Evaluation of the CardioChek Portable Whole Blood Analyzer for Use in the Fitness Industry

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ABSTRACT

Williams AD, Ahuja KDK, Brickwood K, Fell JW. Evaluation of the CardioChek Portable Whole Blood Analyzer for Use in the Fitness Industry. *JEPonline* 2011;14(6):62-71. Pre-exercise screening questionnaires assist in determining the risk of a cardiovascular event occurring during exercise. The purpose of this study was to assess the CardioChek (CC) analyzer for suitability in pre-exercise risk screening and the ongoing assessment of risk factors associated with lifestyle interventions. Eighty-four apparently healthy subjects provided a venous blood sample for laboratory testing and CC analysis and a finger prick sample for analysis with the CC. The CC results and laboratory values were compared for accuracy, precision, and level of bias. Frequencies and percentages of samples outside pre-identified critical values for each measured variable were compared across the different methods of data collection. Multiple samples were collected from a subset of 30 participants for determination of technical error of measurement and precision. The observed bias for the CC capillary method compared to the laboratory method was -18% for total cholesterol, -35% for HDL, and -14.8% for blood glucose. The technical error of measurement for total cholesterol was 0.42 mmol·L⁻¹ (10.5%), HDL cholesterol was 0.14 mmol·L⁻¹ (14.1%), and blood glucose was 0.25 mmol·L⁻¹ (5.7%). The CardioChek may be acceptable for monitoring changes in total cholesterol and blood glucose, however further refinement is required prior to use in the fitness industry.

Key Words: Cholesterol, Blood glucose, Risk factors, Point-of-care systems, Mass screening, Fitness centers
INTRODUCTION

Regular exercise participation imparts a range of health benefits (14). However, exercise is not without risk (20). Pre-existing conditions or chronic disease risk factors, including elevated total cholesterol (TC) or low high-density lipoprotein cholesterol (HDL) levels in the blood, increase the risk of an adverse cardiac event during physical activity (2,20). Exercise intensity also influences the risk, with exercise of a moderate to vigorous nature transiently increasing the risk of acute myocardial infarction and sudden cardiac death (9,20).

Pre-exercise screening questionnaires have been developed to determine an individual’s risk of suffering a cardiovascular event during exercise (1,19). High concentrations of blood cholesterol and glucose are risk factors for cardiovascular events during exercise (2). Questions about these variables are often included in pre-exercise questionnaires to assist in determining whether a client needs medical clearance prior to participating in an exercise program, or to determine safe levels of activity for the individual. However, it is likely that many clients either do not remember their most recent test results or have never had them measured. In this instance, the conservative application of the questionnaire would require these variables to be measured prior to the client receiving clearance to commence an exercise program (11), which may act as an additional barrier towards adoption of healthier lifestyles (12).

Both endurance exercise (4,7) and progressive resistance exercise training (5) favorably influence blood cholesterol levels while lifestyle interventions (including regular exercise) improve glycemic control (6). The ability to monitor parameters such as blood lipids and glucose may assist fitness professionals to identify safe limits to exercise as well as to provide feedback and motivation for clients.

The CardioChek PA (CC; Polymer Technology Systems Inc., Indianapolis, IN, USA) is a portable, battery operated analyzer that can assess TC, triglycerides (TG), HDL, and glucose (BG) from fingerstick capillary samples. The hand-held instrument may provide a means to rapidly screen new clients for risk factors or to monitor the effectiveness of exercise and diet interventions. Consequently, the CC was evaluated as an inexpensive and convenient method for regular monitoring of blood lipids and glucose, and for assisting with pre-exercise risk factor screening within the fitness industry.

METHODS

Subjects

Apparently healthy subjects were recruited using pamphlets placed around the University campus and at commercial fitness centers within the local community. All subjects gave an informed written consent to participate in this study, which received approval from the institutional ethics committee and complied with the principles outlined in the Declaration of Helsinki.

Procedures

Blood lipids (TC and HDL) and BG were measured in venous plasma samples using laboratory techniques (gold standard) and compared with fingerstick capillary samples and venous samples analyzed using the CC. Fingerstick capillary sample results were also compared with venous whole blood samples analyzed using the CC. The reliability and precision of the CC was determined by repeatedly analyzing multiple samples obtained from a subset of subjects. For the purposes of this study, multi-screening PTS Panels Test Strips (Polymer Technology Systems, Indianapolis, USA) that measure TC, HDL, and BG simultaneously from a single blood sample were used.
On arrival at the clinical room, participants were weighed and their height was measured. Participants were then seated and 6 mL venous blood was collected into tubes containing anticoagulant lithium heparin (4 mL) and sodium fluoride/potassium oxalate (2 mL) from the antecubital region in the non-dominant arm via direct needle puncture. Immediately after blood collection and mixing of the tubes, 40 µL of blood was drawn from the lithium heparin tubes and analyzed using the CC. The remaining sample was placed on ice for later centrifugation at 3000 rpm at 4°C for 15 min. The plasma was separated, portioned, and frozen at -80°C until laboratory analysis was completed.

Immediately following the venous sample, a 40 µL capillary blood sample was obtained via fingerstick and analyzed for TC, HDL, BG, and TC/HDL risk ratio using the CC according to previously validated methods (22). The CC did not provide a result below 2.59 mmol·L⁻¹ for TC or below 0.39 mmol·L⁻¹ for HDL values. If this occurred TC/HDL risk ratios were not calculated for those subjects and the comparisons between the different analysis methods were not performed.

For reliability testing of the CC analyzer, two fingerstick blood samples were collected on the same day within 5 min of each other and tested on the same CC analyzer using test strips from the same batch. To test the inter-assay precision of the CC, two participants (one with high and one with low cholesterol and glucose measurements) volunteered to have an additional venous sample taken on a separate day. Repeated (n = 10) 40 µL samples were then drawn into the plastic capillary tubes provided by the manufacturer before being applied to the test strips.

Plasma TC, HDL, and plasma glucose were analyzed on a DataPro clinical analyser (Thermo Electron Corporation, Waltham, MA) using Thermotrace reagents (Thermo Electron Corporation, Waltham, MA). The intra assay coefficient of variation (CV) was 1.86%, 1.88%, and 2.72% for plasma glucose, TC and HDL, respectively.

**Statistical Analyses**

The descriptive data are presented as mean ± SD. Cardiochek fingerstick and venous assay results and laboratory values were compared using linear regression analysis and Pearson product moment correlation coefficients using Microsoft Excel. Bland-Altman plots were generated to evaluate the agreement between the different methods and Pearson product moment correlation coefficients were then determined to establish if bias trends were evident. Frequencies and percentages of samples outside pre-identified critical values for each measured variable (19) were determined and compared across the different methods of data collection using Yates Chi-Square analysis performed on the VassarStats Statistical Computation Web Site (8). A false positive was identified when the critical value was exceeded by the CC, but not the laboratory result. Conversely a false negative indicated the critical value was exceeded by the laboratory, but not the CC results. Blood glucose, TC, and HDL results from the CC were compared to the laboratory results using paired sample t-tests.

Data from the repeated fingerstick samples analyzed with the CC were used to calculate the absolute (mmol·L⁻¹) and percentage (%) technical error of measurement (TEM) for each variable. Precision of the CC was assessed by determining the CV from the 10 repeated assays performed on the high and low concentration venous samples.

**RESULTS**

Eighty-four apparently healthy subjects (36 male; 44.7 ± 12.0 yr; 170 ± 9 cm; 75.3 ± 15.1 kg; BMI 25.7 ± 5.2 kg·m⁻²) participated in this study. There were linear correlations between the values obtained from the laboratory and CC testing of capillary samples across all variables (BG: r = 0.413; TC: r = 0.756; HDL: r = 0.768; TC/HDL cholesterol risk ratio: r = 0.818, all P < 0.0001; Figure 1).
The results from the laboratory analysis were significantly different from those obtained using both venous and capillary blood with the CC for all variables (Table 1). The observed bias for the CC capillary method compared to the laboratory method was -18% (-1.00 ± 0.69 mmol·L⁻¹; 95% CI: -2.35 to 0.36) for TC, -35% (-0.51 ± 0.27 mmol·L⁻¹; 95% CI: -1.00 to 0.02) for HDL, and -14.8% (-0.76 ± 0.65 mmol·L⁻¹; 95% CI: -2.04 to 0.52) for BG (refer to both Table 1 and Figure 2). Bland Altman plots also revealed statistically significant trends in the bias for BG (r = - 0.254; P = 0.0198; Figure 2A), TC (r = 0.2339; P = 0.0322; Figure 2B) and TC/HDL risk ratio (r = 0.857; P < 0.0001; Figure 2D), but not for HDL (r = -0.183; P = 0.096; Figure 2C).

Figure 1. Linear regression comparisons of Laboratory determined values from venous blood with CardioChek PA analyser capillary results for A. Glucose; B. Total cholesterol; C. HDL Cholesterol; and D. Total Cholesterol/HDL Cholesterol Risk Ratio (TC/HDL). Dashed Lines represent critical values.
### Table 1. Comparison of CardioChek venous and capillary sample results with values obtained from laboratory analysis.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD</th>
<th>Observed Bias (%)</th>
<th>Significance Compared to Laboratory</th>
<th>Significance Compared to Capillary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Cholesterol (n = 84)</strong></td>
<td></td>
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</tr>
<tr>
<td>Laboratory</td>
<td>5.30 ± 1.04</td>
<td></td>
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<tr>
<td>CC Capillary</td>
<td>4.30 ± 0.89</td>
<td>-18.0 ± 12.7%</td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>CC Venous</td>
<td>4.34 ± 0.93</td>
<td>-17.6 ± 11.8%</td>
<td>&lt; 0.0001</td>
<td>0.437</td>
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<tr>
<td><strong>HDL Cholesterol (n = 84)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td>1.50 ± 0.35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC Capillary</td>
<td>1.00 ± 0.39</td>
<td>-33.7 ± 17.7%</td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>CC Venous</td>
<td>0.98 ± 0.42</td>
<td>-35.3 ± 17.1%</td>
<td>&lt; 0.0001</td>
<td>0.352</td>
</tr>
<tr>
<td><strong>TC/HDL Risk Ratio (n = 79)</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Laboratory</td>
<td>3.65 ± 0.73</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC Capillary</td>
<td>4.82 ± 1.70</td>
<td>29.8 ± 27.3</td>
<td>&lt; 0.0001</td>
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<tr>
<td>CC Venous</td>
<td>5.23 ± 2.10</td>
<td>33.4 ± 38.4</td>
<td>&lt; 0.0001</td>
<td>0.089</td>
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<tr>
<td><strong>Glucose (n = 79)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td>4.97 ± 0.52</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CC Capillary</td>
<td>4.21 ± 0.66</td>
<td>-14.8 ± 13.0%</td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>CC Venous</td>
<td>3.98 ± 0.58</td>
<td>-19.7 ± 8.7%</td>
<td>&lt; 0.0001</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

CC = CardioChek. The data were obtained in Launceston Tasmania between 1st April and 20th May 2009. The subjects were apparently healthy individuals recruited from around the university campus and local fitness centers.

Strong linear relationships were observed between the laboratory methods and the results from the CC analyzer using venous blood for BG ($r = 0.647; P < 0.0001$), TC ($r = 0.791; P < 0.0001$) and HDL ($r = 0.795; P < 0.0001$). There were significant differences between the CC venous results and the laboratory analysis results for all variables with the mean bias between methods ranging between 17.6% and 35.3% (Table 1).

There were strong linear correlations between the CC results obtained from venous whole blood samples and capillary blood samples for BG ($r = 0.745; P < 0.0001$), TC ($r = 0.909; P < 0.0001$) and HDL ($r = 0.928; P < 0.0001$). A statistically significant difference was observed between venous and capillary BG values ($p < 0.0001$; Table 1). There were no statistically significant differences between the CC venous and capillary values for TC or HDL.

Analysis of critical values frequencies identified zero false positive and two false negative results for blood glucose and Chi-squared analysis revealed no difference in the frequency of participants identified as above the critical values for blood glucose ($P = 0.4751$). However, for TC there was one false positive and 37 false negatives, and for HDL 39 false positives and zero false negatives (both analyses, $P < 0.0001$).
Duplicate samples collected from 30 subjects produced a TEM for BG of 0.25 mmol·L⁻¹ (5.7%), TC 0.42 mmol·L⁻¹ (10.5%) and HDL 0.14 mmol·L⁻¹ (14.1%). The inter-assay precision (CV) of the CC was 4.4%, 11.1%, and 10.0% for BG (3.56 ± 0.15 mmol·L⁻¹), TC (3.19 ± 0.35 mmol·L⁻¹) and HDL (1.07 ± 0.11 mmol·L⁻¹), respectively for the ‘low’ concentration sample, and 3.3%, 6.3%, and 5.0% for BG (7.72 ± 0.25 mmol·L⁻¹), TC (5.49 ± 0.34 mmol·L⁻¹) and HDL (2.26 ± 0.11 mmol·L⁻¹), respectively for the ‘high’ concentration sample.

DISCUSSION

The main findings from this study are that for all measured variables, there were significant differences between results obtained from the CC and the laboratory analyses, which could result in false positives or false negatives if the CC is used to identify risk factors in accordance with the pre-exercise screening questionnaires. However, the CC demonstrated reliability TEM of less than 15%
and a precision CV of below 12%, which may be acceptable as a rapid and convenient method for monitoring changes in response to exercise and/or diet interventions.

Our findings are in general agreement with those of previous studies that have compared the CC with laboratory methods. However, there is no consensus in the literature as to whether the CC produces higher or lower values than laboratory analysis. Two previous studies have reported higher TC results using the CC (16,18), while one reported TC to be significantly lower than the laboratory measured samples (3). An initial argument could be that the contrasting results for TC may be due to the blood sampling method used, with the two studies reporting higher TC results obtained by the CC having used venous samples, while both the current study and that of Dale et al. (3) used capillary samples. However, the current study analyzed both capillary and venous samples with the CC and observed lower values than laboratory analysis for both methods. Furthermore, any speculation that the method of blood collection could cause the CC direction of bias to differ between validation studies is not supported by the results for HDL from previous studies. One study that analyzed venous samples reported significantly higher HDL values obtained from the CC (16), while the two studies that reported lower HDL values used venous (18) or capillary (3) samples. The current study was the first to compare CC results obtained from both capillary and venous blood, and the agreement between these methods for TC and HDL strongly suggests that sample type is not the cause of the different results between studies.

There are several arguments for the difference between the CC and the laboratory results. Our study used a clearly described and validated technique (22) in the absence of any detailed protocol provided by the CC manufacturer to collect capillary blood from fingerstick samples for analysis using the CC. We cannot discount that following other guidelines for the collection of capillary blood samples may be part of the reason for the disparate results between laboratory methods and the CC, but argue the lack of clear guidelines from the manufacturer of the device would potentially result in more variation than following the method of Warnick and colleagues (22). Furthermore, as the CC measures concentrations in whole blood, while the common laboratory approach is to measure plasma concentrations, the hydration status of an individual could impact upon the agreement between the two methods as the CC calculations are likely based on a standard hematocrit. Another potential concern involves the calibration controls used to check the accuracy of the CC analyzer. Each control solution has a wide range of acceptable values (multi test strips: level 1 control cholesterol: 2.59-6.11; glucose: 2.61-7.22; level 2 control cholesterol 2.95-8.37; and glucose: 5.22-15.3 mmol·L$^{-1}$). It is possible that different batches of test strips may contribute to these reported inconsistencies between studies along with other factors such as sample handling and hydration status.

The current findings raise the question of the suitability of the CC analyzer for the fitness industry. The hand-held analyzer produced values that were significantly lower than those obtained from the standard laboratory methods for measuring TC, HDL, and BG. It also produced a significantly higher calculated TC/HDL risk ratio, suggesting questionable CC effectiveness as a pre-exercise risk screening instrument. The significant number of participants whose CC results, in contrast to the laboratory analysis results, were above or below the SMA PESS critical values (19) for TC (>5.2 mmol·L$^{-1}$) and HDL (<0.9 mmol·L$^{-1}$) adds weight to this argument. The lack of significant difference between the two methods for those exceeding critical BG values (>6.1 mmol·L$^{-1}$) is encouraging, but may have more to do with the sample population’s generally low BG values, as the laboratory results were still 14.8 ± 13.0% higher than those obtained using the CC. Therefore, further research using a more heterogeneous population for blood glucose concentration is warranted.
The suitability of the CC analyzer for the fitness industry depends on what constitutes a meaningful change, and whether the CC has the reliability and precision to detect such a change. Recent research demonstrated that exercise interventions can lead to decreases in TC of 0.35 mmol·L\(^{-1}\) and increases in HDL of 0.06 mmol·L\(^{-1}\) after 14 weeks in older adults (10). Lifestyle interventions involving diet and exercise can reduce TC by 0.65 mmol·L\(^{-1}\) (13) and increase HDL by 0.12-0.13 mmol·L\(^{-1}\) (23). However, meta-analyses assessing the effects of diet and/or exercise in overweight, obese, and diabetic clients only report increases in HDL of 0.11 mmol·L\(^{-1}\) (15) and reductions in fasting BG between 0.17 and 0.31 mmol·L\(^{-1}\) (15, 17). Given that reductions in serum TC of around 0.3 mmol·L\(^{-1}\) can reduce the risk of ischemic heart disease by around 15% (21), changes of this magnitude are worth monitoring. For HDL, reported changes are less than the TEM determined in this study, while the TEM for TC and BG may be acceptable depending upon the realistic change expected in line with the intervention type and duration. As a consequence, fitness professionals should exercise caution when interpreting changes of these magnitudes as real changes when using the CC analyzer.

CONCLUSIONS

Values obtained with the CardioChek analyzer were significantly lower for TC, HDL, and BG, and higher for the TC/HDL risk ratio than those obtained using laboratory methods. This would result in discrepancies in the risk stratification of clients with pre-exercise screening. While the reliability and precision of the CC seems reasonable it may be too large to monitor realistic changes in response to lifestyle interventions. We recommend that that the CC undergo additional study and refinement prior to its possible adoption within the fitness industry.

ACKNOWLEDGMENTS

The CardioChek analyzer used in this investigation was provided at no cost by the Australian distributor.

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