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ORIGINAL ARTICLE

Agreement Between a Portable Cholesterol Device and Laboratory-Based Testing in Older Adults

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Abstract

Background: It is crucial to monitor blood lipid levels accurately in older adults to assess cardiovascular risk. Although several portable strip-based devices are commercially available, their accuracy has not been well established.

Objective: To evaluate the agreement of the Mission Cholesterol device and standard laboratory method results, using samples from older adults.

Methods: Forty-nine patients (42 females) with an average age of 70 ± 8 years were included. The participants were instructed to fast for 12 hours before undergoing venous and capillary blood sampling for lipid analysis (total cholesterol [TC], high-density lipoprotein cholesterol [HDL-C], low-density lipoprotein cholesterol [LDL-C], and triglyceride [TG] levels). The agreement between the Mission Cholesterol device and laboratory test results was assessed using the concordance correlation coefficient (CCC) and Bland–Altman plots. The accuracy levels were assessed based on the percentage bias recommended by the National Cholesterol Education Program (NCEP).

Results: The TC measurement had a better accuracy level (bias = 10.91%; CCC = 0.89) than other lipid measurements. However, none of them met the NCEP's acceptable standards for bias and concordance (CCC ≥ 0.90). Furthermore, the device demonstrated modest overall agreement in classifying lipid risk according to clinical reference values (agreement rates: TC, 67.3%; HDL-C, 65.3%; LDL-C, 49.0%; and TG, 61.2%).

Conclusion: The Mission Cholesterol device exhibited insufficient agreement levels for effective lipid profile monitoring and screening in older adults.

Keywords: Lipids; Hyperlipidemias; Data Accuracy; Aged.

Introduction

Dyslipidemia is characterized by abnormal concentrations of lipids, such as total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides (TG), in the bloodstream. It is a significant modifiable risk factor for cardiovascular, cerebrovascular, and peripheral vascular diseases, which can lead to premature death.[1]

The Global Burden of Disease Study estimated that high LDL-C levels contributed to 4.4 million deaths worldwide in 2019, accounting for 12.6% of all risk-related deaths.[2] In Brazil, the 2019 National Health Survey highlighted a worrying prevalence of dyslipidemia; 1 out of every 7 adults had high cholesterol levels, and the condition was more prevalent among females and adults of advancing age.[3]

As the population ages, the incidence of dyslipidemia and its associated risks increase. Aging is a critical risk factor for cardiovascular diseases in older adults because it induces endothelial changes that exacerbate the effects of other atherogenic factors.[4] Because of the increasing incidence of dyslipidemia in the aging population and

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Central Illustration: Agreement Between a Portable Cholesterol Device and Laboratory-Based Testing in Older Adults

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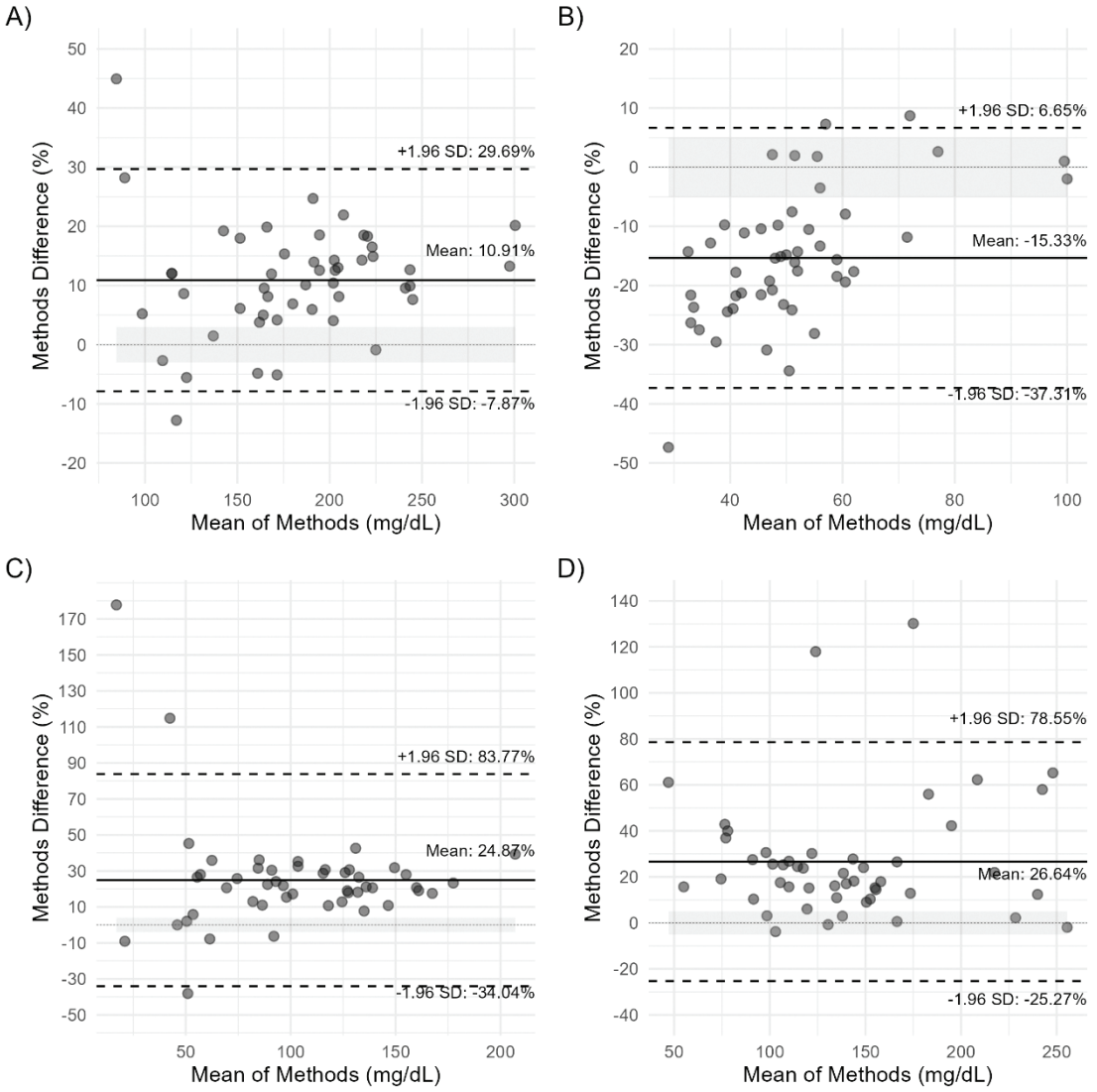

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Bland–Altman plots of the percentage difference between the Mission device and laboratory methods for measuring (A) TC, (B) HDL cholesterol, (C) LDL cholesterol, and (D) TG levels. The solid blue line indicates the mean bias, and the red dashed lines define the upper and lower 95% limits of agreement. The green shaded area indicates the acceptable bias levels recommended by the NCEP. HDL: high-density lipoprotein; LDL: low-density lipoprotein; SD: standard deviation

its serious health implications, there is a pressing need for reliable diagnostic, screening, and self-monitoring methods. Although laboratory analysis is the standard reference method,[5] it has practical limitations in community screening and clinical situations at primary care centers that require rapid results.

Portable strip-based devices for measuring capillary blood lipid levels are easy to handle and carry, making them highly suitable for older adults at increased risk of dyslipidemia. However, the validity and reproducibility of these devices have not been thoroughly evaluated. Kurstjens et al.[6] evaluated several cholesterol self-tests, including the Mission 3-in-1 device, and determined that the devices had variable diagnostic accuracies and inconsistencies in diagnostic performance. Thus, there is a need to comprehensively evaluate the accuracy and

diagnostic capacity of commercially available cholesterol self-test devices, especially those used by older adults who are more prone to dyslipidemia.

Herein, we aimed to evaluate the agreement between the Mission Cholesterol device results and standard laboratory test results, specifically TC, HDL-C, LDL-C, and TG levels, using samples of older adults. This study will bridge the current knowledge gap and determine the reliability of portable capillary blood devices in an aging population that is increasingly being affected by dyslipidemia and its associated complications.

Methods

In this cross-sectional study, the concordance and precision of the portable strip-based Mission Cholesterol device results were assessed against standard automated clinical laboratory test results. Blood samples, both venous and capillary, were collected immediately one after the other to ensure participant safety. The order of collection was determined in advance by a simple random draw without replacement, where each participant received a number for the draw (https://www.randomizer.org/). Participants had been advised to fast for 12 hours. Before sample collection, the participants were required to rest for 15 minutes while seated in a quiet room with a controlled temperature of 28 °C. This study was approved by the local ethics committee (CAAE: 04239518.5.0000.5701), and it adhered to resolution 466/2012 of the National Council of Research Involving Human Beings. Informed consent was obtained in writing from all the eligible participants following screening. All biological materials and sharps were disposed in accordance with the medical waste disposal regulations.

Participants

This study involved a non-probabilistic sampling of older adults who were recruited through posters placed in public establishments (e.g., health centers, pharmacies) and among participants of university extension projects. Initially, 75 individuals volunteered following the recruitment call. Of these, 52 individuals (7 men and 45 women) met the selection criteria and were included in the study. The sample size required for this agreement study was estimated using the approach based on the discordance rate and tolerance probability, as described by Liao.[7] Based on the parameters of a discordance rate (α) of 0.05 (5%), a tolerance probability (β) of 0.95 (95%), and zero allowed discordances (k = 0), the calculated sample size was 59 pairs of measurements. However, due to recruitment limitations and adherence to the inclusion criteria, the final number of participants in the present study was 52 individuals, providing a total of 52 pairs of measurements. This resulted in a tolerance probability (β) of approximately 0.90, slightly below the expected value, but still adequate to assess the agreement between the measurement methods.

The inclusion criteria for the study were as follows: a) individuals aged ≥ 55 years); b) body mass index (BMI) < 35 kg/m^2; c) and nonsmokers who do not use hormone therapy (e.g., testosterone). Non-inclusion criteria included individuals with abnormal liver function tests or elevated creatine kinase concentrations. During the study duration, 3 participants withdrew for personal reasons or were lost to follow-up. The application form completed by the participants included sociodemographic information and anthropometric measurements (weight and height).

Portable cholesterol testing device

The 3-1 panel tests were conducted using the Mission complete lipid profile monitor (ACON Laboratories, Inc., San Diego, California, USA), which is approved by the Brazilian Health Regulatory Agency (registration number: 80102511353). The specific device used in this study (serial number: 80102511353) was purchased through the official distributor, MedLevensohn (Rio de Janeiro, Brazil). The Mission Cholesterol device employs the reflectance photometry method and is capable of quantifying lipids in various biological samples, including heparinized or EDTA-treated whole blood, serum, and heparinized plasma. The device's measurement ranges are 100 to 500 mg/dL (2.59 to 12.93 mmol/L) for TC, 15 to 100 mg/dL (0.39 to 2.59 mmol/L) for HDL-C, and 45 to 650 mg/dL (0.51 to 7.34 mmol/L) for TG. The LDL-C level was estimated using the Friedewald equation.[8]

Before sample collection, a quality control check was performed using the 3-1 lipid panel cholesterol control solutions (lot number: OChM7030015), following the guidelines in the instruction manual. Fresh capillary blood samples (35 µL) were collected via transcutaneous puncture on the upper/medial side of the index finger tip using a sterile disposable lancet. Fingertips were disinfected with 70% alcohol before puncture, and the

first blood drop was wiped away. The following drops were analyzed. All measurements were conducted by a single trained technician. The results generated by the device were promptly recorded and subsequently verified by another laboratory technician to ensure record accuracy.

Laboratory measurements

Whole blood samples were collected from the participants via venipuncture at the antecubital fossa, following tourniquet application for 2 minutes. The samples were collected in red top glass collection tubes (Vacutainer; Becton Dickinson) and allowed to coagulate at room temperature to facilitate serum separation. Subsequently, the samples were centrifuged for 15 minutes at a relative centrifugal force of 1500 g. Thereafter, 1.0-mL aliquots of the resultant serum were carefully extracted and transported to a certified laboratory within the university for biochemical analysis.

The TC, HDL-C, and TG levels were determined using an enzymatic assay. This analysis was performed using an automated analyzer (CMD 600i; Wiener lab, São Paulo, Brazil) and commercial reagent kits (Wiener lab, São Paulo, Brazil). The procedures were performed according to the manufacturer's protocol to ensure the validity of the test results. The LDL-C levels were also estimated using the Friedewald formula.[8] A single skilled technician, who demonstrated proficiency in handling the automated analyzer, was responsible for executing all analyses to maintain consistency. The participating laboratory maintains a rigorous quality control program and has reported average intra-assay variability rates of 1.2%, 2%, and 1.5% for cholesterol, HDL-C, and TG levels, respectively.

Statistical analyses

This study implemented the approach recommended by the National Cholesterol Education Program (NCEP), which has established a specific analytical performance and imprecision level for key lipid parameters such as TC, HDL-C, LDL-C, and TG. A fundamental aspect of this approach is the calculation of percent bias (%), which measures the difference between two methods relative to the reference method values. The NCEP guidelines[9] stipulate that the acceptable bias limits are ≤ ±3% for TC, ≤ ±5% for TG, ≤ ±4% for LDL-C, and ≤ ±5% for HDL-C.

Several metrics were analyzed to assess precision and accuracy, including mean bias, standard deviation (SD) of bias, root mean squared error, coefficient of variation (using mean squared error), and Lin's concordance correlation coefficient (CCC) with 95% confidence interval (CI).[10] We defined agreement between the methods' results as CCC values ≥ 0.90.[9] To evaluate the limits of agreement between the two methods (mean ± 1.96 SD), Bland–Altman plot analysis[11] was performed using percent bias, with the intent of evaluating for compliance with NCEP panel recommendations.

To assess clinical accuracy, we categorized the subjects' lipid levels according to the Adult Treatment Panel III guidelines[9] into the following groups: (1) TC (mg/dL) < 200, 200 to 239, and ≥ 240; (2) HDL-C (mg/dL) < 40, 40 to 59, and ≥ 60; and (3) LDL-C (mg/dL) < 100, 100 to 129, 130 to 159, and ≥ 160. Subsequently, we computed the absolute and relative agreements of the clinical classifications between the methods.

This study focuses on the magnitude of agreement and the qualitative interpretation of bias based on CIs. For the descriptive analysis of numerical variables, the normality of the data distribution was checked using QQ plots, and the data are expressed as the mean ± SD. Qualitative variables are expressed as both absolute and relative values. All statistical analyses were conducted using R (version 4.3.2; R Foundation for Statistical Computing, Vienna, Austria) and the "SimplyAgree"[12] (version 0.1.2) and "ggplot2" (version 3.4.4) packages.[13]

Results

Seventy-five older adults were recruited and assessed for study eligibility. Twenty-three individuals did not meet the inclusion criteria: 10 participants were smokers; 6 were undergoing hormone therapy; and 7 were under 55 years old. Data from 3 participants were excluded because they did not complete the study. Thus, the data from 49 participants were analyzed. The characteristics of the study participants are shown in Table 1.

All analyses were within the measurement range of the device. A comparison of the lipid data between the portable device and standard laboratory method is presented in Table 2. Compared to the laboratory method, the device consistently reported higher values of TC, LDL-C, and TG and lower values of HDL-C. The accuracy and precision indices for TC were superior to those for HDL-C, LDL-C, and TG. Nevertheless, none

Table 1 – Descriptive characteristics of the study participants

Characteristic	All subjects (n = 49)	Female (n = 42)	Male (n = 7)
Age (years)	70 ± 8	70 ± 7	70 ± 12
Age, n (%)			
55 to 60	8 (16.3)	6 (14.3)	2 (28.6)
61 to 70	20 (40.8)	18 (42.9)	2 (28.6)
71 to 80	16 (32.7)	16 (38.1)	0 (0)
≥ 81	5 (10.2)	2 (4.8)	3 (42.9)
BMI (kg/m²)	28 ± 4	28 ± 4	26 ± 4
BMI, n (%)			
20.0 to 24.9	13 (26.5)	10 (23.8)	3 (42.9)
25.0 to 29.9	22 (44.9)	19 (45.2)	3 (42.9)
≥ 30	14 (28.6)	13 (40.0)	1 (14.3)
Erythrocyte (million/mm³)	4.6 ± 0.4	4.5 ± 0.4	4.9 ± 0.4
Hemoglobin (g/dL)	13.4 ± 1.0	13.3 ± 0.9	14.3 ± 1.1
Hematocrit (%)	40.4 ± 3.0	40.0 ± 2.9	44.0 ± 2.8
Medical history			
Diabetes type 2, n (%)	22 (44.9)	20 (47.6)	2 (28.6)
Hypertension, n (%)	37 (75.5)	32 (76.2)	5 (71.4)

Note: Numeric variables are presented as mean ± SD. Categorical variables are presented as absolute (relative) numbers. BMI: body mass index.

of the lipid values measured using the device achieved satisfactory agreement with the laboratory method values, as evidenced by the CCC values below 0.90.

The Central Illustration displays the relative mean differences and dispersion of percentage bias across the measurement range using Bland–Altman plots for each lipid parameter. The percentage biases for TC, HDL-C, LDL-C, and TG exceeded the acceptable ranges defined by the NCEP guidelines. Additionally, the 95% limits of agreement for TC, HDL-C, LDL-C, and TG were broad, indicating considerable measurement uncertainty with the portable device. A limited number of measurements fell within the 3% bias threshold for TC (n = 3), within the 4% bias threshold for LDL-C (n = 2), and within the 5% bias threshold for HDL-C (n = 7) and TG (n = 7). Some data points fell beyond the lower and upper limits, indicating a potential significant divergence between the methods for certain measurements.

Table 3 summarizes the clinical agreement between measurements obtained using the laboratory method and the portable device across different lipid parameters. Agreement rates according to clinical categories demonstrated variable reliability across the different types of lipids measured using the Mission device. However, the device and laboratory methods showed only modest overall agreement for TC, HDL-C, and TG values; the poorest overall agreement was for LDL-C.

Discussion

This study assessed the agreement between the portable Mission device's results (measured TC, HDL-C, and TG levels and calculated LDL-C level) and standard laboratory method results in older adults. Our main findings indicate that, although TC demonstrated the highest accuracy among the lipids tested, no lipid parameter measured using the Mission device achieved satisfactory agreement with the laboratory method results. Moreover, the device's measurements did not comply with the NCEP's acceptable percentage bias standards and demonstrated low clinical agreement. Thus, its reliability for monitoring lipid profiles in older adults remains doubtful.

The accuracy of portable devices is essential, especially because cardiovascular diseases are the leading cause of premature death worldwide.[2] The Mission Cholesterol device is particularly appealing because it provides quick lipid readings and is one of the few devices on the market that measures HDL-C. Its ability to analyze different types of samples, including whole blood, plasma/serum, and capillary blood, makes the Mission Cholesterol device a convenient and flexible option for both clinical and personal use.

In our study, we observed a systematic bias across all lipid measurements. Compared with the standard laboratory method, the device consistently overestimated TC levels by 19 mg/dL (95% CI: 14, 23), TG by 31 mg/dL (95% CI: 22, 40), and LDL-C levels by 20 mg/dL (95% CI: 16, 25). However, it underestimated HDL-C levels by 8 mg/dL (95% CI: −9, −6). The broad range of the limits of agreement (Central Illustration) and the SD of bias (Table 2) highlight a significant and clinically important variability in how the device's readings align with those from the laboratory method.

Table 2 – Accuracy and precision level between lipid variables by device and laboratory methods

	Device	Laboratory					
	Mean ± SD	Mean ± SD	Bias (95% CI)	SD of bias	RMSE	CV (%)	CCC (95% CI)
TC (mg/dL)	190 ± 53	172 ± 42	19 (14, 23)	15	24	5.8	0.89 (0.83, 0.93)
HDL cholesterol (mg/dL)	47 ± 16	55 ± 14	-8 (-9, -6)	6	10	8.0	0.81 (0.72, 0.88)
LDL cholesterol (mg/dL)	113 ± 48	93 ± 38	20 (16, 25)	15	25	10.3	0.85 (0.77, 0.90)
TGs (mg/dL)	155 ± 60	125 ± 46	31 (22, 40)	32	44	16.2	0.70 (0.57, 0.80)

CCC: concordance correlation coefficient; CI: confidence interval; CV: coefficient of variation; HDL: high-density lipoprotein; LDL: low-density lipoprotein; RMSE: root mean squared error; SD: standard deviation; TC: total cholesterol; TG: triglyceride.

These findings contrast with those reported by Quartey et al.[14] They found that HDL-C measurements from the Mission device were within the NCEP's recommended bias percentage limits for both normolipidemic and dyslipidemic samples, despite a slight bias for TG levels in dyslipidemic samples (5.1%) and a more notable bias for TC in normolipidemic samples (11.1%). It is important to highlight that analysis used fresh serum samples, and the study lacked detailed information on the characteristics of the participants and the sample collection process.[14]

Differences in sample processing may account for the discrepancies observed between our findings and those of Quartey et al.[14] Serum samples are typically collected via venipuncture, allowed to clot, and centrifuged to separate the serum. In contrast, capillary blood samples (like those used in our study) can have a significantly different composition from serum because of the mixture of venous, arterial, and interstitial blood. This mixture can result in variations in the concentrations of lipids and other substances.[15,16]

Corroborating our study results, a previous study[6] demonstrated that the Mission device overestimated TC (11%), TG (22%), and LDL-C (21%) levels and underestimated HDL-C (−13%) levels, which deviated from the bias limits recommended by the NCEP guidelines. The ease of capillary blood sampling underlines the device's practicability and viability for self-testing. However, our findings, which agree with those reported by Kurstjens et al.,[6] indicate a poor agreement between the device results and standard laboratory method results. Our data collection, conducted by trained health professionals, suggests the potential for even greater systematic errors in less controlled settings.

Clinical agreement analysis further examined the device's performance. We found only modest agreement rates for TC (67.3%), HDL-C (65.3%), and TG (61.2%) levels between the two methods. This level of agreement, although worrying, becomes even more problematic because of the significantly low agreement for LDL-C levels (49%) between the two methods. Considering the pivotal role of LDL-C levels in the assessment of cardiovascular risk,[1] the reliability of the device's readings for this crucial lipid parameter remains questionable. The disparity in LDL-C readings is especially troubling because it could lead to significant misinterpretations in clinical settings. Incorrect LDL-C levels may misguide treatment strategies and affect patient outcomes.

The strengths of this study include the use of standardized pretesting conditions, such as a 12-hour fasting period and the use of capillary blood samples, which closely resembles the practical usage scenarios of portable devices. Nonetheless, the study has its limitations. The relatively small sample size (n = 49) and the predominance of female participants with comorbidities may limit the generalizability of the results. In addition, even though the serum analyses were conducted in a certified clinical laboratory with low intra-assay variability, independent validation of these analyses was not performed. Furthermore, no evaluations were conducted for potential interferences, such as variations in hematocrit levels due to hydration status or high ascorbic

Table 3 – Clinical agreement between specific ranges of lipid results obtained using the Mission device and laboratory methods

	n	Agreement (n, %)	Disagreement (n, %)
TC (mg/dL)			
< 200	37	26 (70.3%)	11 (29.7%)
> 200 and < 240	10	5 (50.0%)	5 (50.0%)
> 240	2	2 (100%)	0 (0%)
Overall	49	33 (67.3%)	16 (32.7%)
HDL cholesterol (mg/dL)			
< 40	6	6 (100%)	0 (0%)
> 40 and < 60	30	21 (70.0%)	9 (30.0%)
> 60	13	5 (38.5%)	8 (61.5%)
Overall	49	32 (65.3%)	17 (34.7%)
LDL cholesterol (mg/dL)			
< 100	27	20 (74.1%)	7 (25.9%)
> 100 and < 130	14	1 (7.1%)	13 (92.9%)
> 130 and < 160	7	2 (28.6%)	5 (71.4%)
> 160	1	1 (100%)	0 (0%)
Overall	49	24 (49.0%)	25 (51.0%)
TGs (mg/dL)			
< 150	39	25 (64.1%)	14 (35.9%)
> 150 and < 200	7	2 (28.6%)	5 (71.4%)
> 200	3	3 (100%)	0 (0%)
Overall	49	30 (61.2%)	19 (38.8%)

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

acid levels, or the use of dipyrone, which could influence the analytical performance of the automated analyzers used.

Given that the study's sample predominantly consisted of older adult women, one should consider how postmenopausal changes in cholesterol metabolism might influence the discrepancies noted in our analysis. Menopause leads to significant alterations in the lipid profile, such as increase in TC, LDL-C, and TG levels and decrease in HDL-C levels, due to declining estrogen levels.[17] These changes could impact the accuracy of the cholesterol measurement devices employed. The absence of control of the postmenopausal hormonal status may be considered a limitation of this study.

Conclusion

The Mission Cholesterol device demonstrated unsatisfactory accuracy and low agreement levels of lipid profile values in older adults. Thus, using this portable device for capillary blood tests in clinical settings could lead to incorrect interpretations and diagnoses. Healthcare professionals should be cautious about the device's analytical errors and lack of precision. Blood tests performed in laboratories should continue to be the main basis for making clinical decisions. Future studies should include a more diverse and balanced participant pool in terms of sex and health conditions to improve the generalizability of the results and validate these findings.

Author Contributions

Conception and design of the research: Abrahin O, Abrahin RP; acquisition of data: Abrahin O, Souza NSF, Abrahin RP; analysis and interpretation of the data, writing of the manuscript and critical revision of the manuscript for intellectual content: Abrahin O, Souza NSF, Abrahin RP, Crisp AH; statistical analysis: Abrahin O, Crisp AH.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation wor

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the Centro Universitário Metropolitano da Amazônia under the protocol number 04239518.5.0000.5701. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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