-Altman plots were constructed to further examine level of agreement between LTHR and AeTHR measurements using estimation from the NID and the standard measures (Altman & Bland, 1983).

RESULTS

Mean values \pm SD for LTHR, as determined by the NID, and traditional estimations 4mmol, >1mmol, VT methods are shown in Figure 4.

Repeated measures ANOVA showed no significant differences in LTHR between the NID and the three traditional methods (Wilks' Lambda = .798, $F(3,18) = 1.52$, $p > .05$, $\eta_p^2 = .20$).

Mean values \pm SD for AeTHR, as determined by the NID, and a traditional method of estimation are shown in Figure 5. A dependent T-Test showed no significant difference in AeTHR between the NID and the traditional 2mmol estimation method ($t(20) = .52$, $p > .05$).

Table 1 shows the Pearson correlation (r) of LTHR from the NID with all three traditional estimation methods, which ranged from .77 to .88. A fixed value estimation of 4mmol had the highest correlation to the NID estimation for LTHR ($r = .88$). AeTHR, as assessed by the traditional method at 2mmol, was moderately correlated to the NID device ($r = .66$).

Bland Altman plots showing the mean difference and limits of agreement for the NID and all standard methods of LTHR and AeTHR are shown in Figures 6-9. In general, these plots indicate a small discrepancy (approximately within 10 bpm difference) between methods for LTHR, with a larger discrepancy with AeTHR (approximately 20 bpm difference). LTHR estimated by the traditional

4mmol method appeared to have the closest agreement with the NID, especially around mean heart rates of 160 to 175 bpm.

DISCUSSION

The purpose of this study was to determine the validity of a NID to calculate heart rates at both lactate (4mmol) and aerobic thresholds (2mmol) during exercise. In general, the present findings provide preliminary support for the validity of the NID during a treadmill GXT to volitional fatigue.

LTHR and AeTHR

No significant differences in LTHR means were found between the NID and three traditional LTHR estimation methods. The highest correlation with the NID was with the 4mmol method and the NID ($r = .88$), followed by the >1mmol increase method ($r = .85$). The VT estimation of LTHR was correlated at a moderate-high level ($r = .77$). These correlation values indicate initial support for the NID's accuracy at estimating LTHR.

The Bland Altman plots of LTHR for the four traditional estimation methods show most heart rate values falling within the confidence interval. For higher LT heart rates, the NID tends to underestimate the HR by a small degree (approximately 5-10 bpm).

In regards to under or over estimation of LT, recent research (Borges & Driller, 2016) found that the NID had a tendency to overestimate LT when compared with traditional methods but previous research with NIRS (Grassi,

Quaresima, Marconi, Ferrari & Cerretelli, 1999) showed an underestimation of the heart rate at which LT occurred compared with fixed values. Underestimation isn't necessarily a negative for athletes as it would prevent them from crossing their LT in training which could adversely affect their adaptations to training.

No significant difference was found in AeTHR between the NID and a traditional estimation at 2mmol. However, the correlation between the NID and traditional method of AeTHR estimation was only moderate ($r = .66$), indicating that the NID did not perform as well estimating AeTHR as it did with LTHR. The Bland Altman plot shows most heart rate values falling within the confidence interval but more spread out when compared with LT plots. For lower AeT heart rates, the NID tends to overestimate the HR by a moderate degree (approximately 10-20 bpm).

Practical Application

This study was completed on a sample of participants with a wide range of athletic ability (VO_{2max} range = 27.4 to 56.5 ml/kg/min). Compared to the recent research (Borges & Driller, 2016), these participants were older, heavier and had a higher mean BMI. With the lower values, the present sample represented a more recreational group of triathletes than elite. While the present sample might be limited in generalizability to elite triathletes our preliminary results support

accuracy of the NIRS device for those most likely to purchase and use it without the presence of a coach for every test and workout.

Also, these results support that the device has the capability to estimate LTHR with slower athletes which would benefit beginners. Advanced and elite athletes could also benefit from the device but need to be aware that it might underestimate threshold heart rates if threshold is at a high level due to our finding that the NID had a small degree of difference higher LT heart rates.

Not only does the NID collect data from athletes, it analyzes and presents the data in a format that athletes can use immediately. With the standard devices, lactate values are obtained but then a person with specialized training is required to analyze those points and determine LT, training zones, and training paces for an athlete to work within.

Limitations

There are several limitations of the present investigation that should be noted. First, as a preliminary investigation, a relatively small sample was utilized. Our sample of 21 participants is similar to other validation studies with this specific device (Borges & Driller, 2016). However, larger samples and further research could continue to provide further, more concrete support for the validity of this specific device. In addition, the smaller sample did not allow for the testing of gender differences for validity of the device in estimating LTHR and AeTHR.

Also, reliability of the device wasn't examined in the present study, as participants were only tested with the same device, one time. Both inter- and intra-reliability is an important factor in establishing validity as athletes would use this device to track performance over time.

Further Investigation

Several additional investigations need to be done with the NIRS device. This study used the prescribed 3-minute protocol established by the NID but LTHR and AeTHR values need to be compared with those from a more traditional LT test with longer stages at lower intensities. Also, participants need to complete the present test, and then return within 72 hours to complete a more traditional test for reliability.

In addition, the NID requires an input of 10K race pace when it creates the GXT protocol. The pace at which LTHR was reached was highly correlated ($r = .90$) which means that the proprietary algorithm of the device could be related to pace. Tests need to be run where the athlete under- or over-estimates their pace to see if the device is still determining the same LTHR.

Conclusions

This study provides preliminary support for the validity of the NID for estimation of LTHR, but weaker support for validity at AeTHR. Acceptable levels

of agreement were found between the two devices when measuring HR at lactate threshold, with lesser agreement and greater variability in differences at aerobic threshold. However, the preliminary support is encouraging for the recreational athlete who could utilize such a device to assess LTHR for training purposes in their own environment, without relying on a specialized lab in their area.

20:00 min/mi	3 min
The remaining stages become increasingly more difficult.	
If you prefer a more gradual warmup, add additional stages by tapping the button below.	
+ ADD WARMUP STAGE	
13:38 min/mi	3 min
13:20 min/mi	3 min
13:03 min/mi	3 min
12:30 min/mi	3 min
12:00 min/mi	3 min
11:32 min/mi	3 min
11:07 min/mi	3 min
10:43 min/mi	3 min
ANTICIPATED THRESHOLD ⓘ	
10:21 min/mi	3 min

Figure 1. Based on the Assessment questions, the NID establishes a testing protocol.

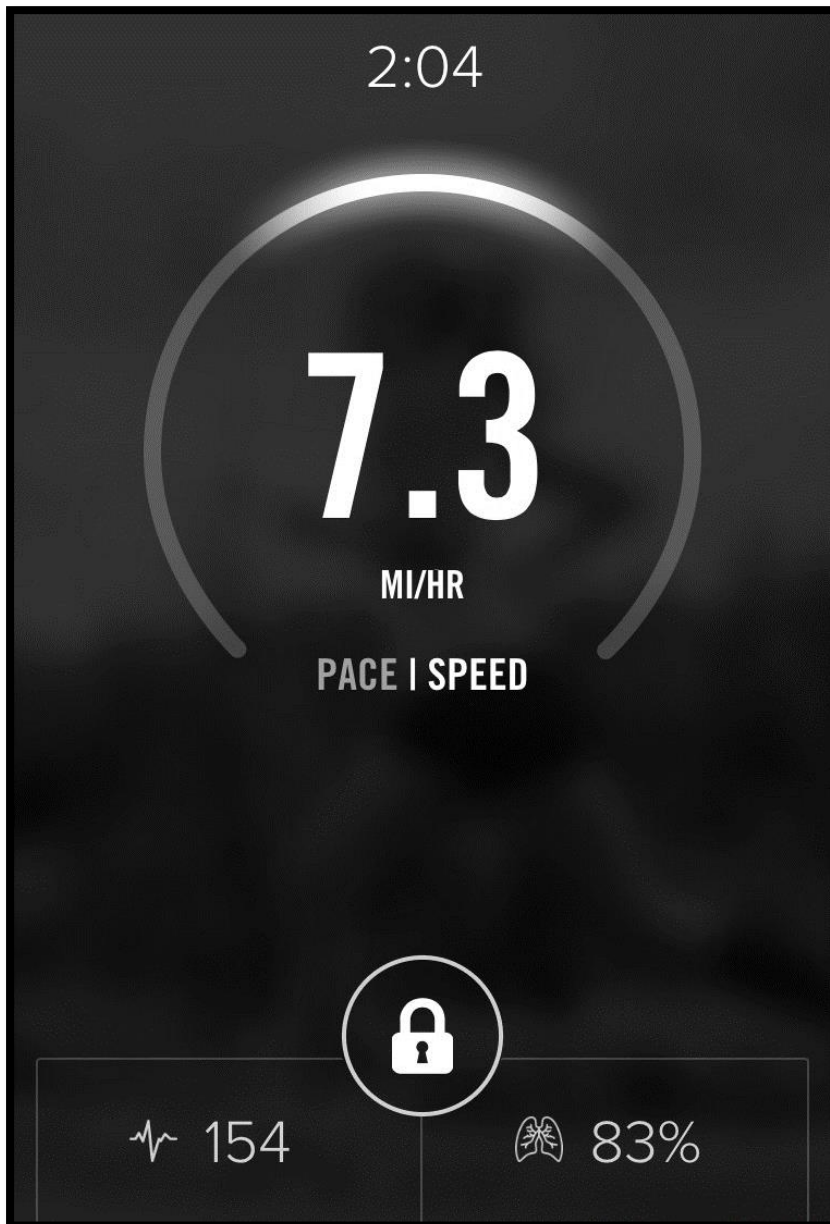


Figure 2. Metrics shown on the NID app during testing.

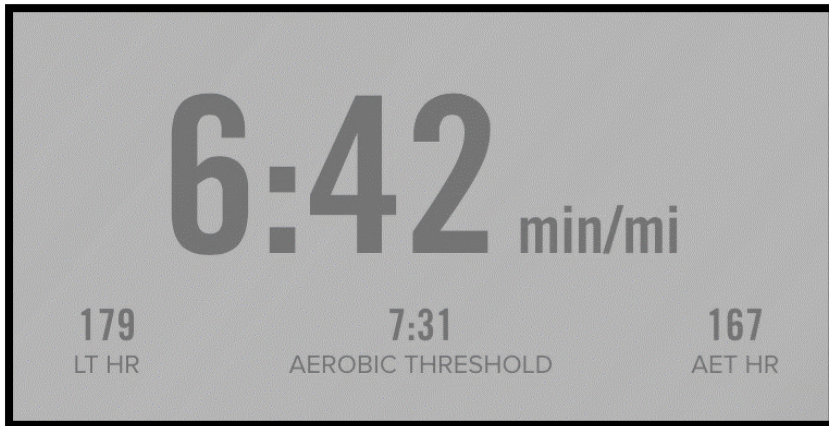


Figure 3. The results shown in the NID app after testing completed.

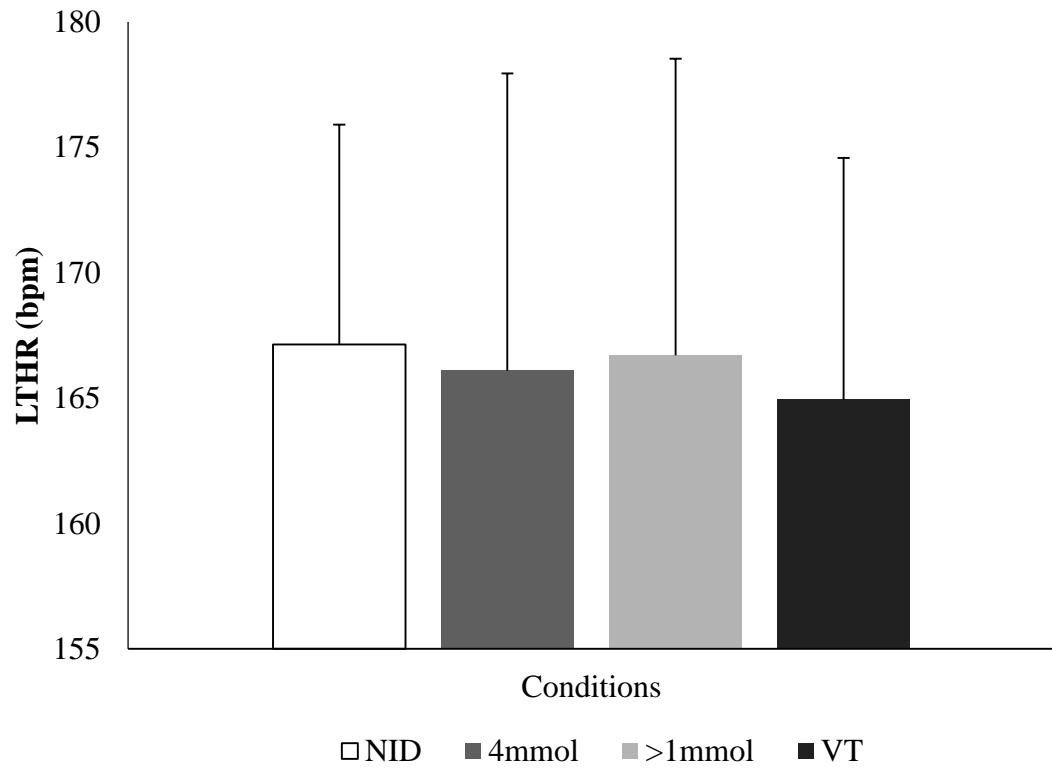


Figure 4. The mean \pm SD of the lactate threshold heart rate (LTHR), as determined by the noninvasive device (NID) and three lactate threshold estimation methods: at 4mmol, >1mmol, and at ventilatory threshold (VT).

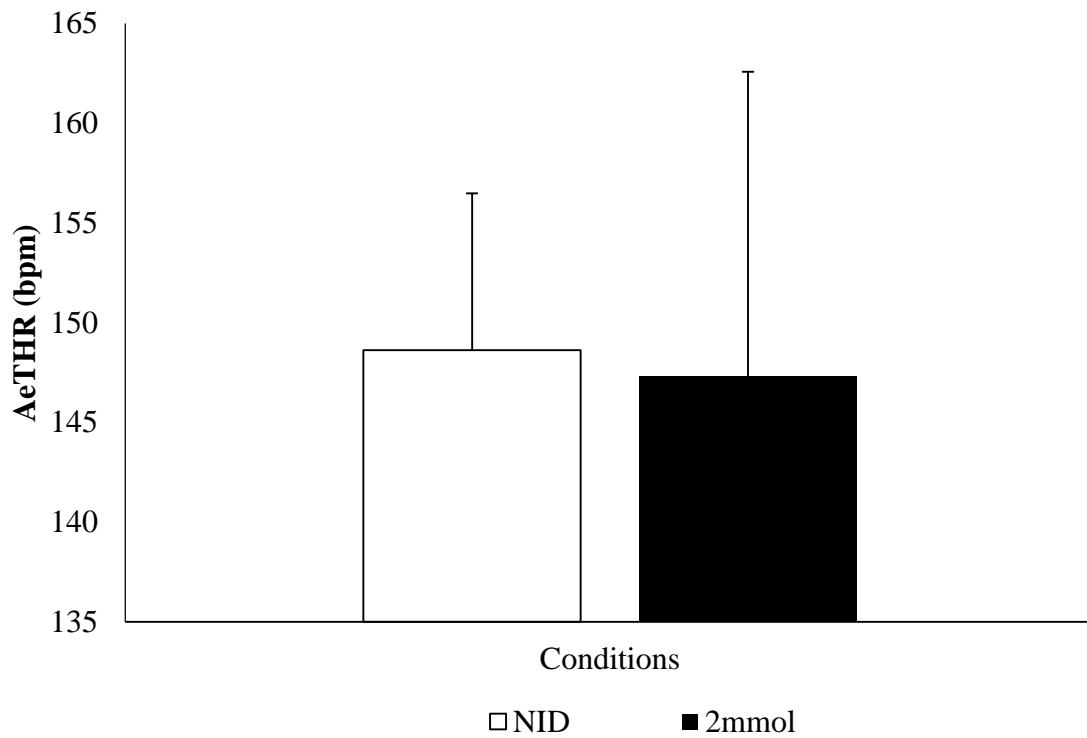


Figure 5. The mean \pm SD of the aerobic threshold heart rate (AeTHR), as determined by the noninvasive device (NID) and an aerobic threshold estimation method (2mmol).

Table 1. The Pearson correlation coefficient and associated p-values for the NID device compared with traditional estimation procedures.

LTHR Traditional Methods	LTHR via NID	
	<i>r</i>	<i>p</i>
4mmol	.88	< .001
>1mmol increase	.85	< .001
VT	.77	.001

AeTHR Traditional Method	AeTHR via NID	
	<i>r</i>	<i>p</i>
2mmol	.66	.001

LTHR = lactate threshold heart rate, AeTHR = aerobic threshold heart rate,
 NID = noninvasive device, VT = ventilatory threshold

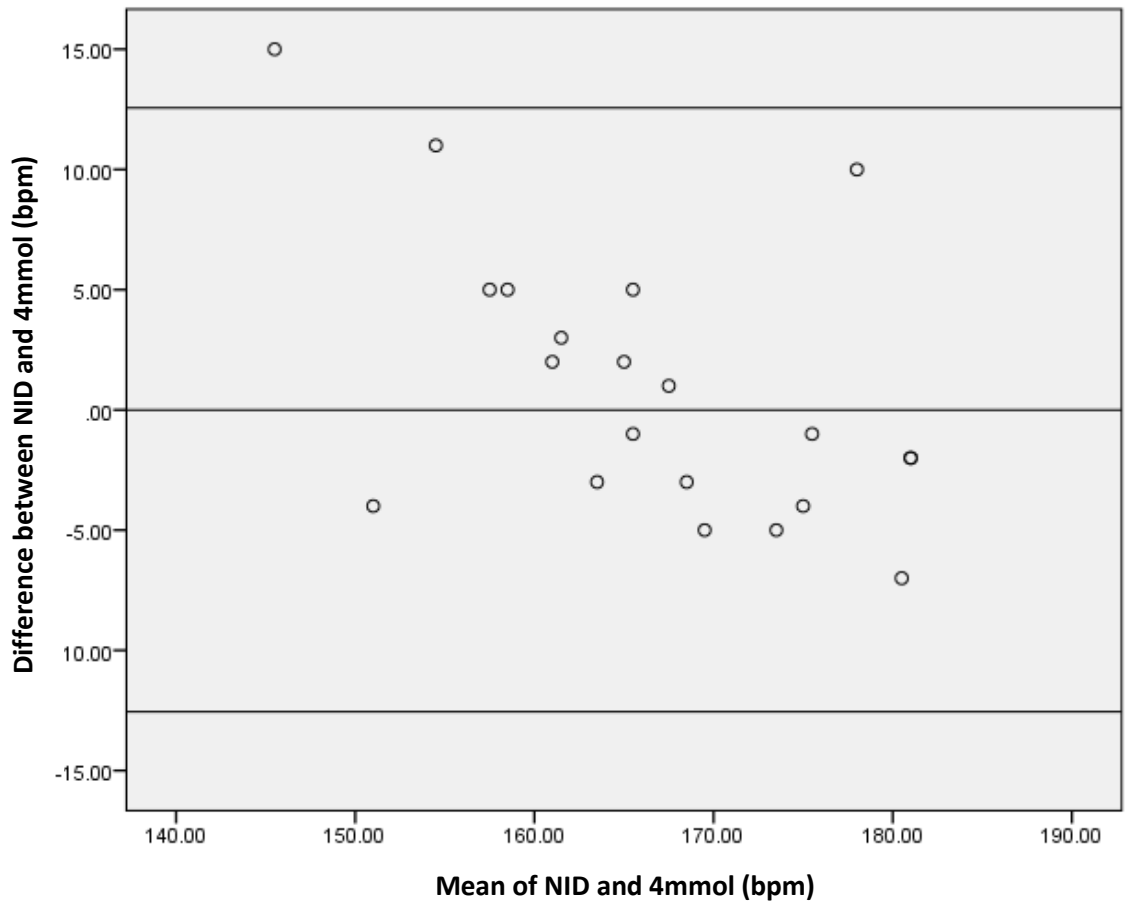


Figure 6. Bland-Altman plot showing levels of agreement of lactate threshold heart rate (LTHR) for the noninvasive device (NID) and the traditional 4mmol estimation method.

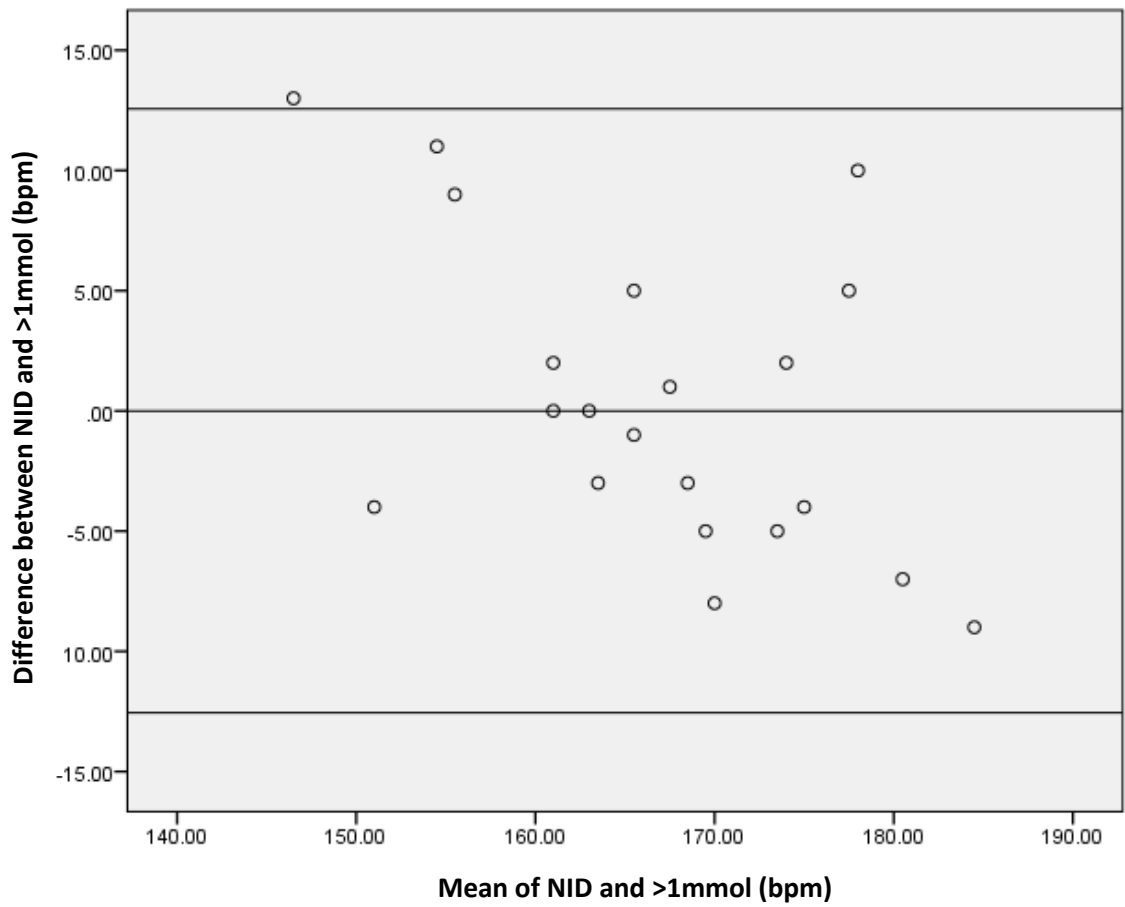


Figure 7. Bland-Altman plot showing levels of agreement of lactate threshold heart rate (LTHR) for the noninvasive device (NID) and the traditional estimation method at >1mmol increase.

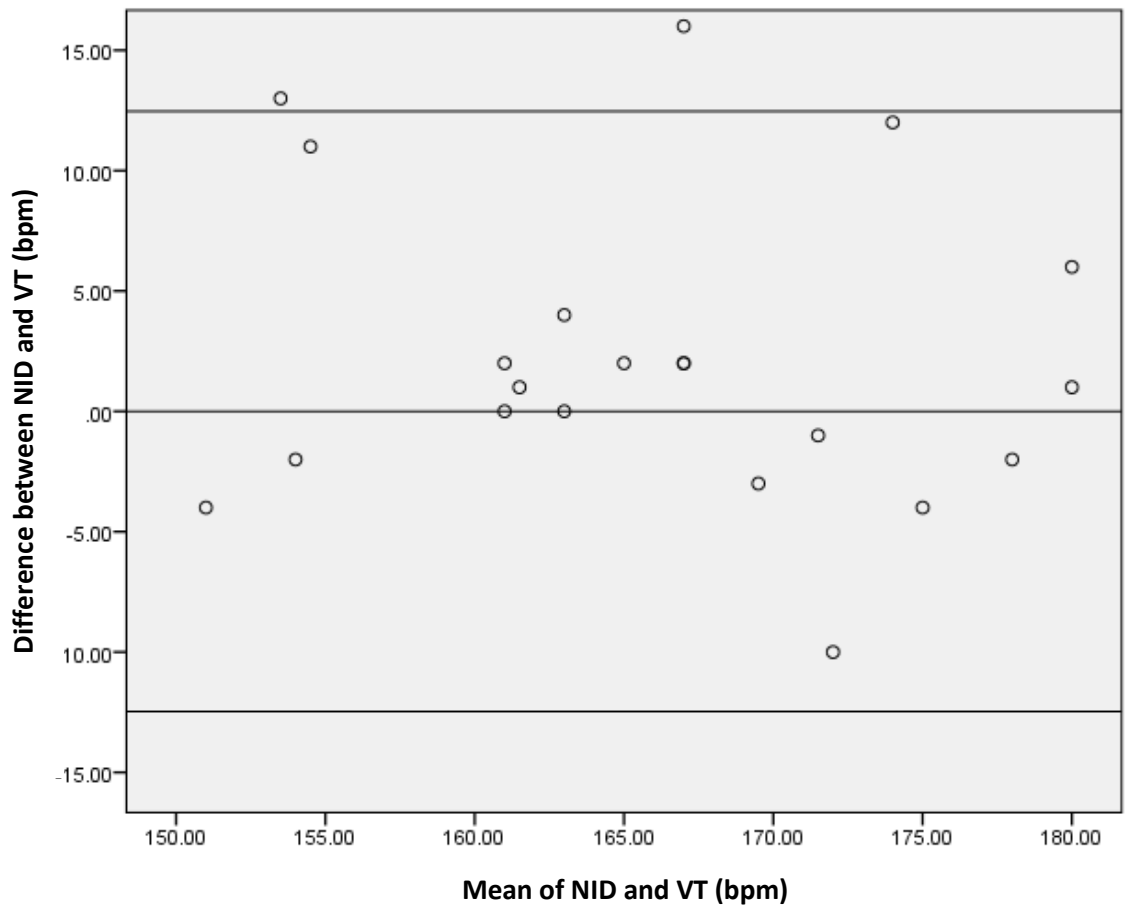


Figure 8. Bland-Altman plot showing levels of agreement of lactate threshold heart rate (LTHR) for the noninvasive device (NID) and the traditional estimation method at ventilatory threshold (VT).

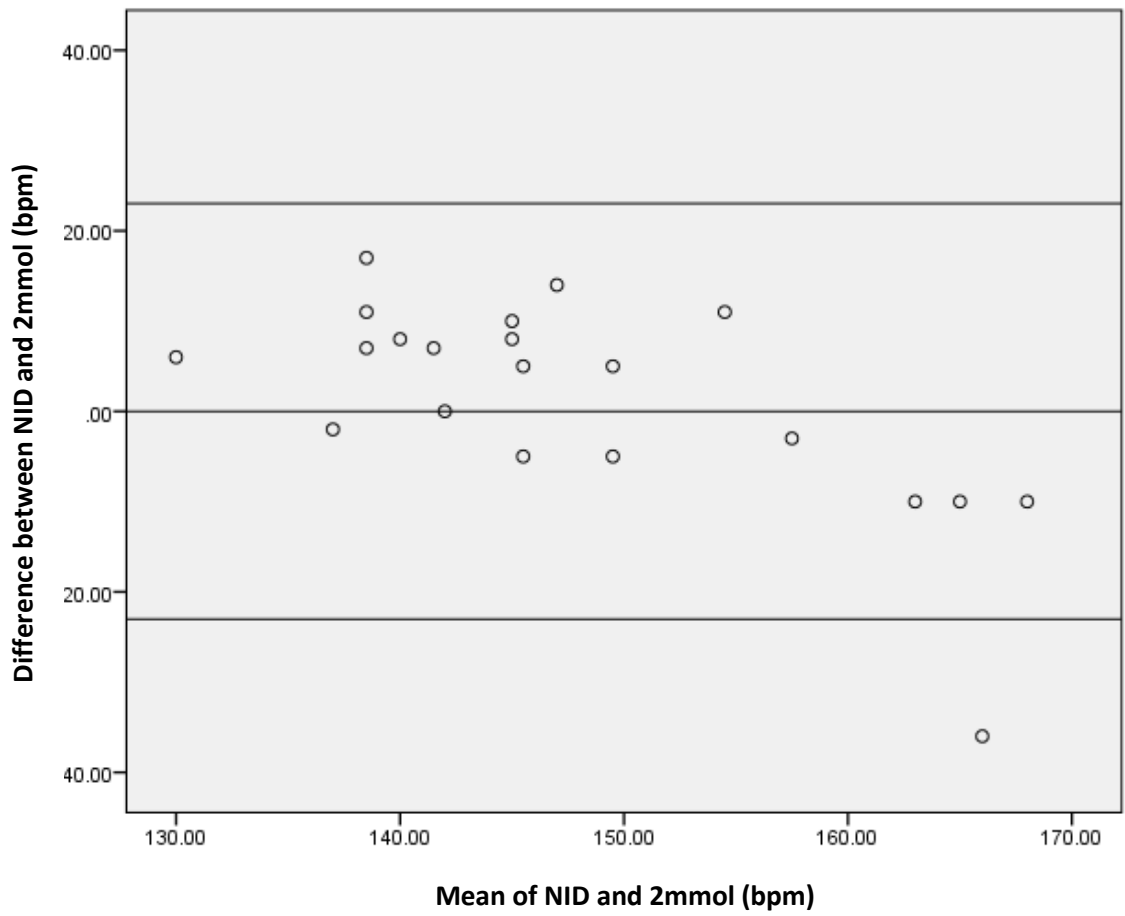


Figure 9. Bland-Altman plot showing levels of agreement of aerobic threshold heart rate (AeTHR) for the noninvasive device (NID) and the traditional 2mmol estimation method.

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