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Sensitivity and Specificity of CardioChek®PA in Detecting Individuals with Abnormal Cholesterol and Glucose Level

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Abstract

Point of care screening to identify individuals with abnormal blood lipid and glucose is recommended eligible individuals for primary prevention of cardiovascular disease. The study was done among 252 clients to determine the ability of CardioChek®PA in identifying individuals with abnormal blood levels of total cholesterol (TC) and Blood Glucose (BG), compared with a reference laboratory. Pearson correlation coefficients between reference laboratory and fingerstick test were fair to moderate and were statistically significant (p<0.05). Categorical agreement between fingerstick analysis and the reference laboratory was fair to moderate for TC and BG respectively. For TC, CardioChek®PA had 62.7% sensitivity, 76.1% specificity, and 76.4% Positive Predictive Value. For glucose, CardioChek®PA had 95.5% sensitivity, 85.4% specificity and 70.3% Positive Predictive Value. In conclusion, CardioChek®PA is a reliable tool to be used as screening tool for identification of individuals at risk for cardiovascular disease. IJBM 2012; 2(2):132-135. © 2012 International Medical Research and Development Corporation. All rights reserved.
Key words: CardioChek®PA, screening, sensitivity, specificity, Malaysia.

Introduction

In Malaysia, cardiovascular disease (CVD) is the leading cause of death in both men and women [1]. CVD includes coronary heart disease (CHD), cerebrovascular disease and peripheral arterial disease. CHD is a spectrum ranging from stable angina to acute coronary syndromes (ACS) [2]. Malaysians develop ACS at a younger age when compared to people in Thailand, Mainland China and western countries. Our local National Cardiovascular Disease and Acute Coronary Syndromes (NCVD-ACS) Registry, showed that most patients (96.8%) had at least one established cardiovascular risk factor–hypertension (72.6%), dyslipidaemia (55.9%) and or diabetes (55%) [3]. In preventing CVD, efforts should be aimed at reducing global risks.

The National Heart, Lung and Blood Institutes that

initiated the National Cholesterol Education programme (NCEP) recommended that all adults aged 20 years and over should have their cholesterol level checked at least once every five years [4]. Screening for diabetes should be considered in the presence of risk factors for Diabetes Mellitus [5]. Point-of-care screening for abnormal blood lipid and glucose values provide immediate patient education, could facilitate communication of risk, and may increase adherence to national guidelines. Fingerstick measurement is a point-of-service assessment tool commonly used in clinical or health promotion settings.

The seminal factor in the acceptance of cholesterol screening as a means of referral and risk prediction is the question of precision, accuracy, validity and reliability of instruments used in the field [4]. Accuracy of portable devices is necessary to avoid the possibility false negative results, which can delay physician referral and tertiary treatment [6]. Contemporary cholesterol and glucose screening has involved capillary and venous samples, with capillary cholesterol and glucose typically collected from the tip of the finger while venous samples are drawn from the antecubital vein found in the bend of the elbow [7-10]. The CardioChek®PA system is a tool to assist Health-Care

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professionals in the primary care level to screen for cardiovascular risk factors.

The purpose of this study was to evaluate the ability of a CardioChek®PA (CCPA) to be used as point-of care fingerstick assessment tool in identifying abnormal blood lipid and glucose values in an individual who was eligible for primary prevention of cardiovascular disease (CVD) by comparing the results from this fingerstick technology with a reference laboratory.

Methods

Design

This study is a cross-sectional analysis of data from 252 clients of four outpatient clinics in two states in Malaysia. The participants voluntarily participate in this screening programme sponsored by the Ministry of Health Malaysia. This research study was reviewed and approved by the Institute for Public Health Institutional Review Board. CardioChek®PA (Polymer Technology Systems, Inc, IN, USA) provided in-kind donations of fingerstick technology. Research Proposal was approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

Sample

Participants were clients from outpatient clinics who voluntarily consented to involve in this study. They were eligible to participate if they were between the aged of 18 and 79 years of age, did not have established CVD or diabetes themselves, and spoke either English or Malay. Participants with congestive cardiac failure, end stage renal disease, liver disease and pregnancy were excluded from this study. Data collection was done in October 2011. Written informed consent was sought from all participants.

Measures

At the clinics, all participants underwent concurrent fasting capillary blood sampling obtained by fingerstick and venous blood draw. Fresh venous blood was analyzed by the Sg Buloh National Public Health Laboratory, as the reference laboratory, using standard methods for serum TC and BG. Capillary samples were analyzed for blood TC and BG by CardioChek®PA technology using multi-screening PTS Panels Test Strips (Polymer Technology Systems, Indianapolis, USA) that measure TC and BG simultaneously from a single blood sample. Readings were available within two minutes, and participants were informed of their results by the Registered Nurse at the same visit. In addition, results obtained were forwarded to Family Physician for further management.

Analysis

Characteristics of participants were described using means and proportions wherever appropriate. For reference laboratory, Clinical Practice Guideline for Management of Dyslipidemia [10], was used to define abnormal serum Total Cholesterol (above 5.1 mmol/L), while Clinical Practice Guideline: Management of Type 2 Diabetes Mellitus [5] was used to define abnormal glucose (7.0 mmol/L and above). Blood TC and BG values were assessed for normality, and Pearson correlation coefficients were calculated to assess reliability of continuous TC and BG obtained by CardioChek®PA (using Total Cholesterol Plus Glucose Panel) against the gold standard from the reference laboratory. Kappa statistics were obtained for assessment of categorical agreement between the gold standard and CardioChek®PA analyzer in categorizing the participants as having abnormal TC or BG results. A value of above 0.7 was noted as strong positive correlation coefficient, while Kappa values between 0.21 and 0.40 were defined as fair, values between 0.41 to 0.60 were defined as moderate, while values between 0.61 to 0.80 were defined as substantial agreement and values above 0.81 were defined as almost perfect agreement [11, 12]. Sensitivity of the fingerstick tests to categorize a participant as having an abnormal TC or BG was calculated separately by taking the total number of participants who were noted as having the abnormal result by both reference laboratory and fingerstick test and dividing by the total number diagnosed as abnormal by the reference laboratory (gold standard). Similarly, specificity of fingerstick technology to categorize participants as having the abnormal results were calculated by taking the total number of participants noted as having abnormal results by both the reference laboratory and fingerstick test and dividing by the total number diagnosed as abnormal by the reference laboratory (gold standard). Statistical analysis was done using SPSS version 19 [13].

Results

Participants had a mean [standard deviation] age of 50.45 [17.21]; 64.3% were female (Table 1). Pearson correlation coefficients between reference laboratory and fingerstick test were fair to moderate and were statistically significant ($p < 0.05$; Table 2). Categorical agreement between fingerstick analysis and the reference laboratory was fair to moderate for TC and BG respectively (Table 2). At a clinical cut-point of 5.2 mmol/L for Total Cholesterol, the fingerstick measurement had 62.7% sensitivity to categorize participants as having abnormal cholesterol and 76.1% specificity to categorize participants as having normal cholesterol levels (Table 2). For glucose, at a clinical cut-point of 7.0 mmol/L, the fingerstick measurement had 95.5% sensitivity to categorize participants as having abnormal glucose and 85.4% specificity to categorize participants as having normal glucose levels (Table 2). Out of all participants found as having abnormal TC (110 participants), CardioChek®PA was noted as able to correctly detect 76.4% (84 participants) of them, while for abnormal BG (91 participants), only 70.3% (64 participants) were correctly identified by CardioChek®PA.

Discussion

Our data showed that there was fair to moderate agreement between fingerstick CardioChek®PA test compared with the reference laboratory in categorizing individuals as having abnormal TC or BG. Studies

Table 1
Demographic and cholesterol levels of cholesterol screening participants (n=252).

Variable	n	%/mean	Standard deviation
Male	90	35.7%	
Female	162	64.3%	
Age (years)		50.45	17.21
Total Cholesterol, TC (mmol/L)			
CardioChek PA		5.02	1.52
Venous		5.31	1.45
Glucose, BG (mmol/L)			
CardioChek PA		6.09	2.84
Venous		5.97	2.42

Table 2
Comparison of total cholesterol (TC) and glucose (BG) using fingerstick screening vs. venous samples analyzed in reference laboratory

	Total Cholesterol, TC	Glucose, BG
Correlation (r)	0.39	0.61
Clinical Cut-Point	5.2 mmol/L	7.0 mmol/L
Kappa (K)	0.38	0.55
Sensitivity (%)	62.7	95.5
Specificity (%)	76.1	85.4
Positive Predictive Value (PPV)	76.4	70.3
Negative Predictive Value (NPV)	62.4	98.1

comparing results of fingerstick with standard laboratory had noted moderate to good agreement [14-16] which indicated suitability to be used as screening tool.

World Health Organization (WHO) had recommended screening programme for Type 2 Diabetes in line with the increasing prevalence of diabetes worldwide [17]. WHO had emphasis that screening tests must be shown to be valid, reliable and reproducible in the population in which screening is to take place. Uniform procedures and methods, standardized techniques, properly functioning equipment, and quality assurance are all necessary to ensure reliability and reproducibility. Fasting capillary blood glucose has also been used for screening. Study in Brazil reported that the best equilibrium between sensitivity and specificity for the diagnosis of diabetes was achieved at a cutoff of 5.6 mmol/L for fasting capillary blood glucose, in their study of 4,019 Brazilian people undergoing an OGTT [18]. Our study had also showed CardioChek®PA has high sensitivity and specificity for the identification of abnormal glucose level based on similar cutoff value.

Our study revealed that that CardioChek®PA had moderate sensitivity and specificity but fairly high PPV in detecting participants with abnormal TC level. A study done using similar tool comparing the results obtained from capillary and venous blood showed strong agreement between these methods for TC and HDL which suggested that sample type is not the cause of the different results between studies [19].

In Malaysia, NCVD-ACS Registry, showed that 55.9% of patients have dyslipidaemia [3]. Based on this large percentage of the population with abnormal risk factors for CVD and the potential barriers to screening, fingerstick test will be able to provide immediate and accurate results. This study has revealed that CardioChek®PA should be considered as a screening tool to detect participants with abnormal BG.

Limitations

The aim of this study was to evaluate this technology as a screening tool; we therefore evaluated accuracy with respect to specific cutoff levels. We cannot draw conclusions regarding the clinical utility of CardioChek®PA for use in ongoing management and treatment decisions.

Conclusion

Our study demonstrated that CardioChek®PA was able to accurately identifies individuals with abnormal BG and fairly good in identifying individuals with abnormal TC, thus is appropriate to be use in health promotion and screening programs. Point-of care testing can be conducted in primary care settings and it can provide immediate cardiovascular risk stratification as well as concurrent health promotion.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this article.

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