

Cholesterol point-of-care testing (POCT) in epidemiological surveys using CardioChek® PA analyser: A validity and reliability study

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Introduction

- The National Health and Morbidity Survey (NHMS) has been using point-of-care testing (POCT) to screen raised blood cholesterol levels (total cholesterol only) since 2011 (1).
- Parameters of blood cholesterol; total cholesterol (TC), triglycerides (TG), high density lipoprotein (HDL) and low-density lipoprotein (LDL) are important to derive the Framingham risk score to determine the 10-year cardiovascular risk in a patient (2).

Objective

This study was conducted to test reliability and validity of the CardioChek® PA analyser 3-in-1 lipid panel.

Methodology

- Cross sectional study design with quota sampling.
- A total of 203 respondents from a research centre under Ministry of Health Malaysia, aged 18 years and above, were recruited.
- Venous blood was sent to the laboratory while the POCT analyser was used for testing of capillary blood.
- Intraclass Coefficient Correlation (ICC) analysis was employed to determine the agreement between capillary and venous blood readings.
- Diagnostic performance was measured using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).
- Descriptive analysis and reliability analysis using ICC were employed. All data were analysed using SPSS version 22.0.

Results

- A total of 196 respondents' data were analysed for agreement and reliability.

Most (76.8%) of the respondents were female and more than half (54.6%) were aged 18 to 39 years old.

- Agreement between capillary and venous blood using CardioChek® PA analyser 3-in-1 lipid panel was TC: 0.670 (95% CI 0.26, 0.81, $p < 0.001$); TG: 0.913 (95% CI 0.88, 0.94, $p < 0.001$); HDL: 0.638 (95% CI 0.20, 0.82, $p < 0.001$); LDL: 0.749 (95% CI 0.55, 0.85, $p < 0.001$).
- Sensitivity ranged from 47.9% to 75.6%, while specificity ranged from 83.6% to 99.4%.

PPV ranged from 91.9% to 95.8% while NPV ranged from 58.2% to 94.6%.

Table 1: Descriptive results of respondents

	n	%
Overall (n)	196	
Sex		
Male	49	23.20%
Female	145	76.80%
Age		
18-39 years	112	54.60%
40-59 years	72	35.10%
60 years and above	12	5.90%

Table 2: Mean cholesterol levels measured by CardioChek® PA analyser for all parameters

	Total Cholesterol	Triglycerides	HDL	LDL
Mean (%) ± SD	4.68 ± 1.14	1.16 ± 0.63	1.27 ± 0.29	2.94 ± 1.01
Minimum	2.2	0.56	0.69	0.94
Maximum	8.3	5.66	2.35	6.33

Table 3: Diagnostic performance of CardioChek® PA analyser

Capillary vs Lab	Sensitivity (%)	Specificity (%)	Positive Predictive Value (PPV)	Negative Predictive Value (NPV)
Total Cholesterol	53.3	96.6	94.9	63.4
Triglycerides	68.0	99.4	95.3	94.6
HDL	47.9	99.2	95.8	82.8
LDL	75.6	83.6	91.9	58.2

Table 4: Agreement between blood tested by CardioChek® PA analyser versus lab

Capillary versus Lab	Agreement	p value
Total Cholesterol	0.670 (0.259, 0.813)	<0.001
Triglycerides	0.913 (0.878, 0.937)	<0.001
HDL	0.638 (0.199, 0.815)	<0.001
LDL	0.749 (0.548, 0.849)	<0.001

Discussion

- In this study, CardioChek® PA analyser 3-in-1 lipid panel showed moderate reliability between capillary and venous blood for TC and HDL whereas good reliability for TG and LDL.
- The CardioChek® PA analyser is one of the devices recommended by WHO STEPS Surveillance for the measurement

Conclusion

- This analyser is a reliable and valid POCT that can be utilised in epidemiological studies as well as in remote areas with restricted access to laboratories.
- Cardiovascular risk could be estimated in the Malaysian population when utilised in nationwide studies.



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