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Clinical correlation between the Point-of-care testing method and the traditional clinical laboratory diagnosis in the measure of the lipid profile in patients seen in medical offices

Correlação clínica entre a metodologia Point-of-care testing *e o diagnóstico laboratorial tradicional na dosagem do perfil lipídico de pacientes atendidos em consultórios médicos*

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ABSTRACT

Introduction: Elevated plasma levels of lipids are considered the main modifiable risk factor for the cardiovascular disease. The Point-of-care testing (POCT) method provides quick results and allows anticipating diagnosis and treatment. **Objective:** To compare the lipid profile results obtained from both POCT and the traditional clinical laboratory. **Methods:** Fasting blood samples were collected from 111 patients who sought, for any reason, the private medical offices participating on this study. Capillary whole blood samples were analyzed in CardioChek® PA (CCPA) equipment, and the serum samples were analyzed in clinical laboratories (LAB) that have internal and external quality control, with certification. The mean values of each variable of the lipid profile obtained by CCPA and LAB were calculated. Linear regression was used to determine the existence of correlation between the two methods. **Results:** We observed a positive correlation between the values obtained by CCPA and LAB for all variables of the lipid profile. Our data, extracted from the routine use of CCPA in private medical offices, supports a substantial contribution of the POCT methodology in the detection of the main cardiovascular risk factors. **Conclusion:** The POCT CardioChek® PA Analyzer is an easy-to-operate tool, with adequate analytical performance and a good correlation with the results of the conventional laboratory method, therefore, considered a reliable method.

Key words: lipids; point-of-care testing; cardiovascular diseases.

INTRODUCTION

High levels of cholesterol in blood are considered the main modifiable risk factor for cardiovascular disease. A large body of scientific evidence supports this premise by unambiguously establishing that reductions of low-density lipoprotein cholesterol (LDL-c), through lifestyle changes and/or use of medicaments have a major impact in lifetime, in reduction of cardiovascular events and mortality[1].

The "point-of-care testing" (POCT) method is intended to provide rapid and accurate results. The evaluation of the complete lipid profile on a single reagent strip using capillary whole blood provides results in less than two minutes. This agility allows us to anticipate the beginning of clinical treatment. For example, physicians in their office can identify early the individuals at risk for cardiovascular disease, monitor their therapeutic response to the medication prescribed, adjust the dose of medication, and monitor target achievement and treatment compliance[2].

Through the data obtained in this study, we aimed to evaluate the advantages of the POCT measure in comparison to the traditional methodology and its viability in the clinical routine of the medical offices.

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METHODS

Study design and patient selection

For this study, we recruited 111 patients who sought, for any reason, the private cardiology and endocrinology clinics participating in this study. Patients who met the inclusion and exclusion criteria after being informed by the physician about the procedures, risks, benefits and rights were considered eligible to participate in the protocol, with all their doubts clarified. All agreed to sign the informed consent form.

The study required two collections of blood samples on the same day: 1) in the office, through finger puncture, to collect a capillary blood drop; and 2) in the clinical analysis laboratory, in a conventional way, by venipuncture. For both samples, 8 to 12 fasting hours was required, and the interval between the two collections was less than 60 minutes.

The laboratory parameters determined were total cholesterol (TC), high-density lipoprotein cholesterol (HDL-c) and triglycerides (TG); the LDL-c values were calculated by the Friedewald formula[3] and the POCT analyzer provided them automatically.

Diagnostic methodology

Total capillary blood samples obtained by the clinics were analyzed on CardioChek® PA (CCPA) (PTS Diagnostics, Indianapolis, USA) equipment on lipid panel test strips. The guidelines of the manufacturer's protocol were observed and the operation of the electronic and optical parts of the analyzer was verified with ChekMateTM at all the wavelengths used by the equipment. The lipid panel test strips were tested using the quality control of the CardioChek® Level 1 and Level 2.

The reactive strips for the lipid profile present an initial membrane that removes the red blood cells and, by the horizontal flow, the plasma lipids are determined by a dry chemical reaction. TC and HDL-c evaluations use the same enzymatic reaction. HDL lipoprotein is separated from the other plasma lipoproteins in the presence of phosphotungstic acid and magnesium chloride. The HDL resulting fraction in plasma reacts with surfactants and enzymes for the determination of the cholesterol concentration. The TG measure is performed by an enzymatic colorimetric method, using lipoprotein lipase, glycerol kinase, glycerol-phosphate oxidase and peroxidase. The Cardiochek analyzer employs reflectance photometry[4].

Blood samples from the venipuncture were collected and analyzed in clinical laboratories (LAB) that present internal and external quality control, with certification. The methodology for the analysis of TC, HDL-c, TG and LDL-c has the same principle as the reactive strips.

Statistical analysis

Data analysis was performed using the Microsoft Excel (2010). The mean values of each lipid profile variable obtained by CCPA and LAB were calculated. Linear regression was used to determine the existence of correlation between the two methods. Statistical significance was defined as $p < 0.05$.

RESULTS

The mean values of each variable of the lipid profile from the 111 participating patients, obtained by both CCPA and LAB methods, are presented in **Table 1**.

The graphs presented in **Figures 1**, **2**, **3** and **4** demonstrate the existence of correlation between the two methods for the variables TC, HDL-c, TG and LDL-c, respectively.

Table 2 shows the statistical data for the calculation of the correlation coefficients (R) and the coefficient of determination (R^2) by the linear regression analysis.

TABLE 1 – Mean values of each variable of the lipid profile of the 111 patients, obtained by the two methods CCPA and LAB

	TC		HDL-c		TG		LDL-c	
	CCPA	LAB	CCPA	LAB	CCPA	LAB	CCPA	LAB
n	111		111		111		111	
Mean values (mg/dl)	158.1	179.1	52.3	53.5	126.4	125.5	82.4	100.1

CCPA: CardioChek® PA; LAB: clinical laboratories; TC: total cholesterol; HDL-c: high-density lipoprotein cholesterol; TG: triglycerides; LDL-c: low-density lipoprotein cholesterol.

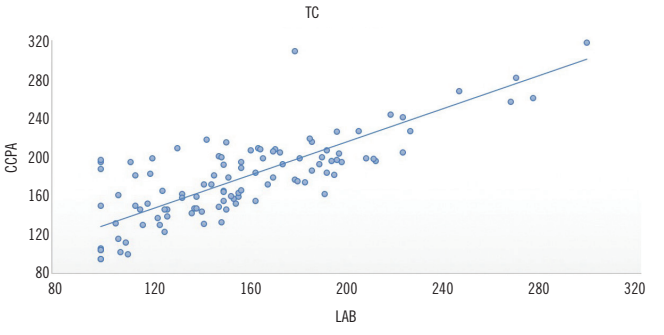

FIGURE 1 – *Correlation between CCPA and LAB for TC values (R = 0.796)*

CCPA: CardioChek® PA; LAB: clinical laboratories; TC: total cholesterol.

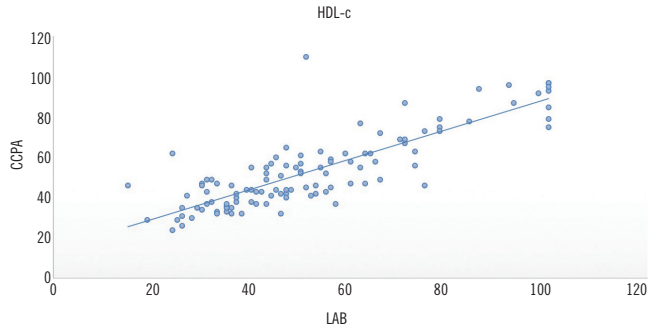

FIGURE 2 – *Correlation between CCPA and LAB for HDL-c values (R = 0.838)*

CCPA: CardioChek® PA; LAB: clinical laboratories; HDL-c: high-density lipoprotein cholesterol.

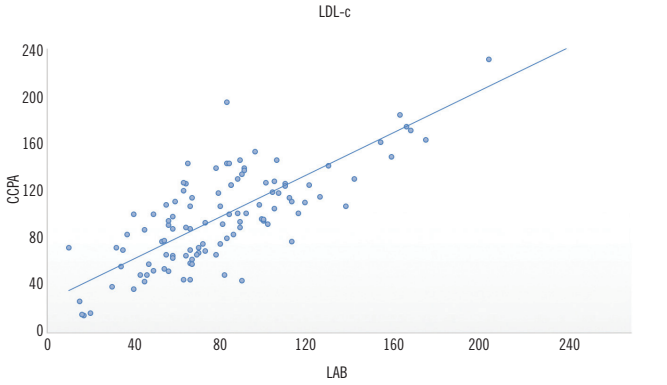

FIGURE 4 – *Correlation between CCPA and LAB for LDL-c values (R = 0.777)*

CCPA: CardioChek® PA; LAB: clinical laboratories; LDL-c: low-density lipoprotein cholesterol.

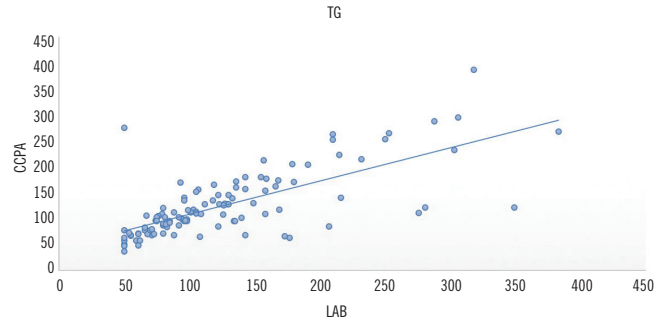

FIGURE 3 – *Correlation between CCPA and LAB for TG values (R = 0.716)*

CCPA: CardioChek® PA; LAB: clinical laboratories; TG: triglycerides.

TABLE 2 – Linear regression analysis between the two methods for the values of each lipid profile variable

	TC	HDL-c	TG	LDL-c
Correlation coefficient (R)	0.796	0.838	0.716	0.777
Coefficient of determination (R^2)	0.63	0.7	0.51	0.6

TC: total cholesterol; HDL-c: high-density lipoprotein cholesterol; TG: triglycerides; LDL-c: low-density lipoprotein cholesterol.

DISCUSSION

Our results demonstrate a positive relationship between the values obtained by the POCT methodology and the conventional laboratory for all the variables of the lipid profile, as demonstrated in a previous Brazilian study that, evaluating the clinical correlation between the CCPA and the clinical reference laboratory of the Hospital of the Universidade Federal de São Paulo, Escola Paulista de Medicina (Unifesp/EPM)[5], confirmed that the analytical performance of this POCT equipment is suitable for use in population screening programs and as a service in healthcare systems, providing fast and reliable results. Other studies that compared the performance of CCPA with that of the conventional LAB, in different populations showed results similar to those found in our study. Panz *et al*. (2005), evaluated 100 South African patients with familial hypercholesterolemia (HF), and found a significant correlation between the methods[6]. Yang *et al*. (2013), in 1,263 Chinese patients over 40 years of age demonstrated the effectiveness of CCPA in detecting the lipid levels of patients at high cerebrovascular risk[7].

Our data, extracted from the routine use of CCPA in private medical practices, supports the substantial contribution of the POCT methodology in the detection of the main cardiovascular risk factors, representing a new tool and excellent diagnostic option.

CONCLUSION

The POCT CardioChek PA analyzer is an easy-to-operate tool with adequate analytical performance and very good correlation with the results of the conventional laboratory method, therefore reliable.

RESUMO

Introdução: *Níveis plasmáticos elevados de lipídios são considerados como principal fator de risco modificável para a doença cardiovascular. A metodologia* Point-of-care testing *(POCT) fornece resultados rápidos e permite antecipar o diagnóstico e o tratamento.* ***Objetivo:*** *Comparar os resultados do perfil lipídico obtidos pelo POCT e pelo laboratório convencional.* ***Métodos:*** *Foram coletadas amostras em jejum de 111 pacientes que procuraram, por qualquer motivo, os consultórios médicos privados participantes desta pesquisa. As amostras de sangue total da punção capilar foram analisadas no equipamento CardioChek® PA (CCPA) e as de sangue da punção venosa, coletadas e analisadas em laboratórios clínicos (LAB) que apresentam controle de qualidade interno e externo, com certificação. Os valores médios de cada variável do perfil lipídico obtidos pelo CCPA e pelo LAB foram calculados. Regressão linear foi utilizada para determinar a existência de correlação entre os dois métodos.* ***Resultados:*** *Observamos correlação positiva entre os valores obtidos pelo CCPA e pelo LAB para todas as variáveis do perfil lipídico. Nossos dados, extraídos do uso rotineiro do CCPA em consultórios médicos privados, suporta substancial contribuição da metodologia POCT na detecção dos principais fatores de risco cardiovascular.* ***Conclusão:*** *O analisador POCT CCPA configura-se como uma ferramenta de fácil operação, com performance analítica adequada e excelente correlação com os resultados do método laboratorial convencional, portanto confiáveis.*

Unitermos: *lipídios; testes laboratoriais remotos; doenças cardiovasculares.*

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