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The sensitivity, specificity, and agreement of a *point of care* method: an assessment of the diagnostic accuracy

Sensibilidade, especificidade e concordância do método point of care: um estudo de precisão diagnóstica

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Abstract *The use of new technologies can improve screening in communities with difficult access to health. This article aims to evaluate the sensitivity, specificity, and agreement of a point of care test in comparison to laboratory methods for the determination of glucose (GLI), triglyceride (TG), and total cholesterol (TC) concentrations. This prospective study used data from the remaining adult population of quilombolas in Brazil. Laboratory tests using conventional methods for the analysis of venipuncture samples were used as a standard method to measure the concentrations of GLI (mg/dL), TG (mg/dL), and TC (mg/dL) and compared to the metered dose from the collection of fingertip capillary blood (point of care). Contingency tables (2x2) were used to estimate the sensitivity and specificity of the methods. Lin and Bland & Altman coefficients were used to statistically assess agreement, the level of significance was 5%. There was substantial agreement between the methods for measuring TG and poor agreement for of TC and GLI. Analysis of the Bland & Altman coefficients revealed that the fingertip method did not produce good measures. The point of care method did not offer a good ability to measure compared to that of the reference laboratory method.*

Key words *Point of care, Laboratory tests, Technology Assessment.*

Resumo *O uso de novas tecnologias pode melhorar o screening em comunidades de difícil acesso à saúde. O objetivo deste artigo é avaliar a sensibilidade, especificidade e concordância do teste de point of care em comparação com método laboratorial para dosagem de Glicose (GLI), Triglicerídeo (TG) e Colesterol total (CT). Estudo prospectivo com dados de população de adultos remanescentes de quilombolas no Brasil. Exames laboratoriais convencionais para análise foram obtidos por venopunção, utilizados como método padrão para mensuração das concentrações de GLI (mg/dL), TG (mg/dL) e CT (mg/dL) e comparados a mensuração por meio de técnica de ponta de dedo (point of care). Tabelas de contingência (2x2) foram utilizadas para estimar sensibilidade e especificidade dos métodos e o coeficiente de Lin* e análises de *Bland & Altman foram métodos de concordância com nível de significância de 5%. Houve concordância substancial entre os métodos para mensuração de TG e fraca concordância para mensuração de CT e GLI. Os coeficientes de Bland & Altman indicam que o método de ponta de dedo não apresentou boa mensuração. O método point of care não apresentou boa capacidade de mensuração de Glicose, Triglicerídeo e Colesterol total tendo como referência o método laboratorial.*

Palavra-chave *Point of care Systems, Testes Laboratoriais, Avaliação da tecnologia biomédica.*

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Introduction

Advances in laboratory tests for patient diagnosis and follow-up have been implemented in recent years, but the centralization of physical and professional infrastructure in more developed areas limits access to exams in less accessible regions[1].

Limited access to health care in populations located outside of large centers, such as rural populations, *quilombolas*[2], riverside, and *sertanejos*, has been one associated with the high prevalence of health problems in these populations[3,4]. Lack of basic sanitation, geographic distance, and low socioeconomic status do not favor the availability of healthcare human resources; thus, the health monitoring network is fragile at various levels of health care. This difficulty in accessing health care influences disease prevention, health promotion, diagnostic testing, medicine availability[5], treatment administration, post-treatment monitoring[2], and chronic disease screening.

Amongst laboratory tests, blood tests are performed to help diagnose diseases such as diabetes, dyslipidemias, and parasitic and bacterial infections, among others[6,7], as well as for health monitoring.

Fingertip blood collected for glycemic evaluation is already performed for follow-up purposes in patients with diabetes mellitus; there is a certain reliability for this purpose, but not for the diagnosis of this condition[8]. Thus, there is a gap in the reliability of this method for screening for changes in triglyceride, glucose, and total cholesterol levels[9].

This method is convenient and rapid and its sensitivity and specificity have been tested and approved for epidemiological studies in difficult to reach places[10]. However, the *point-of-care* method has been criticized for the accuracy of diagnosis[11], with recommendations for additional studies to determine their accuracy and applicability[12].

In populations such as *quilombolas* and riverside communities, the laboratory methods tests become complex and other methods of measurement are used in an attempt to optimize care. The point-of-care method may provide high sensitivity and specificity and good reliability for the measurement of triglyceride, glucose, and total cholesterol compared to laboratory tests.

Thus, the objective of the present study was to evaluate the sensitivity, specificity, and agreement of the fingertip test compared to those of the laboratory measurements of glucose, triglycerides, and total cholesterol in a *quilombola* community.

Materials and methods

Study design

In accordance with the prior planning, this prospective study collected fasting, venous puncture samples. Following laboratory examinations, measurements were also performed using the point-of-care equipment.

Participants

The study participants were residents of a *quilombola* rural community located in the Southeastern region of the state of Tocantins. The eligibility criteria were:

- Over 18 years of age of both sexes;
- A resident of the community;
- Provided voluntary consent to participate in the research;

Test methods

Index test

The Accutrend Roche Plus® device (enzymatic method) was used to measure capillary parameters. (registration ANVISA: 10287410740). A drop of blood was collected by puncture from the tip of the finger for each tested parameter using a specific reagent strip. The readings were performed immediately after blood collection.

Reference standard

Laboratory tests using conventional enzymatic-colorimetric methods and venipuncture samples were performed to measure the concentrations of glucose (mg/dL), triglycerides (mg/dL), and total cholesterol (mg/dL). Two tubes were collected by venipuncture containing fluoride to evaluate glucose and with a separator gel to obtain blood serum to allow the measurement of cholesterol and triglyceride concentrations. The samples were placed in isothermal cases and transported to the University Laboratory of Clinical Analysis for testing, followed good laboratory practices; we used registered reagents (ROCHE®).

The same classification criteria were used for the index and reference tests.

For the diagnosis of a change in glucose concentration, the normal 8-hour concentration was defined as 126 mg/dL, according to American Diabetes Association guidelines[13]. The evaluation of total cholesterol and triglyceride levels adopted the cutoff values of 200 and 150 mg/dL, respectively, according to the reference values recom-

mended by the V Brazilian Directive on Dyslipidemia and Prevention of Atherosclerosis[14].

Analysis

Contingency (2x2) tables were used to calculate the sensitivity and specificity of the classification methods. To analyze the agreement between the methods, we used Lin's correlation, Spearman's correlation, and Bland & Altman's concordance coefficients. The level of significance was 5%. Stata® was used to perform these analyses (Stata Corp., College Station, USA) 11.0.

Ethical aspects

The following project was approved by the Committee of Ethics in Research with Human Beings.

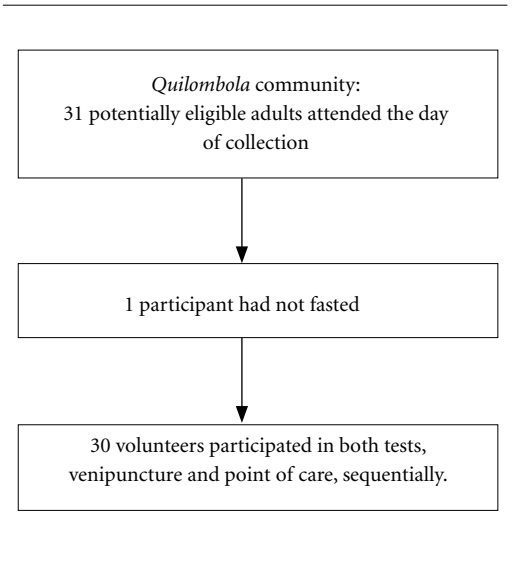

Figure 1. Participant flowchart.

Results

Participants

All residents of the *quilombola* community who met the eligibility criteria were invited to participate voluntarily. Since there are no baseline studies on the use of point of care kits in *quilombola* communities, the sample size calculation was not performed and the number of individuals living in the communities during the study determined the sample size. A survey previously conducted with community leaders estimated the total population of 146 adults and elderly, but only 31 volunteers participated in the study. On the date scheduled for data collection, there were 31 potentially eligible adults. (Figure 1)

Only one of these individuals did not participate in the study because they were not fasting at the time of collection. Thus, blood samples were collected from 30 participants with a mean age of 47 years (SD = 18.28). All participants had been residents of a rural *quilombola* community for more than one year.

Test results

The sensitivities and specificities of the point-of-care method in relation to the laboratory method for the diagnosis of glucose concentration > 126 mg/dL, total cholesterol level > 200 mg/dL, and triglyceride level > 150 mg/dL were 25% and 95.45%, 100% and 69.23%, and 100% and 80%, respectively (Table 1).

The concordance, as assessed by Lin, Spearman correlation, and Bland & Altman concordance coefficients, are shown in Table 2 and plotted in Figures 2, 3, and 4.

There was substantial agreement between the methods for the measurement of triglyceride concentration (Lin coefficient = 0.91, 95% confidence interval [CI] 0.84-0.98), and poor agreement for measuring cholesterol and glucose (Lin coefficient = 0, 86, 95% CI 0.74-0.98, and 0.63, 95% CI 0.44-0.82, respectively). However, analysis based on the Bland & Altman coefficients, suggested that the point-of-care method was not a good procedure for evaluating triglyceride (Bland & Altman = 5.35, 95% CI: -22.50, 95% CI: -70.20, 25.10) or total cholesterol (Bland & Altman = 8.70, 95% CI -18.64; 36.16) concentrations (Table 2).

Discussion

When evaluating the sensitivity, specificity, and agreement of the fingertip test in comparison to those of laboratory measurements of glucose, triglycerides, and total cholesterol concentrations in the *quilombola* community, we found a significant correlation, but comparison of the classification of the results based on the changes in concentrations can result in confusion and, therefore, increased errors in the use of the point-of-care method.

The sensitivity of the point-of-care method showed good results for the measurement of tri-

glycerides and total cholesterol concentrations. As for specificity, the result was satisfactory only for fasting blood glucose assessment, where the test could correctly diagnose approximately 96% of the cases.

Despite few studies on fingertip devices, there is some agreement with the potential for error in the independent measurement of the component to be evaluated (glucose, total cholesterol, or triglycerides)[9,15], as we observed in the present study.

When comparing glycemic rates based on laboratory techniques, similar results were obtained with handheld glucometers, even different brands and models, with close agreement and statistically nonsignificant differences, although the characteristics of these devices, such as fast return times, small sample volumes, and ease of handling are indisputable[16].

The device used in the present study for the analysis of cholesterol levels has shown good accuracy compared to other brands and models. Since dyslipidemia is a risk factor for cardiovascular disease, it is recommended to screen populations; thus, the use of fingertip devices appears to be an appropriate alternative[15].

The characteristics that may influence measurements include pH variations, blood oxygen, hematocrit, changes in microcirculation, and vasopressor therapy in addition to external factors, which include room temperature and incorrect

Table 1. Sensitivity and specificity of laboratory analysis (gold standard) and fingertip point-of-care methods

Evaluated parameter (mg/dL)	Sensitivity (%)	Specificity (%)
Glucose	25	95.45
Cholesterol	100	69.23
Triglycerides	100	80

Table 2. Lin's concordance, Spearman's correlation, and Bland & Altman's concordance coefficients of laboratory and fingertip methods for the measurement of triglyceride, glucose, and cholesterol levels.

Variables	Lin's coefficient (95%CI)				Bland &Altman (95%CI)
		p*	Spearman	p**	
Triglycerides	0.91 (0.84; 0.98)	<0.001	0.4	<0.001	5.35 (-44.16; 54,86)
Glucose	0.63 (0.44; 0.82)	<0.001	0.78	<0.001	-22.50 (-70.20; 25.10)
Total cholesterol	0.86 (0.74; 0.98)	<0.001	0.89	<0.001	8.70 (-18.64; 36.16)

*Lin's coefficient; ** Spearman's correlation; 95%CI: 95% confidence interval

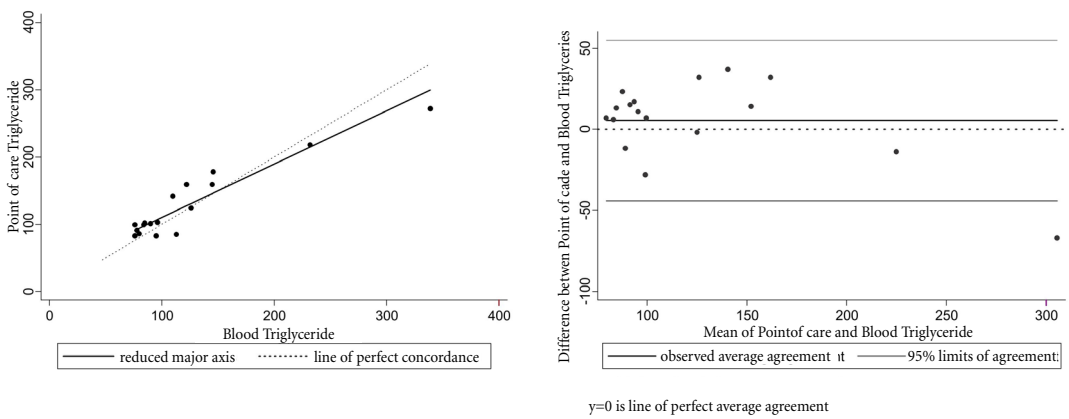

Figure 2. Lin (A) and Bland & Altman (B) correlation coefficients between laboratory and fingertip methods for the measurement of triglyceride levels.

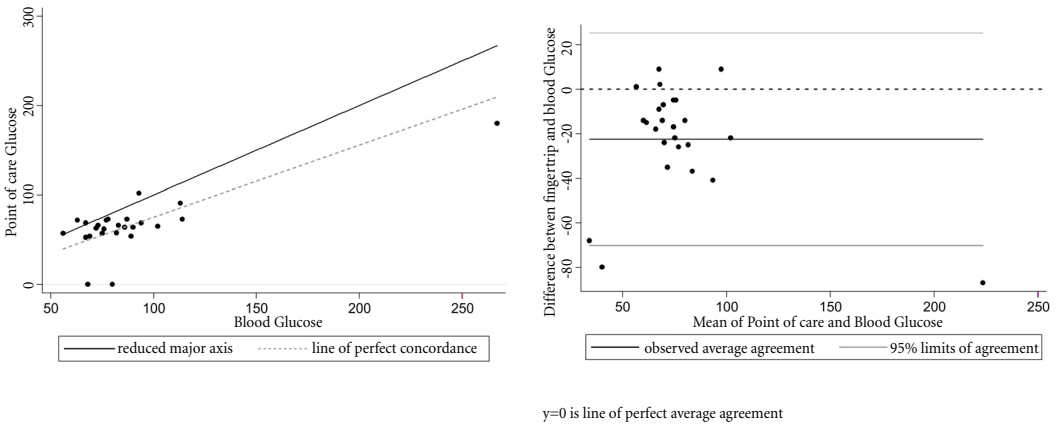

Figure 3. Lin (A) and Bland & Altman (B) correlation coefficients of laboratory and fingertip methods for glucose measurement.

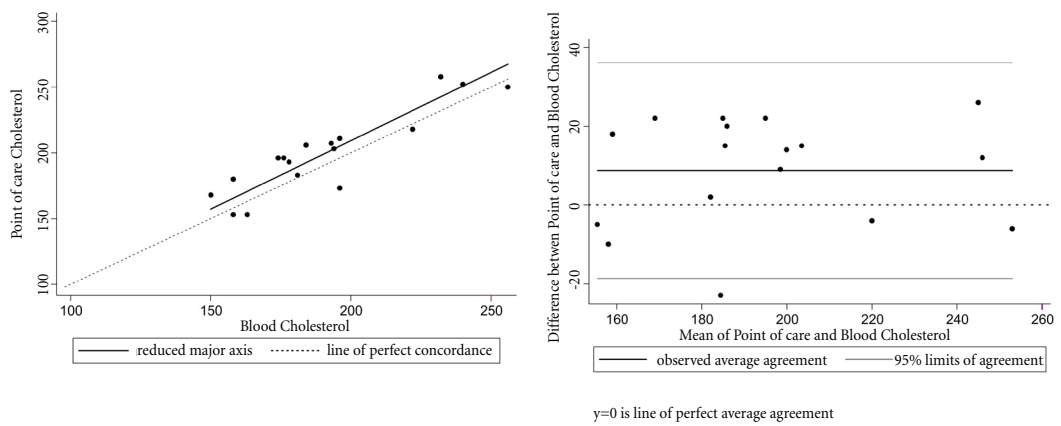

Figure 4. Lin (A) and Bland & Altman (B) correlation coefficients of laboratory and fingertip methods for cholesterol measurement.

handling of reagent tape. These elements alone or combined can significantly impact the accuracy of the devices[17].

Fingertip testing can accelerate clinical management and increase the sensitivity of cardiovascular disease screening campaigns in populations with limited resources[1]. This is a low-cost test for cholesterol and triglyceride assay, which may serve as an alternative strategy for conducting epidemiological studies and screening for cardiovascular diseases in these populations, as these indicators are directly related to cardiovascular events as well as monitoring fasting blood glucose values[10,18].

Point-of-care devices offer a practical option in epidemiological studies, which allows access in places where conventional techniques are limited[10,19]. Since these devices are used in situations with limited resources, the benefits need to outweigh the costs[20] in addition to increasing convenience without sacrificing data reliability.

Cardiovascular disease is the leading cause of death worldwide, with 80% of cardiovascular events occurring in low- and middle-income

countries; thus, reliable data on the prevalence of risk factors in developing countries could be obtained from door-to-door epidemiological studies using automatic devices[2].

Similarly, the prevalence of diabetes has increased in recent years; monitoring is necessary to maintain glycemic control within an acceptable range, both in the hospital and outpatient settings. The accuracy of the measurements plays an important role in treatment decisions for glycemic control[17].

A systematic review of published studies on point-of-care tests in limited resource settings observed that there is no clearly defined metric for the clinical utility of these tests in different pathologies[20]. As there is a risk of error in the diagnosis, especially regarding the critical values, both high and low, that compromise the proper use of the devices[9], the high probability of a measurement error and subsequent unsuitable treatment should be considered when using this technology[21,22].

Based on the concordance methods proposed by Bland & Altman[23] that compare methods and the variation in the observed results, the fingertip test did not appear to be a good predictor for triglyceride, fasting glucose, and total cholesterol indicators in the present study. However, the results of the present study should be interpreted with caution since, although there was statistical agreement between the methods, there were also some limitations.

The main limitation, in this case, was in establishing how acceptable measurement variations are in comparison with the reference method, since these variations may lead to errors in treatment and diagnosis[17]. To minimize the potential bias of the point-of-care method, some researchers have suggested that studies consider retesting with the device[9,21].

In addition, the reduced sample size, despite recruiting the entire resident adult population, is a limitation of the study and may have been responsible for observed variations, limiting statistical inference[24].

Thus, in the present study, there did not appear to be a good correlation between the evaluated methods; the accuracy of the fingertip device was similar to the trends reported in the literature and suggest the need for more evidence on this topic[4-6].

Conclusion

In this study, the point-of-care method did not show a good capacity to measure glucose, triglyceride, and total cholesterol levels compared to the laboratory method in this study population. This result implies the potential for improper classification when using this method. Caution is advised in the use of the point-of-care methods in population and epidemiological studies. Additional studies with larger samples are necessary to demonstrate their usefulness.

Authors' contributions

ES Maciel contributed in the generation of the topic, preparation of proposal, data acquisition, analyses, interpretation drafting and development of the manuscript. FRP Quaresma and FWS Figueiredo contributed to the study design, analysis, and interpretation of results. JS Sarraf and TP Luis contributed to study conception, and interpretation of results. LFC Sesti, FLA Fonseca and F Adami contributed to the interpretation of results and development of the manuscript. All authors read and approved the final manuscript.

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