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Clinical correlation between a point-of-care testing system and laboratory automation for lipid profile

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ABSTRACT

Background: We evaluated the clinical correlation between the CardioChek PA analyzer and a clinical laboratory reference method to use for screening program purposes.
Methods: Fasting blood samples were collected on 516 patients (age 20–85 y). One venous sample was collected using a serum tube for the evaluation on a COBAS reference analyzer. A second venous sample was collected in a lithium heparin tube and was evaluated on the CardioChek PA analyzer (CCPA venous). A fingerstick sample (CCPA fingerstick) was evaluated only on the CardioChek PA analyzer. Linear regression analyses were performed for each measured analyte, total cholesterol, HDL-cholesterol and triglycerides.
Results: The correlation between the CCPA fingerstick and CCPA venous was extremely high for HDL-C and triglycerides, and good for total cholesterol. Our results demonstrated a good clinical agreement for total cholesterol, HDL-C and triglycerides between 97.7% and 94.6% in the comparison of the CCPA to the reference analyzer.
Conclusions: We identified the pre-analytic phase as an important step to guarantee the quality of results and indicate that the CardioChek PA is a reliable lipid point-of-care testing system that can be used for the application of clinical screening anywhere.

1. Introduction

Cardiovascular disease (CVD) is the most frequent cause of morbidity and mortality in the contemporary world. Reducing serum lipid concentrations can decrease atherosclerotic plaques, thus contributing to prevention of CVD. Population screening for the detection of dyslipidemias aims at early identification of individuals at high risk of developing CVD [1].

Point-of-care testing (POCT) provides fast results, with easy operation, making it highly suitable for population screening tests. The clinical application of POCT has been demonstrated to be efficient in raising awareness about the importance of lipid levels to prevent future CVD and stroke events [2].

The CardioChek PA analyzer (PTS Diagnostics) is a portable whole blood test system that uses a single test strip to measure total cholesterol (TC), HDL cholesterol (HDL-C) and triglycerides (TG) [3]. The use of the CardioChek PA analyzer by health professional workers is highly recommended for the proposed screening programs in Brazil; the analytical performance is suitable for use as part of national health services, providing fast and reliable results.

In general, POCT devices may have greater variability compared to large equipment found in the clinical laboratory. These analytical differences could be due to a combination of environmental variations (temperature, humidity, the use of a whole blood sample, and training of individual operators) [4].

2. Methods

2.1. Study design and patients

In this study, 516 fasting blood samples (12 h) were collected from patients (age between 20–85 y) at the outpatient department of the University Medical Center UNIFESP/EPM, Brazil. The study was submitted to the local ethics and research committee; the patient participation was voluntary upon completion of the consent form, according to the Helsinki Declaration. From each outpatient presenting at the medical center, two venous whole blood samples were collected from a single venipuncture and an additional single, whole blood fingerstick sample was collected with a lithium heparin coated capillary pipette.

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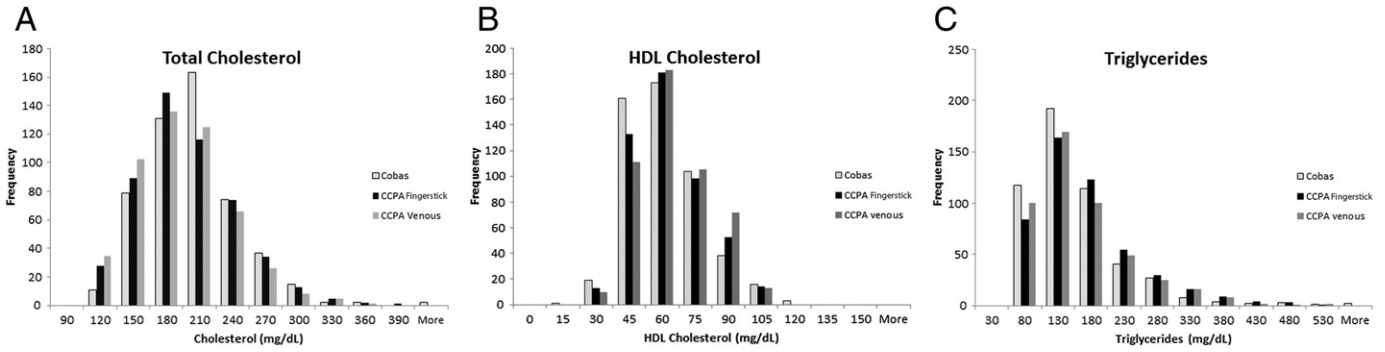

Fig. 1. Distribution of each specific test (Cobas, CCPA Fingerstick and CCPA venous) in the population studied. A: Total cholesterol, B: HDL cholesterol; C: triglycerides.

One venous sample was collected in a tube without additives for the separation of serum and was evaluated on a Cobas 6000® (COBAS) from Roche Diagnostics at the Central Laboratory within 1 h of collection. Specimens that demonstrated hemolyzed serum after centrifugation in the Laboratory were discarded from the study. The Central Laboratory has a proficiency-testing program in place that guarantees the quality of lipid profile results (Controllab proficiency-testing program). A coefficient of variation (CV) of ±5% for lipid profile has been consistently achieved. The Central Laboratory performed the measurement of total cholesterol (TC) and triglycerides (TG) by standard enzymatic colorimetric assay (Roche Diagnostics) methods. The HDL cholesterol (HDL-C) was measured by a homogenous enzymatic colorimetric test, (Roche HDL-C plus 3rd generation (HDLC3)). This assay uses magnesium ions and dextran sulfate to selectively react with LDL, VLDL and chylomicrons which are resistant to polyethylene glycol (PEG)-modified enzymes. The cholesterol concentration of HDL is determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG.

The second venous sample (collected in a lithium heparin coated tube) was evaluated on a CardioChek PA analyzer (CCPA venous). The fingerstick sample (CCPA fingerstick) was also evaluated on the CardioChek PA analyzer. The use of both venous and capillary samples on the CardioChek PA allows the clinician confidence in the interchangeability of sample types. CCPA uses dry-chemical testing for measurement of TC, HDL-C and TG in whole blood using PTS Diagnostics lipid panel test strips. A membrane removes the red blood cells, and via horizontal flow the test strip analyzes plasma lipid concentrations. The evaluations of total cholesterol and HDL-C use the same enzymatic reaction. The HDL lipoproteins are separated from lipoproteins LDL and VLDL using phosphotungstic acid and a magnesium salt layer above the membrane fractionation layer. The resulting HDL fraction in plasma reacts with surfactants and enzymes for measuring cholesterol concentration. The evaluation of TG is carried out by a colorimetric enzymatic method using lipoprotein lipase, glycerol kinase, glycerol phosphate oxidase and peroxidase. The CCPA analyzer uses reflectance photometry [3].

The sample collection location was temperature controlled (23–24 °C) and humidity controlled (40–50%) and the procedure was conducted under aseptic conditions using traditional methods of antecubital venipuncture. The time of tourniquet used did not exceed 1 min, as recommended in the Clinical and Laboratory Standards Institute Guidelines [5].

The fingerstick was performed according to the CardioChek PA manufacturer's instructions. The temperature of the testing environment was between 20–27 °C and the humidity < 80%. The site temperature was recorded before, during and after the test. The individuals responsible for the collection of venous and capillary samples are technicians and running of the CCPA was trained following routine manufacturer's instructional procedures.

The lipid panel test strips from PTS Diagnostics were tested using the CardioChek PA quality control level 1 and level 2. ChekMate™ Strips were also used to verify that the optics of the analyzer are functioning properly in all wavelengths used by the equipment. The ChekMate MEMo Chip was inserted in the analyzer, followed by the ChekMate, levels 1 and 2. Manufacturer's instructions recommend the use of ChekMate Strips on a daily basis as well as testing liquid quality controls with each new lot of test strips, each new shipment of test strips, for troubleshooting the analyser or to comply with each facility's quality control requirements. In this study, more stringent quality control was performed by running the liquid controls each day of testing and running the ChekMate Strips only at the initiation of the evaluation. Each test result was associated with a sequential number and the name of the operator. All data was recorded in a data collection sheet and later transferred to a Microsoft Excel file.

2.2. Statistical analysis

Data analyses were performed using Microsoft Excel (2010). The difference between the CardioChek PA results and the laboratory results was calculated in a pair-wise fashion. The average differences were calculated. Linear regression was used to analyze paired data, describing the relationship between the two methods. Statistical significance was defined as a $p < 0.05$.

Table 1
Linear regression analyses.

	Total cholesterol		HDL cholesterol		Triglycerides	
	Fingerstick	Venous	Fingerstick	Venous	Fingerstick	Venous
n[a]	511	504	492	494	489	472
Slope	0.92	0.87	1.01	1.00	1.16	1.06
Offset	9.4	11.8	3.0	5.5	−4.0	−2.6
Correlation coefficient (R)	0.854	0.856	0.936	0.923	0.969	0.953
Sample range (mg/dl)	101–370	101–339	20–97	21–100	50–498	50–486

[a] Samples beyond the reporting range of the CardioChek PA were excluded.