International Journal of Medical and Health Research
ISSN: 2454-9142; Impact Factor: RJIF 5.54
Received: 17-12-2019; Accepted: 18-01-2019
www.medicalsciencejournal.com
Volume 6; Issue 2; February 2020; Page No. 137-139

Evaluation of the analytical performance of the *mission cholesterol meter* for serum lipids using NCEP criteria

Perez Quartey[1*], Dordzeavudzi Gator[2], Mayfair Adwapa Mpiani[3], Vivenne Oheming Dapaah[4]
[1-4] Faculty of Health Sciences, Garden City University College, Kenyase, Ghana

Abstract
Introduction: A new point-of-care testing device recently introduced on the Ghanaian medical market is the Mission Cholesterol Meter.
Aim of the study: The overall aim of the study was to evaluate the analytical performance of the *Mission Cholesterol meter* using NCEP performance criteria.
Methods: Same-day testing of fresh normolipidaemic and dyslipidaemic serum samples were done using a certified laboratory method and the *Mission Cholesterol meter* in 10 replicates.
Results: The results showed that the analytical imprecision for all the lipid parameters measured were in the allowable limits. However, the analytical biases for triglycerides and total cholesterol were out of the allowable limits.
Conclusion: The *Mission Cholesterol meter* meets most of the limits of analytical acceptability by the NCEP guidelines. Further validation using a bigger sample size, in terms of its performance to properly classify individuals in different lipid ranges and potential metabolic interference factors is recommended

Keywords: mission cholesterol meter, cardiovascular diseases, dyslipidaemia, imprecision, bias, total analytical error

1. Introduction

Cardiovascular diseases (CVD) are the leading cause of death with increased co-morbidity and socio-economic consequences [1]. The burden of CVD have shown an increasing prevalence in lower and middle-income countries [1, 2]. Dyslipidaemia is considered a primary independent and modifiable major risk factor for cardiovascular disease and consequential controlling of blood lipid levels may reduce the associated risks [3, 4]. Diagnosis and monitoring of dyslipidaemia is therefore significant in achieving reductions in dyslipidaemia. Dyslipidaemia has been reported to be common among hospital attendants in Ghana [5]. Establishment of dyslipidaemia is primarily a laboratory-based assessment [6]. Laboratory measurements to diagnose dyslipidaemia include elevated levels of total cholesterol, low-density lipoprotein cholesterol (LDL-C), triglycerides, and/or decreased high-density lipoprotein cholesterol (HDL-C), as part of the guidelines in assessment of lipaemic status [6]. This requires the existence of a physical laboratory and therefore lacks mobility, presenting a difficulty for use in a field work. To circumvent these potential difficulties, several point-of-care testing (POCT) lipid devices, determining lipid levels in less than 5 minutes have been produced [7, 8]. Presently available devices include CardioChek PA [9], Cholestech LDX [10], Elemark™ [11] and Accutrend® Plus [12] though with reported variations in analytical performance of these devices. A new POCT device recently introduced on the Ghanaian medical market is the *Mission Cholesterol Meter*, which is being used as a cheaper, easy-to-use alternative for routine laboratory lipid measurement. The device can measure a number of lipid fractions and calculated LDL-C in whole blood, plasma or serum and give results in both mg/dl and mmol/l using single-use disposable cartridges. The overall aim of the study was to evaluate the analytical performance of the *Mission Cholesterol meter* in comparison to NCEP performance criteria [13-16] through the estimation of the analytical imprecision, analytical bias, and total analytical error of the device. A supplementary objective was to estimate the correlation between the reported LDL-C results of the device with the manually calculated Friedewald formular for estimation of LDL-C.

2. Materials and methods

2.1. Study protocol

Same-day testing of fresh normolipidaemic and dyslipidaemic serum samples were done using a certified method with an autoanalyzer (Cobas Intergra 400 PLUS) and the Mission Cholesterol meter in 10 replicates. Samples for the Mission Cholesterol meter were measured in both mg/dl and mmol/l units.

2.2. Data analysis

Mean laboratory results of analytes were used as ‘‘reference values’’. Data were expressed as mean ± standard deviation. Coefficient of variation (CV), % bias, and total error were calculated using standard formulas. The analytical imprecision, bias and total error were compared with the recommended limits as set out by NCEP guidelines for analytical goals [Table 1]. Linear regression analysis was done to ascertain the relationship between Friedewald equation for estimation of LDL-C and reported LDL-C results by the Mission Cholesterol meter.

3. Results & Discussion

3.1 General characteristics of normolipidaemic results.

The general characteristics of the normolipidaemic results are displayed on tables 2 and 3. The results showed that the analytical imprecision for all the lipid parameters measured in both mmol/l and mg/dl were all in the allowable limits. The analytical biases and total errors for HDL-C and triglycerides

were also in the allowable limits. However, the analytical biases and total analytical errors for total cholesterol were out of the allowable limits.

3.2 General characteristics of dyslipidaemic results.

The general characteristics of the dyslipidaemic results in mmol/l and mg/dl are illustrated on tables 4 and 5 respectively. The results showed that the imprecision, bias and total analytical errors for both total cholesterol and HDL were in the allowable limits. The analytical biases for triglycerides were minimally out of the allowable limits.

3.3 Relationship between *Mission Cholesterol Meter* LDL results and Friedewald formular

The relationship between reported LDL-C results by the *Mission Cholesterol meter and* Friedewald equation are presented on table 6. The results showed that there was a very good relationship (*p*-value = <0.0001) between manually calculated LDL-C results with the Friedewald formular and those reported by the *Mission Cholesterol meter* measured in mmol/l and mg/dl in both normolipidaemic and dyslipidaemic samples.

3.4 Discussion

Presently, POCT devices provide several potential advantages including portability, low cost, ease of use, instant results and limited physician or laboratory visits [7, 8]. However, there have been reported variations in the analytical performance of these devices in meeting certified analytical
performance acceptability criteria [9-12, 18-24]. Despite these challenges, POCT devices can be critical in the change of service provision in health care delivery. The *Mission Cholesterol meter* was compared to a standard routine laboratory analyser using repeated measurements on both normolipidaemic and dyslipidaemic samples. The *Mission cholesterol meter* results performance was assessed in both mg/dl and SI units (mmol/l). The results showed that the analytical imprecision for all the lipid parameters measured in both mmol/l and mg/dl were all in the allowable limits in both normolipidaemic and hyperlipidaemic samples. The analytical biases and total errors for HDL-C were also in the allowable limits. The analytical bias for triglycerides were slightly out of range so it did not translate into the total error being out of the allowable range. However, the bias for total cholesterol in the normolipidaemic sample was significantly out of range and hence resulted in the total error also being outside the allowable limits. The results suggest that the *Mission cholesterol meter* overestimates total cholesterol and triglycerides because all the reported biases were positive. Additionally, the results showed that the reported LDL-C by the device has a very good correlation with the Friedewald formular for estimation of LDL. However, the study did not evaluate potential influence of factors such as bilirubin, haemoglobin, free glycerol or ascorbic acid on cholesterol and/or triglyceride concentrations using an enzymatic assay as is the case with the *Mission Cholesterol meter*. Therefore, the interference effects of these biomolecules on its accuracy cannot be excluded [25, 26]. Despite the relatively small sample size used, this study showed that most of the lipid parameter measurements were in the acceptable recommended limits as determined by the NCEP criteria.

4. Tables

Table 1: NCEP acceptability criteria

Analyte	Imprecision (%)	Bias (%)	Allowable Total error
Total cholesterol	≤3%	≤ ±3%	≤8.9
HDL	≤4.0	≤ ±5%	≤13%
LDL	≤4	≤ ±4%	≤12
Triglycerides	≤5	≤ ±5	≤15

Table 2: General characteristics of normal sample measured in mmol/l.

Parameter	Mean	SD	Imprecision (%)	Bias (%)	TE (%)
Total cholesterol	3.54	0.05	1.4	10.3$^{\beta}$	12.6$^{\beta}$
HDL-C	0.88	0.03	3.4	4.3	9.91
Triglycerides	1.19	0.04	3.2	4.4	9.7

β: Outside allowable limits; SD: Standard deviation; TE: Total analytical error.

Table 3: General characteristics of normolipidaemic sample measured in mg/dl

Parameter	Mean	SD	Imprecision (%)	Bias (%)	TE (%)
Total cholesterol	138	1.39	1.0	11.1$^{\beta}$	12.8$^{\beta}$
HDL-cholesterol	36.4	1.11	3.1	2.2	7.2
Triglycerides	110.7	4.50	3.2	4.3	9.6

β: Outside allowable limits; SD: Standard deviation; TE: Total analytical error.

Table 4: General characteristics of dyslipidaemic sample measured in mmol/l.

Parameter	Mean	SD	Imprecision (%)	Bias (%)	TE (%)
Total cholesterol	7.16	0.21	2.9	3.3	8.1
HDL-cholesterol	0.69	0.01	1.5	2.8	5.28
Triglycerides	3.42	0.15	4.4	5.3$^{\beta}$	12.56

$^{\beta}$**:** Outside allowable limits; SD: Standard deviation; TE: Total analytical error.

Table 5: General characteristics of dyslipidaemic sample measured in mg/dl.

Parameter	Mean	SD	Imprecision (%)	Bias (%)	TE (%)
Total cholesterol	277.3	9.50	2.11	3.5	7.0
HDL-cholesterol	26.68	0.04	0.15	3.0	3.25
Triglycerides	307.2	23.17	3.23	5.3$^{\beta}$	10.6

$^{\beta}$**:** Outside allowable limits; SD: Standard deviation; TE: Total analytical error.

Table 6: Linear regression analysis of manually calculated LDL-C and Mission Cholesterol meter results.

Sample type and units	r^2	*p-value*
Normolipidaemic (mmol/l)	0.9974	<0.0001
Normolipidaemic (mg/dl)	0.9907	<0.0001
Dyslipidaemic (mmol/l)	0.9907	<0.0001
Dyslipidaemic (mg/dl)	0.9994	<0.0001

5. Conclusions

This is the first independent study on the analytical performance of the *Mission Cholesterol meter* in Ghana and typically assessed the performance in both mg/dl and mmol/l measurements. The study concludes that the *Mission Cholesterol meter* meets most of the limits of analytical acceptability by the NCEP in terms of precision, accuracy and total analytical error. Further validation using a bigger sample size, in terms of its performance to properly classify individuals in different lipid ranges and potential metabolic interference factors is recommended. On the whole, the device system may provide useful information for general screening and the referral of persons at cardiovascular risk. The device should however not be used as a substitution for the certified laboratory methods in the diagnosis of dyslipidemia but can be used in fieldwork and for self-monitoring.

6. References

1. Cardiovascular Diseases. World Health Organization, 2019. Available at www. who.int/ health/factsheet. Accessed January 2020.
2. Horton R. Chronic diseases: The case for urgent global action. Lancet. 2007; 370:1881-1882.
3. Di Angelantino E, Gao P, Pennells L. emerging Risk Factors Collaboration. Lipid-related markers and cardiovascular disease prediction. JAMA. 2013; 307(23):2499-506.
4. Yusuf S, Hawken S, Ounpuu S. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case control study. Lancet. 2004; 364:937-52.
5. Dyslipidemia in Outpatients at General Hospital in Kumasi, Ghana: Cross-sectional Study. Croatian Medical Journal. 2003; 44(5):576-8.
6. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Circulation. 2002; 106(25):3143-421.
7. Taylor JR, Lopez LM. Cholesterol: point-of-care testing. Ann Pharmacother. 2004; 38(7-8):1252-57.
8. Plüddemann A, Thompson M, Price CP, Wolstenholme J, Heneghan C. Point-of-care testing for the analysis of lipid panels: primary care diagnostic technology update. Br J Gen Pract. 2012; 62(596):224-226.
9. Shephard MD, Mazzachi BC, Shephard AK. Comparative performance of two point-of-care analysers for lipid testing. Clin Lab. 2007: 53(9-12):561-566.
10. Whitehead SJ, Ford C, Rousseau G. A combined laboratory and field evaluation of the Cholestech LDX and CardioChek PA point of care testing lipid and glucose analysers. Ann Clin Biochem. 2013; 51(1):54-67.
11. Bolodeoku J, Pinkney S. Imprecision Evaluation of Self-Monitoring of Blood Cholesterol (SMBC) Handheld Point of Care Testing Devices: Elemark™ and Cardiochek PA. Ann Clin Lab Res. 2019; 7(1):290.
12. Scafoglieri A, Tresignie J, Provyn S, Clarys P, Bautmans I. Reproducibility, accuracy and concordance of Accutrend® Plus for measuring circulating lipid concentration in adults. Biochemia Medica. 2012; 22(1):100-108.
13. Current status of blood cholesterol measurement in clinical laboratories in the United States: A report from the Laboratory Standardization Panel of the National Cholesterol Education Program. Clin Chem. 1988; 34:193-201.
14. Bachorik PS, Ross JW. National Cholesterol Education Program Recommendations for low-density lipoprotein cholesterol: Executive summary. Clin Chem. 1995; 41:1414-1420.
15. Stein EA, Myers GL. National Cholesterol Education Program Recommendations for triglyceride measurement: Executive summary. Clin Chem. 1995; 41:1321-1426.
16. Warnick GR, Wood PD. National Cholesterol Education Program Recommendations for measurement of high-density lipoprotein cholesterol: Executive summary. Clin Chem. 1995; 41:1427-1433.
17. Park PH, Isabel C. Hagedorn AK, Bloomfield GS, Pastakia SD. Assessing the accuracy of a point-of-care analyzer for hyperlipidaemia in western Kenya. Tropical Medicine and International Health. 2016; 21:437-444.
18. Santee J. Accuracy and precision of the Cholestech LDX System in monitoring blood lipid levels. Am J Health Syst Pharm. 2002; 59:1774-1779.
19. Taylor JR, Lopez LM. Cholesterol: point-of-care testing. Ann Pharmacother. 2004; 38:1252-1257.
20. Dale RA, Jensen LH, Krantz MJ. Comparison of two point-of-care lipid analyzers for use in global cardiovascular risk assessments. Ann Pharmacother 2008; 42:633-639.
21. Volles DF, McKenney JM, Miller WG, Ruffen D, Zhang D. Analytic and clinical performance of two compact cholesterol-testing devices. Pharmacotherapy. 1998; 18:184-192.
22. Bard RL, Kaminsky LA, Whaley MH, Zajakowski S. Evaluation of lipid profile measurements obtained from the Cholestech LDX analyzer. J Cardpulm Rehabil. 1997; 17:413-418.
23. Gialamas A, Laurence CO, Yelland LN. Assessing agreement between point of care and laboratory results for lipid testing from a clinical perspective. Clin Biochem. 2010; 43:515-518
24. Matteucci E, Bartola LD, Rossi L, Pellegrini G, Giampietro O. Improving CardioCheck PA analytical performance: three year study. Clin Chem Lab Med. 2001; 52:1291-1296.
25. Spain MA, Wu AH. Bilirubin interference with determination of uric acid, cholesterol, and triglycerides in commercial peroxidase-coupled assays, and the effect of ferrocyanide. Clin Chem. 1986; 32:518-21.
26. Martinello F, Luiz da Silva E. Mechanism of ascorbic acid interference in biochemical tests that use peroxide and peroxidase to generate chromophore. Clin Chim Acta. 2006; 373:108-16.