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Performance evaluation of Barozen Lipid Plus for point-of-care testing of lipid profiles: a method comparison study

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Background: The quick and easy nature of point-of-care (POC) testing devices allows regular monitoring of serum lipid levels to increase efficiency. The purpose of this study was to assess a POC lipid analyzer, Barozen Lipid Plus (MICO Biomed Co., Ltd.), which uses capillary blood to measure total cholesterol (TC), triglycerides (TGs), and high-density lipoprotein cholesterol (HDL-C).
Methods: Capillary and venous blood samples were collected from 110 participants at a single center in Korea between June 10 and June 26, 2021. TC, TG, and HDL-C measurements using Barozen Lipid Plus were compared with measurements using our reference device, the Roche-Hitachi Cobas 8000 c702 (Hitachi High-Technologies Corporation). This study followed the guidelines of the Clinical and Laboratory Standards Institute and the Clinical Laboratory Improvement Amendments. We surveyed participants regarding the convenience of the POC device using a questionnaire following the completion of blood collection.
Results: When compared to the reference equipment, the measurements obtained using Barozen Lipid Plus were more than 95% satisfactory within TC ± 10%, TG ± 25%, and HDL-C ± 30%. The coefficient of variation in the repeatability testing was within 5% for TC, 5% for TGs, and 7% for HDL-C. The survey results indicated high levels of satisfaction. No adverse events were reported.
Conclusion: These findings suggest that Barozen Lipid Plus is reliable for measuring lipid profiles and can therefore be used to monitor lipid levels at the time and place of patient care.

Keywords: Cholesterol; Dyslipidemias; Lipids; Point-of-care testing; Triglycerides

Introduction

Dyslipidemia is an imbalance of blood lipid levels characterized by elevated total cholesterol (TC), elevated triglycerides (TGs), elevated low-density lipoprotein cholesterol (LDL-C), and decreased high-density lipoprotein cholesterol (HDL-C). Hypercholesterolemia is a well-established causal factor of atherosclerotic cardiovascular diseases [1]. In 2008, the World Health Organization reported a global hypercholesterolemia prevalence of 39% [2]. Hypertriglyceridemia is observed in up to 35% of acute pancreatitis cases [3]. Furthermore, HDL-C levels are useful in predicting the risk of coronary heart disease [4,5]. In Korea, the prevalence of dyslipidemia increased from 8% in 2005 to 22.3% in 2019 [6].

It is widely advised that adults aged 20 years and older should be tested for traditional atherosclerotic cardiovascular disease (ASCVD) risk factors, including plasma lipid profiles, at least every 4 to

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6 years [7]. In patients with elevated LDL-C levels, LDL-C is measured every 4 to 12 weeks until the target level is reached, repeating the test every 3 to 12 months thereafter to assess adherence [8]. Lipid levels are easily affected by lifestyle changes and drug adherence and therefore require frequent and regular monitoring. Point-of-care (POC) testing devices are widely used in primary care settings because of their convenience. POC testing reduces the discomfort associated with venous puncture, requires smaller volumes of blood, and produces results on the spot.

We conducted a study to test the validity of a new POC lipid analysis device named Barozen Lipid Plus (MICO Biomed Co., Ltd. Seongnam, Korea). In accordance with the guidelines of the Clinical and Laboratory Standards Institute (CLSI) and the Clinical Laboratory Improvement Amendments (CLIA), we evaluated the system accuracy, measurement repeatability, intermediate measurement precision, interference, and patient satisfaction level.

Methods

Ethical statements: This study was conducted in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board (IRB) of Soonchunhyang University Seoul Hospital (IRB No: 2021-03-027). Ethical approval and written informed consent were obtained prior to enrollment.

1. Study design

This study was conducted at a single center in Korea from June 10 to June 26, 2021. Healthy individuals and patients with dyslipidemia aged > 19 years were included in this study. Participants were excluded if they had incapacitating psychological conditions, had a change in medication within 1 month, or had participated in other clinical trials within 1 month. This study followed the CLSI guidelines and 100 participants were required [9]. We recruited 110 participants who met our inclusion criteria, accounting for 10% of possible dropouts during the trial.

Capillary and venous blood samples were collected on the same day from each subject. The fingertip skin was punctured using a lancet, and we obtained up to 300 μL of capillary blood from each participant using a 15-μL capillary tube for multiple testing. Barozen Lipid Plus MMD-1/MLS-2 was used to test the capillary blood. Three test-strip lots manufactured on different dates were used. A single venous blood sample of approximately 4 mL was obtained after capillary blood collection using the conventional method of venipuncture and then tested using the Roche-Hitachi Cobas 8000 c702 standard analyzer (Hitachi High-Technologies Corporation, Tokyo, Japan). In this study, the Roche-Hitachi Cobas 8000 c702 was used as the reference equipment to measure lipid levels twice, conforming to the ISO 17511:20200 metrological traceability requirements [10]. The Roche-Hitachi Cobas 8000 c702 is a widely used chemistry analyzer with proven reliability [11]. The TC, TG, and HDL-C levels were measured. The ambient temperature was maintained at 23°C ± 5°C throughout this clinical trial. The ambient relative humidity was maintained at < 80% and the ambient light was maintained at < 2,000 lux.

Demographic and clinical data were collected by interviewing participants prior to blood collection. The height, weight, and blood pressure of the participants were measured before sampling, along with a general physical examination of all systems. The participants were instructed to report any abnormal reactions during the investigation. After completing the measurement procedures, the participants were asked to complete a feedback survey.

2. Measurement repeatability

Precision was evaluated according to CLSI EP05-A3 [12]. Capillary samples from six concentration ranges were used for repeatability testing of TC, TGs, and HDL-C (Supplementary Table 1). Each sample was allocated to three test-strip lots, and each lot was tested using 10 different Barozen Lipid Plus devices.

3. Intermediate measurement precision

TC, TG, and HDL-C levels were individually divided into three concentration ranges. Capillary samples representing each concentration range were tested with three test-strip lots with 10 different Barozen Lipid Plus devices twice per day (Supplementary Table 2). This measurement was repeated for 10 consecutive days, with each sample resulting in 600 measurements.

4. System accuracy

The measurement procedure and bias estimation were compared between instruments according to CLSI EP09-A3 [13]. Each participant's capillary blood sample was tested on three test strips from three different lots using two different Barozen Lipid Plus meters, resulting in six measurements per participant. These values were compared with those obtained from the participant's venous blood tested on the Roche-Hitachi Cobas 8000 c702. TC, TG, and HDL-C concentrations in blood samples were distributed among four, five, and four groups, respectively, according to clinical relevance (Supplementary Table 3).

5. Interference testing

Based on CLSI EP07, two samples of TC, TGs, and HDL-C were

acquired separately and mixed with 11 potentially interfering substances [14]. The 66 samples were tested with three test-strip lots using two Barozen Lipid Plus devices, and each measurement was repeated five times. The same samples were tested without the interfering substances, also using three test-strip lots and two devices and repeating each measurement five times. These values were compared with the measurements obtained using the reference equipment.

6. Barozen Lipid Plus (MMD-1/MLS-2)

Barozen Lipid Plus is a compact POC device that measures blood TC, TG, and HDL-C levels. The measurement ranges for TC, TGs, and HDL-C were 50 to 450 mg/dL, 30 to 650 mg/dL, and 10 to 100 mg/dL, respectively. The results are reported in the following order: TC, TGs, HDL-C, LDL-C, TC/HDL-C, and LDL-C/HDL-C, first in mg/dL and then in mmol/L. Similar to portable glucometers, this device uses capillary blood injected into a dedicated test strip. The measurement takes up to 3 minutes. The device is powered by three AAA batteries and weighs up to 91 g.

7. Statistical analysis

Data analysis was performed according to the requirements of CLIA. Passing-Bablok regression analysis was performed to examine accuracy. Other data were evaluated using the mean, standard deviation, and coefficient of variation (CV). All statistical analyses were performed using Microsoft Excel 2016 (Microsoft Corporation, Redmond, WA, USA) and SAS version 9.4 (SAS Institute Inc., Seattle, WA, USA) at a significance level of 0.05.

Results

The age and sex distributions of the participants included in this study are presented in Table 1. This study included 110 participants, 37.3% of whom were in their twenties. Fifty-three participants (48.2%) were male.

1. Measurement repeatability evaluation

For all six concentration levels of TC, TGs, and HDL-C, the CV was within 5%, 5%, and 7%, respectively (Table 2).

Table 1. Demographic information of participants

Variable	Total
No. of patients	110
Age (yr)	
20s	41 (37.3)
30s	27 (24.5)
40s	23 (20.9)
50s	12 (10.9)
≥ 60s	7 (6.4)
Male sex	53 (48.2)

Values are presented as number only or number (%).

Table 2. Measurement repeatability for total cholesterol, triglycerides, and HDL cholesterol obtained by the Barozen Lipid Plus

Level	Lot	Total cholesterol (mg/dL)		Triglyceride (mg/dL)		HDL cholesterol (mg/dL)	
		Mean ± SD	CV (%)	Mean ± SD	CV (%)	Mean ± SD	CV (%)
1	1	112.6 ± 5.2	4.6	69.0 ± 3.2	4.7	16.9 ± 1.0	6.1
	2	107.1 ± 4.9	4.6	68.6 ± 3.3	4.8	17.3 ± 1.2	6.8
	3	107.1 ± 4.8	4.5	69.2 ± 3.2	4.6	16.9 ± 1.1	6.5
2	1	153.3 ± 7.1	4.6	159.2 ± 7.2	4.5	32.1 ± 2.0	6.2
	2	154.5 ± 6.9	4.5	157.8 ± 7.5	4.8	33.8 ± 2.1	6.2
	3	154.1 ± 6.9	4.5	158.9 ± 7.2	4.6	31.7 ± 2.0	6.2
3	1	216.4 ± 9.8	4.5	255.2 ± 11.0	4.3	44.2 ± 2.8	6.4
	2	206.7 ± 9.0	4.4	256.1 ± 11.3	4.4	42.0 ± 2.6	6.1
	3	207.1 ± 9.3	4.5	268.6 ± 11.7	4.4	44.1 ± 2.7	6.2
4	1	257.2 ± 11.6	4.5	356.2 ± 15.4	4.3	65.3 ± 3.8	5.9
	2	255.6 ± 11.4	4.4	359.4 ± 14.8	4.1	62.2 ± 3.5	5.7
	3	255.3 ± 12.2	4.8	379.8 ± 15.9	4.2	65.4 ± 3.7	5.7
5	1	312.6 ± 14.5	4.7	412.1 ± 18.9	4.6	77.2 ± 5.0	6.5
	2	314.0 ± 14.0	4.4	409.8 ± 18.9	4.6	76.9 ± 4.9	6.4
	3	311.6 ± 14.1	4.5	390.3 ± 17.9	4.6	74.3 ± 4.9	6.6
6	1	384.1 ± 16.3	4.3	639.0 ± 25.8	4.0	93.4 ± 5.2	5.6
	2	397.3 ± 17.5	4.4	606.9 ± 25.4	4.2	94.6 ± 5.1	5.4
	3	382.5 ± 17.1	4.5	639.7 ± 26.2	4.1	93.2 ± 5.3	5.6

Barozen Lipid Plus: MICO Biomed Co., Ltd. Seongnam, Korea.
HDL, high-density lipoprotein; SD, standard deviation; CV, coefficient of variation.

2. Intermediate measurement precision evaluation

For all three concentration levels of TC, TGs, and HDL-C, the CV was within 5%, 5%, and 7%, respectively (Table 3).

3. System accuracy evaluation

Passing-Bablok regression analysis revealed an excellent correlation for the values obtained between the Barozen Lipid Plus and Roche-Hitachi Cobas 8000 c702 systems. The correlation coefficients for TC, TG, and HDL-C levels were 0.977, 0.993, and 0.984, respectively. The regression coefficients for TC, TG, and HDL-C levels were 0.958 (95% confidence interval [CI], 0.942–0.974), 0.980 (95% CI, 0.971–0.989), and 0.936 (95% CI, 0.923–0.949), respectively. In accordance with the CLIA guidelines, we confirmed that the tolerance was greater than 95% for TC ± 10%, TG ± 25%, and HDL-C ± 30% (Table 4, Fig. 1).

4. Impact of potential interfering substances

Eleven potential interfering substances (acetaminophen, ascorbic acid, citric acid, ibuprofen, urea, unconjugated bilirubin, uric acid, heparin [Li], heparin [Na], K_2-ethylenediaminetetraacetic acid, and caffeine) were evaluated in accordance with the CLSI and CLIA guidelines. No substance produced a measured value of more than ± 10% of the control sample value without the substance, thus meeting the acceptance criteria (Table 5).

5. Questionnaire and adverse reactions

The questionnaire analysis to evaluate the convenience of the POC cholesterol measuring device showed relatively high satisfaction. A total of 81.8% of the participants found the measuring system easy to use by themselves (Supplementary Table 4). No adverse reactions were observed or reported during this clinical trial (Supplementary Table 5).

Discussion

Lipid profiles have been widely evaluated for disease prevention and management. LDL-C, the most abundant apolipoprotein B-100 (ApoB)-containing lipoprotein, is the established cause of ASCVD, and efforts to lower LDL-C levels are being made to reduce the risk of cardiovascular events [15]. TGs, which are found in ApoB-containing lipoproteins, also increase the risk of ASCVD [16]. With its inverse relationship with ASCVD, HDL-C aids in the prediction of cardiovascular events; however, its preventive role has not yet been proven [17,18]. The LDL-C target goal is tailored to the level of cardiovascular risk determined by age, sex, race, region, TC level, HDL-C level, blood pressure, smoking status, and comorbidities: < 116 mg/dL, < 100 mg/dL, < 70 mg/dL, and < 55 mg/dL for low-, moderate-, high-, and very high-risk groups, respectively [19-21]. The treatment goal for lowering TGs has not

Table 3. Measurement precision for total cholesterol, triglycerides, and HDL cholesterol obtained by the Barozen Lipid Plus

Level	Lot	Total cholesterol (mg/dL)		Triglyceride (mg/dL)		HDL cholesterol (mg/dL)	
		Mean ± SD	CV (%)	Mean ± SD	CV (%)	Mean ± SD	CV (%)
1	1	167.1 ± 7.9	4.74	82.5 ± 3.7	4.49	26.5 ± 1.6	5.95
	2	165.7 ± 6.9	4.16	81.5 ± 3.6	4.41	27.2 ± 1.4	5.11
	3	166.7 ± 5.4	3.24	82.9 ± 3.7	4.43	26.7 ± 1.3	5.04
2	1	223.6 ± 10.4	4.64	152.0 ± 6.5	4.28	52.9 ± 3.2	6.05
	2	223.2 ± 10.0	4.46	153.3 ± 6.7	4.39	53.6 ± 2.4	4.43
	3	227.0 ± 10.1	4.47	150.5 ± 6.8	4.50	52.8 ± 2.2	4.24
3	1	251.0 ± 11.4	4.52	217.8 ± 8.4	3.87	80.4 ± 4.6	5.68
	2	255.1 ± 10.9	4.27	202.5 ± 9.0	4.45	79.7 ± 3.4	4.22
	3	251.9 ± 11.8	4.67	202.5 ± 8.7	4.29	79.7 ± 3.3	4.18

Barozen Lipid Plus: MICO Biomed Co., Ltd. Seongnam, Korea.
HDL, high-density lipoprotein; SD, standard deviation; CV, coefficient of variation.

Table 4. Measurement accuracy of the Barozen Lipid Plus compared to that of the Roche-Hitachi Cobas 8000 c702

Variable	Correlation coefficient	Regression coefficient (95% CI)	Coefficient of determination	Accuracy within ± 5%	Accuracy within ± 10%
Total cholesterol	0.977	0.958 (0.942–0.974)	0.9544	440/660 (66.7%)	660/660 (100%)
Triglyceride	0.993	0.980 (0.971–0.989)	0.9858	654/660 (99.1%)	660/660 (100%)
HDL cholesterol	0.984	0.936 (0.923–0.949)	0.9683	655/660 (99.2%)	660/660 (100%)

Barozen Lipid Plus: MICO Biomed Co., Ltd. Seongnam, Korea; Roche-Hitachi Cobas 8000 c702: Hitachi High-Technologies Corporation, Tokyo, Japan.
CI, confidence interval; HDL, high-density lipoprotein.

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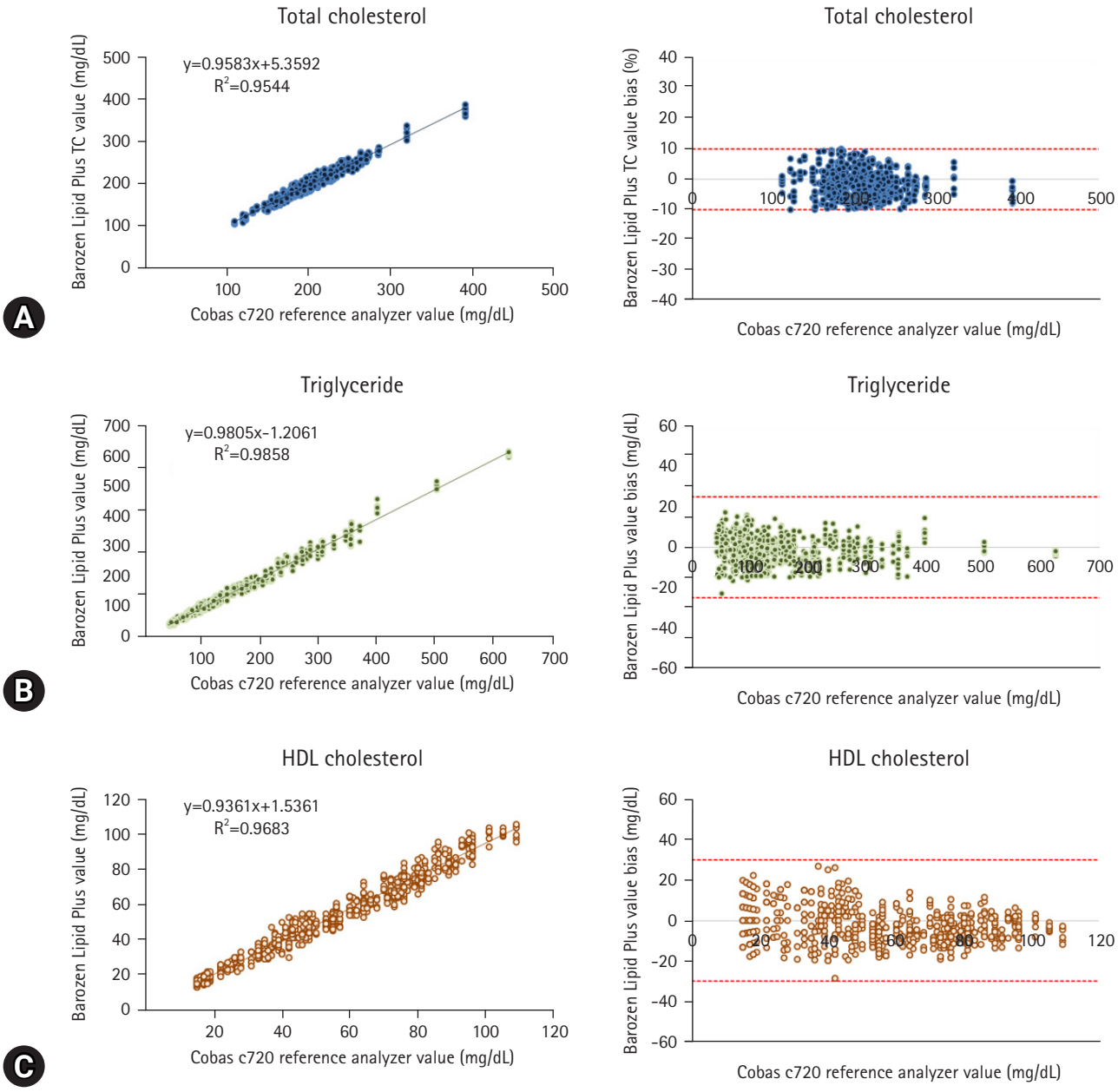

Fig. 1. Passing-Bablock regression analysis of the correlation between Barozen Lipid Plus (MICO Biomed Co., Ltd. Seongnam, Korea) and Roche-Hitachi Cobas 8000 c702 (Hitachi High-Technologies Corporation, Tokyo, Japan) for (A) total cholesterol (TC), (B) triglycerides, and (C) high-density lipoprotein (HDL) cholesterol.

yet been established, although TG levels of > 150 mg/dL are known to increase cardiovascular risk [22]. Therefore, based on the 2019 European Society of Cardiology/European Atherosclerosis Society guidelines, drugs that lower TG levels can be considered for high-risk patients when their TG level is > 200 mg/dL [19]. TG-lowering drugs are also used in hypertriglyceridemia-induced acute pancreatitis, as TG levels of > 500 mg/dL are associated with an increased risk [23].

Current medical evidence does not indicate exactly which test should be performed at which intervals [24]. The expert consensus is to test the patient's lipids twice at an interval of 1 to 12 weeks before beginning treatment and 4 to 12 weeks after starting lipid-lowering treatment or adjusting the treatment dose [8,19]. Dietary habits, body weight, physical activity, alcohol consumption, and smoking significantly affect lipid profiles. These lifestyle factors can change daily, consequently causing fluctuations in lipid

Table 5. Impact of potential interfering substances using the guidelines of the Clinical and Laboratory Standards Institute and Clinical Laboratory Improvement Amendments

Interfering substance	Highest interference level tested (mg/dL)	Therapeutic/physiologic concentration range (or upper limit) (mg/dL)	Total cholesterol % recovery			Triglyceride % recovery			HDL cholesterol % recovery		
			147 mg/dL	200 mg/dL	241 mg/dL	58 mg/dL	175 mg/dL	210 mg/dL	17 mg/dL	48 mg/dL	81 mg/dL
Acetaminophen	16	5.2	101.2	101.1	102.2	99.1	102.3	101.9	101.2	101.4	99.7
Ascorbic acid	5	2	101.1	102.1	102.0	99.8	101.2	101.8	101.1	102.7	100.5
Citric acid	30	1.7–3.0	102.2	102.0	101.3	99.8	102.5	102.1	101.2	100.5	101.6
Ibuprofen	22	7.3	101.2	101.2	102.0	99.1	101.0	101.6	101.1	101.8	100.7
Urea	120	6–20	100.7	102.7	101.5	99.4	101.9	102.2	101.1	101.3	101.7
Bilirubin [unconjugated]	40	0–2	101.2	102.2	102.7	98.7	102.5	102.3	101.2	101.4	100.3
Uric acid	24	2.3–7.6	101.6	101.2	100.7	98.7	101.7	101.6	101.1	102.2	100.2
Heparin (Li)	330 μg/dL	110 μg/dL	101.9	102.4	101.5	99.8	101.9	102.1	101.1	99.6	101.0
Heparin (Na)	330 μg/dL	110 μg/dL	101.2	100.9	101.5	99.0	101.3	102.6	101.2	100.5	100.5
K_2-EDTA	0.1	0	101.6	101.3	101.9	98.7	102.5	102.1	101.2	103.6	101.6
Caffeine	10.8	3.6	100.6	102.0	100.9	99.5	101.9	101.7	101.1	100.0	99.1

HDL, high-density lipoprotein; EDTA, ethylenediaminetetraacetic acid.

measurements [25]. For this reason, regular and frequent lipid monitoring has been shown to enhance treatment adherence and improve disease management [26-28]. General practitioners and patients were also satisfied with POC cholesterol testing in terms of convenience, efficiency, and cost [29]. POC devices are minimally invasive, enable rapid diagnoses, and are available at clinical management sites for efficient patient care. They also decrease examination costs and diminish the space requirements for large equipment and storage, thus allowing use in smaller primary care settings. Barozen Lipid Plus integrates all the aforementioned advantages of POC testing for screening and monitoring plasma lipids. Full lipid profiles of TC, LDL-C, HDL-C, and TGs are recommended for lipid measurements, all of which are provided by Barozen Lipid Plus. Based on our study results, the measurements using the POC device were reliable, although the CVs for HDL-C were higher than those for TC and LDL-C. This may be due to the smaller interval ranges defined in the Supplementary Tables. The ratio of TC to HDL-C is also reported by this device, which, in an analysis of data from the Framingham study, showed an association with coronary heart disease, whereas LDL-C did not [4]. Therefore, our findings suggest that the POC lipid analyzer is an easy and effective way to test lipids that is especially well-suited for primary care settings. Further meta-analyses on the reliability of different POC lipid analyzers will be helpful for broader implementation in clinical settings.

This study had some limitations. First, the fasting duration was not specified. Although studies have shown that fasting is not routinely required, many clinicians still ask their patients to fast for 8 to 12 hours in accordance with the National Cholesterol Education Program guidelines [30,31]. This study did not require the participants to fast; this inconsistency may have affected the test results. Second, this device uses the Friedewald formula, LDL-C = TC−HDL-C−(TG/5), which limits its use in monitoring patients with TG levels of > 400 mg/dL. This formula is known to become less accurate as TG levels increase, especially when LDL-C is < 70 mg/dL [32,33]. Nonetheless, it is the most widely used formula to determine LDL-C levels, and most treatment guidelines for dyslipidemia have been developed based on studies performed using calculated LDL-C levels. In the primary care setting, the use of calculated LDL-C is assumed to be sufficiently accurate [34]. Third, the measurement of non-HDL-C and ApoB is recommended in patients with diabetes or hypertriglyceridemia and concomitantly low LDL-C levels, which the Barozen Lipid Plus does not measure [35-37].

In conclusion, when compared with the Roche/Hitachi Cobas 8000 c720 reference device, the performance of the Barozen Lipid Plus was acceptable in terms of system accuracy, precision, and potential substance interference according to the CLSI and CLIA guidelines.

Supplementary materials

Supplementary Tables 1 to 5 can be found via https://doi.org/10.12701/jyms.2023.00528.

Notes

Conflicts of interest

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

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Author contributions
Conceptualization, Formal analysis, Project administration: all authors; Data curation, Software: SY, HS; Resources, Supervision: SY, BWY; Methodology, Investigation, Visualization, Validation: SY; Writing-original draft: SY; Writing-review & editing: SY, BWY.

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