

Reproducibility, accuracy and concordance of Accutrend® Plus for measuring circulating lipid concentration in adults

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Abstract

Introduction: The determination of lipid biomarkers by capillary sampling may be useful in the screening, diagnosis and/or personal management of hyperlipidemia and cardiovascular risk. It remains unclear whether the use of the Accutrend® Plus system is appropriate. This study aimed to assess its reproducibility, accuracy and concordance for blood lipid profiling in adults.

Materials and methods: Fasting capillary total cholesterol (TC) and triglyceride (TG) concentration on Accutrend® Plus were compared with their venous analogues obtained by a laboratory reference method in sixty-one adults (27 men and 34 women, aged 33.0 years). Supplementary capillary sampling was performed at two consecutive days taking into account macro-nutrient intake.

Results: The day-to-day reproducibility of the Accutrend® Plus system proved to be high for TC (ICC = 0.85, $P < 0.001$), but moderate for TG (ICC = 0.68, $P < 0.001$). Strong correlations ($r \geq 0.80$, $P < 0.001$) with the reference method were found for TC and TG. Mean difference (limits of agreement) were: 0.26 mmol/L (-0.95, 1.47) for TC, and -0.16 mmol/L (-1.29, 0.98) for TG. The concordance for subject classification according to the National Cholesterol Education Program (NCEP) guidelines was significant ($P < 0.001$), with substantial agreement for TC ($\kappa_w = 0.67$), and moderate agreement for TG ($\kappa_w = 0.50$).

Conclusions: Day-to-day reproducibility of the Accutrend® Plus device for TC and TG is not optimal and lacks accuracy when compared to the reference laboratory method. The concordance between both methods for classifying subjects according to the NCEP is inadequate. Accutrend® Plus device should not be interchangeably used as a substitution for the standard laboratory methods in the diagnosis of hyperlipidemia.

Key words: reproducibility of results; cholesterol; triglycerides

Received: September 11, 2011

Accepted: January 04, 2012

Introduction

Elevated concentrations of lipids in the blood have been associated with an increased risk of cardiovascular morbidity and mortality (1). Monitoring cardiovascular disease risk and reducing the onset of cardiovascular events by therapeutic lifestyle changes and drug therapy has received increasing international attention since 1980 (2,3). The detection, evaluation and treatment of hyperlipidemia are based on circulating blood lipid concentrations among which total cholesterol (TC) and triglycerides (TG). The classification of individuals based on lipid profile represents a general guidance for clinical decision making.

In this context, portable devices such as the Accutrend system (Roche Diagnostics GmbH, Mannheim, Germany) offer a number of advantages over conventional laboratory machinery. The major benefits include fast, minimally invasive and easy blood collection, and immediate ambulatory determination of blood lipid profile. In the past, validation of the capillary Accutrend system for the measurement of circulating lipids has led to conflicting results (4-11). In a number of studies, the Accutrend was found to be sufficiently accurate for clinical use; conversely, others concluded that the precision and the control range of the

measuring device (i.e. range of 3.88-7.76 mmol/L for TC and 0.80-6.86 mmol/L for TG) are insufficient for patient evaluation (4-11). The control range is the measurement range in which the Accutrend produces "real" values of the concentration of blood markers. Within this range linearity of the method is insured by the manufacturer. Below or above this measurement range the Accutrend produces no exact values, but gives an indication of the value with "low" or "high". There is evidence indicating that the newly developed Accutrend® Plus device (Roche Diagnostics GmbH, Mannheim, Germany) has been improved for *in vivo* diagnostic use (9). However, validation of this upgraded optical reflectance system is scarcely reported in the scientific literature. Since it remains unclear under which circumstances the use of this particular system is appropriate, the aims of this study were: 1) to determine the day-to-day reproducibility of the Accutrend® Plus device; 2) to assess the accuracy of the Accutrend® Plus system by comparing its results to those obtained by a reference laboratory method for monitoring lipid profile in adults; and 3) to assess the concordance between both methods for classifying subjects according to the National Cholesterol Education Program (NCEP).

Materials and methods

Subjects

Twenty-seven male volunteers with a median age of 32.0 years (ranging from 19 to 70 years) and thirty-four female volunteers with a median age of 33.5 years (ranging from 20 to 69 years) were recruited by advertising in the Greater Brussels area, Belgium. All participants were apparently healthy and without cardiovascular history. The study procedures were in accordance to the World Medical Association's Declaration of Helsinki (12). The study protocol was approved by the local ethical committee and all participants provided written informed consent.

Methods

All venous and capillary blood lipid concentrations were determined in the morning after an over-

night fasting period of at least eight hours. In each subject venous and capillary blood samples were collected at the same time. Supplementary capillary sampling was performed at two consecutive days following the first collection. Capillary TC and TG concentrations were determined with the Accutrend® Plus using two drops of blood (15-40 µL) collected from different fingers, by using a lancing device (Accu-chek® Softclix® Pro, Roche Diagnostics GmbH, Mannheim, Germany). The Accutrend® Plus test is a capillary serum test. It is based on the retention of blood cells by filtration *via* a glass fibre fleece when a drop of blood is applied to the test strip. The enzymatic reaction that takes place in the underlying zone of the strip requires an adequate oxygen supply and results in the formation of a colored oxidation product. The reflectance of the strip (measured at 660 nm) is converted to concentration through a simple algorithm. The intra-assay precision of Accutrend® Plus, as determined by the manufacturer, was 3.7% and 3.4% for TC and TG respectively. The inter-assay precision for Accutrend® Plus determined with control solution by the manufacturer was lower than 5.0% for TC and 2.4% for TG.

Venous blood was collected in Sarstedt S-Monovette® 4.9 mL lithium heparin gel tubes (Sarstedt AG & Co., Nümbrecht, Germany), by using a Termuro® Surflo® winged infusion set (Termuro Europe N.V., Leuven, Belgium). Sera obtained from the venous blood samples were analyzed (blinded for capillary-based values) on a Vitros® 5.1 FS chemistry system (Ortho-Clinical Diagnostics, Johnson & Johnson, Beerse, Belgium), a Cholesterol Reference Method Laboratory Network certified system, using the manufacturer's reagents and calibrators (13,14). For TC and TG, 5.5 µL of sample was measured by multilayer film dry-slide chemistry with colorimetric detection. The intra-assay precision of Vitros® 5.1 FS, as determined by the manufacturer, was 0.7% for TC and TG. The inter-assay precision was 1.5% and 1.4% for TC and TG respectively. Venous blood sample analysis was performed at the hematology laboratory of the Universitair Ziekenhuis Brussel (Brussels, Belgium), an ISO 15189 accredited laboratory for clinical biology. TC concentration was classified as: 'normal'

when TC < 5.18 mmol/L; 'borderline' when 5.18 mmol/L ≤ TC < 6.22 mmol/L and 'high' when TC ≥ 6.22 mmol/L. TG concentration was considered as: 'normal' when TG < 1.69 mmol/L, 'borderline high' when 1.69 mmol/L ≤ TG < 2.26 mmol/L; 'high' when 2.26 mmol/L ≤ TG < 5.64 mmol/L and 'very high' when TG ≥ 5.64 mmol/L (3).

In order to assess differences in daily caloric and nutritional intake all participants completed a self-administered questionnaire containing a personal three-day food diary based on the National Health Survey (a validated instrument used to estimate health-related issues in the Belgian population every 5 years (15)), that started at the day of venous blood collection. Daily nutritional intake was calculated using an online diet planner (Nubel vzw, Brussels, Belgium) supported by the Federal Public Service for Health, Food Chain Safety and Environment (16).

Statistical analysis

The control range of the Accutrend® Plus has not changed compared to the older Accutrend devices (Accutrend GC, Accutrend GCT). Values outside the control range set up by the manufacturer (3.88–7.76 mmol/L for TC, and 0.80–6.86 mmol/L for TG) were excluded for statistical analysis. Normality of all data was verified using Kolmogorov-Smirnov goodness of fit tests.

The day-to-day reproducibility of the Accutrend® Plus system was assessed by computing differences between two consecutive assessments (24 h and 48 h following baseline) using paired samples t-tests and by calculating intra-class correlation coefficients (ICC, model 2.1) (17). The standard error

of measurement ($SEM = \sigma \times \sqrt{1 - ICC}$, with σ = standard deviation of the test and the retest capillary values) and the smallest detectable change ($SDC = 1.96 \times \sqrt{2} \times SEM$) were calculated (18). To verify that test-retest results obtained by the Accutrend® Plus were unaffected by the diet of the volunteers, macro-nutrient intake obtained by 24h food diaries preceding both test and retest were compared by paired samples t-tests or Wilcoxon signed rank tests.

The accuracy of the Accutrend® Plus for measuring TC and TG was determined by comparing the results with those of the simultaneously sampled ve-

nous blood results using paired samples t-tests and Pearson's correlation coefficients. The agreement between capillary Accutrend and reference method was assessed using Passing and Bablok regression and Bland and Altman analysis (19,20). A difference between methods not exceeding 8.9% for TC and 15% for TG, as stated by NCEP recommendations, was regarded as clinically acceptable (3).

Additionally the classification of the participants according to the NCEP for TC and TG was compared between both methods using Fisher's exact tests and weighted kappa statistics (κ_w). For the interpretation of the kappa values the following criteria were applied: $\kappa > 0.80$ "excellent agreement", $0.80 \leq \kappa < 0.60$ "substantial agreement"; $0.40 \leq \kappa \leq 0.60$ "moderate agreement", and $\kappa < 0.40$ "poor to fair agreement" (21).

Data were analyzed by using IBM® SPSS® Statistics version 20 (2011, SPSS Inc., New York, USA) or Medcalc version 12 (Medcalc Software, Mariakerke, Belgium). Group data are expressed as mean ± SD and statistical significance was set at $P < 0.05$.

Results

Out of the 61 measurements obtained by the Accutrend® Plus, one value for TC level (above the higher limit) and 13 values for TG level (11 below the lower limit and 2 above the higher limit) fell outside the measurement range determined by the manufacturer.

Reproducibility of the Accutrend® Plus

No significant differences in calorie or nutrient intake were found between the first and second day of observation (Table 1).

The day-to-day reproducibility of the Accutrend® Plus proved to be high for TC concentration ($ICC = 0.85$, $P < 0.001$), but moderate for TG concentration ($ICC = 0.68$, $P < 0.001$). No significant differences in mean lipid concentration between both assessments were found (Table 2). At a 24 h interval, smallest detectable changes of 0.75 mmol/L for TC concentration and 0.88 mmol/L for TG concentration were found.

Accuracy of the Accutrend® Plus

Table 3 summarizes the results for TC and TG concentration obtained by Accutend® Plus compared with the criterion method.

TABLE 1. Daily caloric and nutrient intake of the volunteers before capillary Accutrend® Plus test and retest assessments.

Parameter	Day 1	Day 2	P
Total energy (kcal)	2153.5 ± 827.9	2241.1 ± 783.5	0.571 ^a
Total energy (kJ)	9008.0 ± 3463.8	9384.3 ± 3272.4	0.560 ^a
Protein (g)	84.6 ± 52.8	80.5 ± 42.6	0.531 ^a
Fat (g)	71.8 ± 32.9	77.5 ± 34.8	0.525 ^a
Saturated fatty acid (g)	24.7 ± 15.7	26.2 ± 13.1	0.674 ^a
Monounsaturated fatty acid (g)	17.3 ± 9.0	17.5 ± 13.5	0.956 ^a
Polyunsaturated fatty acid (g)	8.2 ± 4.5	9.7 ± 8.2	0.363 ^a
Omega-3 fatty acid (g)	0.2 (0.2-0.7)	0.4 (0.2-0.6)	0.147 ^b
Omega-6 fatty acid (g)	3.2 ± 1.8	4.0 ± 3.3	0.290 ^a
Linoleic acid (g)	3.7 ± 2.2	4.3 ± 3.7	0.470 ^a
Trans fatty acid (g)	0.4 ± 0.4	0.5 ± 0.6	0.441 ^a
Cholesterol (mg)	187.7 ± 179.7	162.6 ± 133.5	0.372 ^a
Carbohydrate (g)	228.0 ± 85.2	244.5 ± 87.9	0.317 ^a
Sugar (g)	89.2 ± 45.3	98.8 ± 55.0	0.441 ^a
Amylum (g)	103.3 ± 55.0	103.4 ± 58.8	0.991 ^a
Fiber (g)	14.9 ± 6.6	15.8 ± 8.6	0.475 ^a
Water (g)	1160.2 ± 698.5	1131.0 ± 738.0	0.812 ^a
Alcohol (g)	0.0 (0.0-46.4)	19.8 (0.0-49.5)	0.852 ^b

Data are presented as mean ± standard deviation or as median (interquartile range). ^apaired t-test, ^bWilcoxon signed rank test.

TABLE 2. Measurement reproducibility of capillary lipid concentrations (mmol/L) at 24h interval obtained by Accutrend® Plus.

	N	24 h	48 h	Mean difference (95% CI)	ICC (95% CI)	SEM	SDC	P
Total cholesterol	39	4.83 ± 0.70	4.86 ± 0.70	-0.03 (-0.15-0.10)	0.85 (0.73-0.92)	0.27	0.75	0.670
Triglycerides	29	1.46 ± 0.56	1.46 ± 0.57	0.002 (-0.17-0.18)	0.68 (0.42-0.83)	0.32	0.88	0.975

Data are presented as mean ± standard deviation.

ICC - Intra Class Correlation coefficient (model 2.1); CI - confidence interval; SEM - standard error of measurement; SDC - smallest detectable change.

TABLE 3. Comparison between venous and capillary lipid concentration (mmol/L).

	N	Vitros ¹	Accutrend Plus ²	r	P	Passing-Bablok regression		P
						Intercept (95% CI)	Slope (95% CI)	
Total cholesterol	60	5.18 ± 1.20	4.92 ± 0.78	0.89	<0.001	-1.66 (-2.73-0.71)	1.38 (1.19-1.60)	0.002
Triglycerides	48	1.47 ± 0.89	1.63 ± 0.91	0.79	<0.001	-0.24 (-0.62-0.01)	1.07 (0.85-1.33)	0.067

Data are presented as mean ± standard deviation.

¹ venous - obtained by venipuncture in the anterior cubital region; ² capillary - obtained by pin-prick in the fingertip;

r - Pearson correlation coefficient; CI - confidence interval.

Despite a good correlation for the measurement of TC ($r = 0.89$, $P < 0.001$) between methods, the Accutrend® Plus significantly ($P = 0.002$) underestimated TC concentration. Passing-Bablok regression indicated a systematic (constant and proportional) difference between methods (Figure 1A). For TC, the estimated bias was 0.26 mmol/L (95% CI 0.10 to 0.42) and 95% limits of agreement were (-0.95, 1.47 mmol/L) (Figure 1B).

For the determination of TG a fair correlation ($r = 0.79$, $P < 0.001$) between methods was found without significant difference ($P = 0.067$). Passing and Bablok regression analysis indicated good agreement between methods, without systematic and proportional difference between methods (Figure 2A). Although the small mean difference of -0.16 mmol/L (95% CI -0.32 to 0.01) was not significant, 95% limits of agreement of (-1.29, 0.98 mmol/L) were wide, reflecting substantial variability of individual differences between methods (Figure 2B).

Concordance of the Accutrend® Plus

The classification of individuals according to the NCEP based on lipid profile obtained by both methods is shown in Table 4.

For TC level, the percentage of subjects within 'risk'-groups did not differ between methods ($P < 0.001$, Fisher's exact test). A substantial agreement was found ($\kappa_w = 0.67$). Eighty-two percent of the volunteers were classified in the same group by

the Accutrend® Plus and the reference method, while 18% was classified in a 'lower' risk group by Accutrend® Plus.

For TG level, the percentage of subjects within 'risk'-groups did not differ between methods ($P < 0.001$, Fisher's exact test). A moderate agreement was found ($\kappa_w = 0.50$). Seventy-seven percent of the volunteers were equally classified using values obtained by both methods. Based on the Accutrend® Plus, 7% was classified in a group with 'less' risk, while the remaining 16% was classified in a group at 'higher' risk compared to the reference method.

Discussion

Today the Accutrend® Plus system is used by physicians, nutritionists, patients as well as researchers in screening and diagnosis of hyperlipidemia; or to monitor the effects of diet or drug therapy on lipid profile (22,23). Subjects that are at increased CVD risk may benefit from a user-friendly system to monitor the effects of treatment thus stimulating personal health management. In this context, it has recently been shown that self-monitoring of blood lipids in patients with severe hypertriglyceridemia favors treatment compliance (24). Most of the previous validation studies involving the Accutrend system have been carried out in laboratory circumstances. However this portable device has

TABLE 4. Concordance between Accutrend® Plus and Vitros® 5.1 FS for classifying 61 subjects following total cholesterol and triglyceride levels according to the NCEP guidelines.

		VITROS® 5.1 FS				
		Normal	Borderline high	High	Very high	
ACCU-TREND® PLUS	TC*	Normal	33	6	1	-
		Borderline high	0	13	4	-
		High	0	0	4	-
		Very high	-	-	-	-
ACCU-TREND® PLUS	TG*	Normal	39	1	1	0
		Borderline high	5	3	1	0
		High	2	2	5	1
		Very high	0	0	1	0

NCEP - National Cholesterol Education Program; TC - total cholesterol: normal (< 5.18 mmol/L), borderline high (5.18-6.21 mmol/L), high (≥ 6.22 mmol/L); TG - triglycerides: normal (< 1.69 mmol/L), borderline high (1.69-2.25 mmol/L), high (2.26- 5.63 mmol/L), very high (≥ 5.64 mmol/L); *P < 0.001, Fisher's exact test.

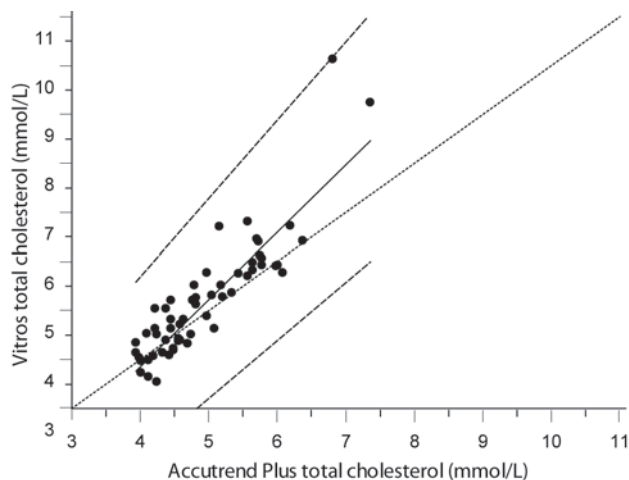


FIGURE 1A. Passing-Bablok regression plot for total cholesterol determined on Vitros® 5.1 FS and Accutrend® Plus, N = 60; concentration range 3.88–7.77 mmol/L; Pearson correlation coefficient $r = 0.89$, $P < 0.001$.

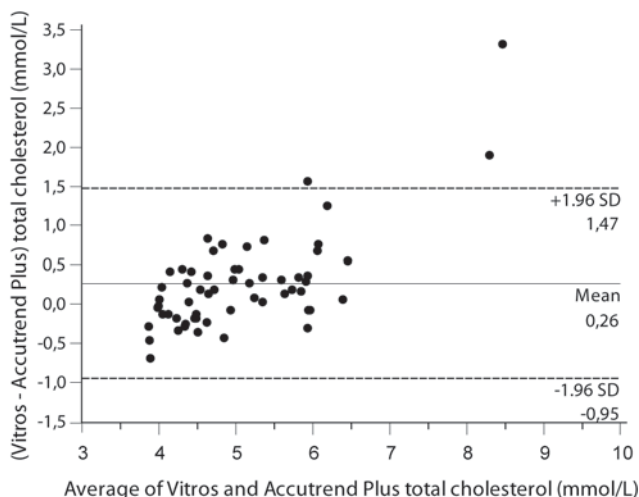


FIGURE 1B. Bland and Altman plot for the difference between Vitros® 5.1 FS and Accutrend® Plus total cholesterol concentration (mmol/L).

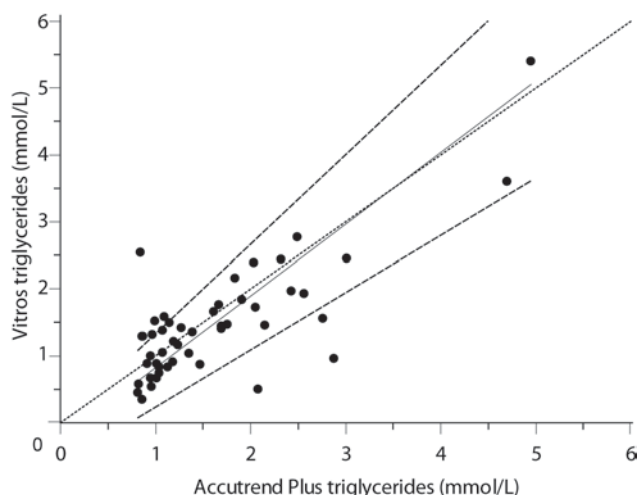


FIGURE 2A. Passing-Bablok regression plot for triglycerides determined on Vitros® 5.1 FS and Accutrend® Plus, N = 48; concentration range 0.79–6.77 mmol/L; Pearson correlation coefficient $r = 0.79$, $P < 0.001$.

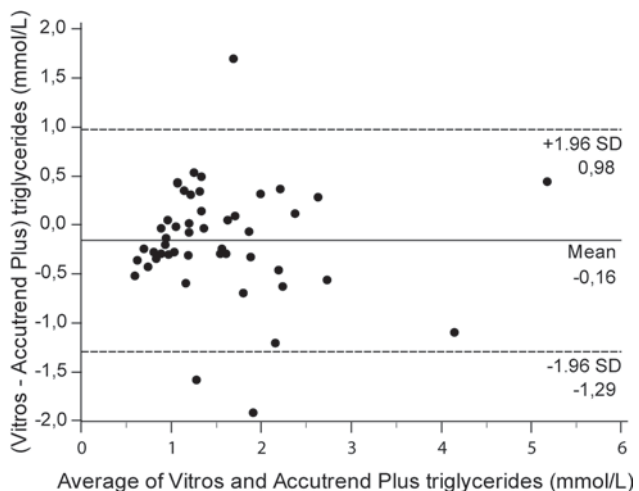


FIGURE 2B. Bland and Altman plot for the difference between Vitros® 5.1 FS and Accutrend® Plus triglyceride concentration (mmol/L).

been designed for home or ambulatory use. This study is the first to validate the Accutrend® Plus outside a laboratory setting.

In the present study, the day-to-day reproducibility of the Accutrend® Plus proved to be high for the measurement of TC (ICC = 0.85) and moderate for TG (ICC = 0.68). Since the measurement of lipid concentration was carried out after a fasting peri-

od of at least 8 hours without differences in nutrient intake 24h before sampling, one might expect similar values at a 24 hour interval. It is generally accepted that an intra-individual biological variability of respectively 3.9% and 14.0% for TC and TG concentration is to be considered as normal (25). Taking this natural variability into account, the day-to-day reproducibility for lipid concentration

by Accutrend® Plus remained within the limits of biological variability. However, day-to-day differences less than 0.75 mmol/L (29 mg/dL) for TC and 0.88 mmol/L (78 mg/dL) for TG are to be considered non-significant. It is therefore suggested that the values mentioned above represent the smallest detectable changes during follow-up using the Accutrend® Plus system.

The results of our study show that capillary blood lipids are well correlated (r -values ≥ 0.80 , $P < 0.001$) with their venous analogues. Bland-Altman analysis showed that, on average, Accutrend® Plus tended to underestimate venous TC by 0.26 mmol/L. This is in agreement with previous findings (7,26). The agreement between methods fell outside clinically acceptable limits of $\leq 8.9\%$, as stated by NCEP recommendations for cholesterol measurement. Further research is required to determine the exact reasons for the consistence differences in TC concentration. In the present study, Accutrend® Plus overestimated venous TG concentration by 0.16 mmol/L. This overestimation in capillary blood has been reported previously (5,10,26,27). Since lipids are being consumed by the cells, fingerstick capillary TG concentration should be higher than venous TG concentration. Therefore, overestimation of TG concentration by the Accutrend® Plus in the present study might be explained by different hemodynamic conditions in the capillary bed. However, the level of agreement between capillary and venous TG resulted in clinically important discrepancies of $\pm 75\%$ (± 1.14 mmol/L), and appeared to worsen with increasing values. This variability should not be ignored when developing a protocol for triglyceride screening.

Based on the 'cardiovascular risk' classification of subjects according to lipid concentration, an acceptable concordance between Accutrend® Plus and the laboratory reference was found. However, the former tended to underestimate CVD risk based on TC concentration, while mainly overestimating CVD risk based on TG level.

All results considered, the present study suggests that day-to-day reproducibility of the Accutrend® Plus device for TC and TG is not optimal and lacks accuracy when compared to the reference laboratory method. The concordance between both methods for classifying subjects according to the NCEP is not adequate. Accutrend® Plus device should not be interchangeably used as a substitution for the standard laboratory methods in the diagnosis of hyperlipidemia.

This study did not evaluate potential influence of bilirubin, hemoglobin, free glycerol or ascorbic acid on cholesterol and/or triglyceride concentration using an enzymatic oxidase/peroxidase assay as is the case with the Accutrend® Plus. Therefore the interference of the above mentioned biomolecules with Accutrend® Plus accuracy cannot be excluded (28,29). However the volunteers in the present study did not follow any specific diet, nor used vitamin supplements or medications, thereby reducing the risk of erroneous measurements.

Conclusion

Accutrend® Plus TC and TG concentration correlates satisfactorily with its laboratory analogue. However, higher precision for the determination of lipid profile is warranted, especially for the measurement of TG concentration. Although the Accutrend® Plus system may provide useful information for the referral of persons at cardiovascular risk, this device should not be used as a substitution for the laboratory methods in the diagnosis of hyperlipidemia. Given its day-to-day reproducibility, the Accutrend® Plus might be used as a system for self-monitoring. Under constant diet circumstances, fluctuations of 0.75 mmol/L (29 mg/dL) for TC and 0.88 mmol/L (78 mg/dL) for TG are to be considered as non-significant.

Acknowledgements

The authors wish to thank Dr. E. Probyn (MD) for her technical assistance.

Potential conflict of interest

None declared.

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Ponovljivost, točnost i podudarnost sustava Accutrend® Plus pri određivanju koncentracije cirkulirajućih lipida kod odraslih

Sažetak

Uvod: Određivanje lipida uzorkovanjem kapilarne krvi može se primijeniti pri probiru, dijagnozi i/ili osobnom praćenju hiperlipidemije i kardiovaskularnog rizika. Pitanje je li sustav Accutrend® Plus primjeren za taj zadatak ostaje još nerazjašnjeno. Ovim istraživanjem želimo procijeniti ponovljivost, točnost i podudarnost sustava pri određivanju lipidnog statusa krvi kod odraslih osoba.

Materijali i metode: Rezultati određivanja koncentracije ukupnog kolesterola (engl. *total cholesterol*, TC) i triglicerida (TG) natašte iz kapilarne krvi na sustavu Accutrend® Plus uspoređeni su s rezultatima analognih pretraga iz venske krvi dobivenih referentnim laboratorijskim metodama kod 61 odrasle osobe (27 muškaraca i 34 žena, median dobi 33,0 godine). Dodatno uzorkovanje kapilarne krvi provedeno je dva dana za redom vodeći računa o unosu makronutrijenata.

Rezultat: Ponovljivost iz dana u dan na sustavu Accutrend® Plus bila je visoka za TC (ICC = 0,85, $P < 0,001$), no umjerena za TG (ICC = 0,68, $P < 0,001$). Za oba parametra TC i TG dobivene su jake korelacije ($r \geq 0,80$, $P < 0,001$) s referentnom metodom. Granice podudaranja srednjih statističkih razlika bile su: 0,26 mmol/L (-0,95, 1,47) za TC, i -0,16 mmol/L (-1,29, 0,98) za TG. Podudarnost za klasifikaciju ispitanika prema smjernicama Nacionalnog programa za edukaciju o kolesterolu (engl. *National Cholesterol Education Program*, NCEP) bila je statistički značajna ($P < 0,001$) sa značajnom podudarnošću za TC ($\kappa_w = 0,67$) te umjerenom za TG ($\kappa_w = 0,50$).

Zaključak: Ponovljivost iz dana u dan na uređaju Accutrend® Plus za TC i TG nije optimalna i nedostaje joj točnosti u usporedbi s referentnom laboratorijskom metodom. Podudarnost između te dvije metode za klasifikaciju ispitanika prema smjernicama NCEP je neodgovarajuća. Uređaj Accutrend® Plus se ne bi trebao primjenjivati kao potpuna zamjena standardnih laboratorijskih metoda u dijagnostici hiperlipidemije.

Ključne riječi: ponovljivost rezultata; kolesterol; trigliceridi