Clinical Evaluation of a Disposable Test Strip for Potassium Level Measurement in Patients Treated with Maintenance Hemodialysis

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Key Points
- Potassium level test strip showed excellent performance with accuracy and reliability in experimental setting with standard electrolyte solutions.
- Potassium levels obtained with test strips yielded satisfactory agreement with those measured by central laboratory equipment.

Abstract

Background Hyperkalemia is a common electrolyte imbalance leading to an increased risk of serious cardiac dysrhythmias and mortality in patients undergoing hemodialysis. A convenient point-of-care testing (POCT) of potassium levels is considered to improve patient outcomes. However, POCT for potassium level using capillary blood with satisfactory performance is not available.

Methods We tested the performance of disposable test strips for potassium level using various concentrations of potassium solutions with or without interfering electrolytes in an experimental setting. Subsequently, we examined the agreement between potassium levels measured by disposable test strips and those measured by central laboratory equipment using various types of blood samples, including capillary blood obtained by finger prick, in 40 patients undergoing maintenance hemodialysis. In the analysis, Passing-Bablok regression and Bland-Altman analysis were used.

Results Potassium concentrations measured by disposable test strips showed a high degree of agreement with potassium levels achieved using inductively coupled plasma atomic emission spectroscopy. The coefficient of variations for disposable test strips were <5% across potassium concentrations ranging from 2 to 9 mM. Furthermore, potassium levels measured by disposable strips from capillary blood demonstrated a high degree of agreement with potassium levels obtained by central laboratory equipment using serum, showing the slope achieved from Passing-Bablok regression was 1.04 (95% confidence interval, 0.97 to 1.12). Additional analysis with various blood samples also showed similar results.

Conclusions POCT for potassium level using the disposable test strip could be used for self-monitoring of blood potassium levels in clinical practice.

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Introduction

CKD is a global health concern affecting approximately 850 million persons worldwide, approximately 10% of global population.[1–4] CKD is associated with a higher risk of premature death and contributed to 3.1 million deaths worldwide in 2019.[4,5] In addition, patients with CKD are at increased risk of various comorbidities, such as hypertension, cardiovascular disease, and electrolyte imbalances, compared with general population.[4–6]

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Patients with ESKD who receive maintenance hemodialysis have the highest risk of comorbidities and mortality.[7–12] Among various morbid conditions, hyperkalemia is a critical issue leading to an increased risk of serious cardiac dysrhythmias and mortality in patients undergoing hemodialysis.[6–9,12–14] Accordingly, monitoring potassium levels is an important component in the management of patients treated with maintenance hemodialysis.[15,16] Given the clinical significance of potassium level disturbances, frequent monitoring of blood potassium concentration has been considered as a measure to improve outcomes in these patients.[6] However, a hurdle exists for measuring potassium levels, including a need to visit a medical facility, blood sampling, and a time lag between the blood draw and result reporting. Hence, a convenient point-of-care testing (POCT) for potassium levels is of merit. However, such a reliable and brief test using capillary blood obtained by a finger prick is not practically available.[17]

In this context, we examined the performance of a disposable test strip for potassium level measurement and evaluated the validity of the device for measuring potassium levels in patients undergoing maintenance hemodialysis.

Methods

Study Design and Participants

This prospective, method-comparative study was conducted at a single tertiary care hospital (Severance Hospital, Seoul, Republic of Korea) between January 2025 and May 2025. The study protocol, including data collection and analysis, was determined before study initiation. This study was approved by the Institutional Review Board of Severance Hospital (No. 4-2023-0352) and conducted in accordance with the provisions of the Declaration of Helsinki. All participants were informed of the study and provided written informed consent.

Participants were eligible for enrollment if they were 19 years or older and undergoing outpatient or inpatient hemodialysis for kidney failure with replacement therapy. The exclusion criteria were as follows: (1) unwillingness of inability to provide written informed consent, (2) current malignancy treated with chemotherapy or radiotherapy, and (3) pregnancy or lactation. The enrollment was conducted in a consecutive manner until a total of 40 participants were enrolled.

Sample Collection and Potassium Level Measurements

The blood sampling procedures for agreement tests are shown in Figure 1. In brief, capillary blood samples were obtained immediately before the initiation of the dialysis session at the fingertips using a lancet. To minimize the issue of hemolysis, any manipulation of the fingertips, such as squeezing, was strictly prohibited and used capillary blood that spontaneously bled on prodding with a lancet. Then, the capillary blood samples were loaded onto disposable test strips for potassium level measurement (THEDONEE Inc., Seoul, Republic of Korea) and analyzed using a portable electrochemical meter (THEDONEE Inc.). Simultaneously, venous blood samples were collected through a dialysis line to minimize hemolysis during the initiation of dialysis treatment. The time intervals between the capillary blood sampling and venous blood collection were <5 minutes. The venous blood samples were drawn into vacuum tubes containing acrylic gel (AB Medical Co., Gwangju, Republic of Korea) or lithium heparin (Becton Dickinson, Franklin Lakes, NJ) to separate serum or plasma, respectively, according to the manufacturer's instructions. Subsequently, the tubes were sent to the central laboratory of Severance Hospital to determine serum or plasma potassium levels, respectively. The central laboratory was fully blinded to the study samples and conducted potassium level measurement independently of the study team. Potassium concentrations were measured using Atellica CH
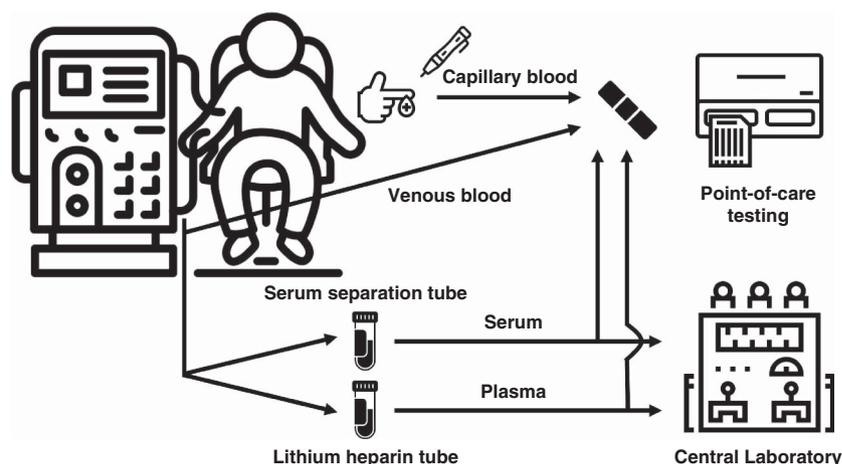

Figure 1. Sample collection and potassium measurements. Capillary blood samples were obtained immediately before the initiation of the hemodialysis treatment at the fingertips using a lancet. Then, the capillary blood samples were loaded onto disposable test strips for potassium level measurement. Simultaneously, venous blood samples were collected through a dialysis line. The venous blood samples were sent to the central laboratory to determine serum or plasma potassium levels. Remnant venous blood samples were used to measure potassium levels using disposable test strips. Subsequently, serum and plasma, which were retrieved from the central laboratory, were also used to determine potassium concentrations using disposable test strips.

Analyzer (SIMENS Healthineers, Erlangen, Germany) in the central laboratory according to the manufacturer's instructions and the central laboratory protocol independent from the study. Remnant venous blood samples were used to measure potassium levels using disposable test strips immediately after blood sampling, as capillary blood samples. After measuring potassium concentrations in the serum and plasma using the central laboratory equipment, the residual serum and plasma were also used to determine potassium concentrations using disposable test strips. Trained medical staff took all blood samples, and three independent operators who were blinded to potassium levels determined by the central laboratory equipment conducted potassium concentration measurements using the disposable test strips. Supplemental Figure 1 illustrates the interoperator variability of potassium levels, as measured using the disposable test strips, among the three operators evaluated during the device development process.

Potassium Level Measurements Using Disposable Test Strips

The handheld device consists of a main reader, a disposable strip containing working and reference electrodes, and standard solutions. Before the measurement of potassium levels using patient samples, a two-step calibration was performed. In brief, the calibration solution 1 (THEDONEE Inc.) was loaded to ensure complete coverage of both the working electrode and the reference electrode of a disposable test strip.[18] After removing the calibration solution 1, the calibration solution 2 (THEDONEE Inc.) was applied in the same manner as the calibration solution 1. The calibration process usually requires approximately 30 seconds for each calibration solution. On the completion of calibration, a small volume of sample (5–10 μl) was loaded onto the strip, as the calibration solutions and the potassium level were measured subsequently. Photographs of disposable test strip and portable electrochemical meter, calibration procedure, and potassium level measurement are presented in Supplemental Figure 2.

Verification of Disposable Test Strips

To test the accuracy of disposable test strip, potassium concentration measurements using standard potassium solutions with various concentrations (10 μM–1 M) and mixed electrolyte solution containing diverse interfering ions (calcium ion, magnesium ion, lithium ion, and sodium ion) in addition to potassium were performed.

To verify the performance of the test strip, we also compared the potassium concentrations measured by disposable test strip with those obtained by inductively coupled plasma atomic emission spectroscopy (ICP-AES; OPTIMA 8300, PerkinElmer Inc., Waltham, MA) using potassium solutions with concentration of 2–9 mM.

The coefficient of variation (CV) was calculated by the following formula when measuring the potassium concentrations of the standard potassium solution.

$$Coefficient\ of\ variation\ (\%) = \frac{SD}{Average} \times 100$$

Statistical Analysis

The linearity between measured potassium concentrations and potassium level of standard potassium solutions was assessed using linear regression.

Table 1. Baseline characteristics of study participants according to sex			
Characteristics	Total	Male	Female
	N=40	n=21	n=19
Age, yr	63 (55–74)	63 (56–78)	63 (54–73)
BMI, kg/m^2	21.9 (19.0–25.6)	22.6 (19.9–28.5)	21.5 (18.4–24.7)
Cause of ESKD, No. (%)			
Diabetic	18 (45)	12 (57)	6 (32)
Hypertensive	10 (25)	3 (14)	7 (37)
GN	4 (10)	2 (10)	2 (11)
Polycystic kidney disease	3 (8)	2 (10)	1 (5)
Others/unknown	5 (13)	2 (10)	3 (16)
Dialysis vintage, yr	5.5 (8.0)	2.1 (5.1)	9.2 (9.1)
Comorbidities, No. (%)			
Hypertension	35 (88)	17 (81)	18 (95)
Diabetes mellitus	22 (55)	15 (71)	7 (37)
Myocardial infarction	5 (13)	2 (10)	3 (16)
Cerebrovascular disease	2 (5)	2 (10)	0 (0)
Heart failure	11 (28)	6 (29)	5 (26)
Malignancy	2 (5)	0 (0)	2 (11)
Hemoglobin, g/dl	10.3 (1.5)	10.3 (1.8)	10.3 (1.0)
Ca, mg/dl	8.5 (0.7)	8.3 (0.6)	8.7 (0.7)
P, mg/dl	4.8 (1.3)	4.8 (1.3)	4.8 (1.2)
Albumin, g/dl	3.7 (0.5)	3.6 (0.6)	3.7 (0.5)
K (serum), mmol/L	4.5 (4.0–5.1)	4.5 (4.1–4.9)	4.6 (4.0–5.4)
K (plasma), mmol/L	4.3 (3.6–4.7)	4.2 (3.7–4.6)	4.5 (3.5–5.1)
RAS blockade, No. (%)	20 (50)	12 (57)	8 (42)
Potassium binder, No. (%)	11 (28)	5 (24)	6 (32)

Data are presented as means (SD), medians (interquartile range), or numbers (percentages). BMI, body mass index; RAS, renin-angiotensin system.
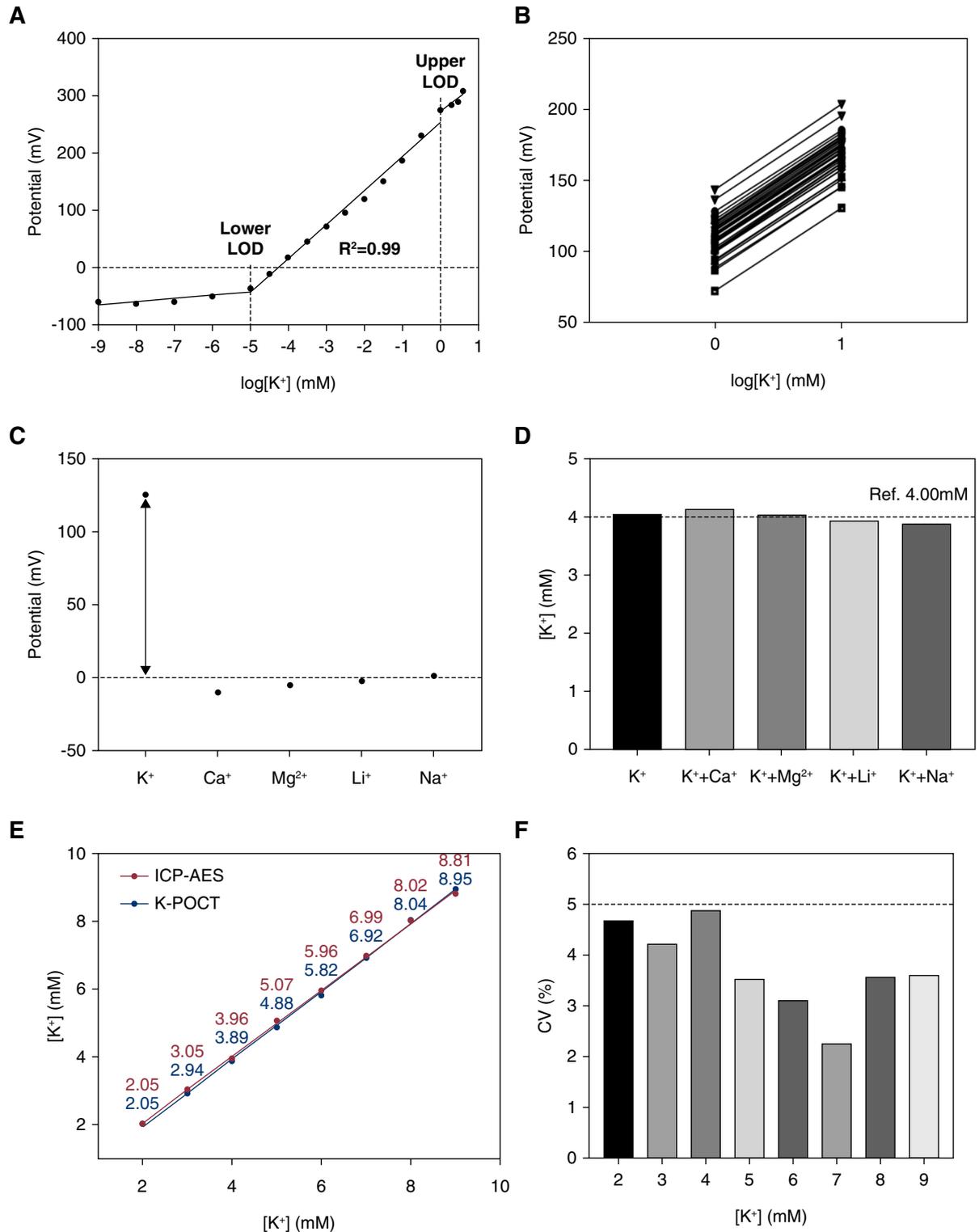
Figure 2. Performance of disposable test strip for potassium concentration measurement. (A) Lower and upper LOD of the disposable test strip for potassium. (B) Sensitivity of the disposable test strip for potassium. (C) Electrolyte selectivity of the disposable test strip for potassium. (D) Interference resistance of the disposable test strip for potassium against nontarget electrolytes. (E) Accuracy of the disposable test strip for potassium validated by comparison with ICP-AES results. (F) CV of the disposable test strip for potassium at various concentrations of potassium solution. Ca^{2+}, calcium ion; CV, coefficient of variation; ICP-AES, inductively coupled plasma atomic emission spectroscopy; K^+, potassium ion; K-POCT, point-of-care testing using disposable test strip for potassium; Li^+, lithium ion; LOD, limits of detection; Mg^{2+}, magnesium ion; Na^+, sodium ion. Figure 2 can be viewed in color online at www.cjasn.org.

Table 2. Comparison of potassium concentrations according to measurement methods and sample types

| Patient | K-POCT | | | | | | | | | | | | Central Laboratory | |
| | Capillary Blood | | | Venous Blood | | | Serum | | | Plasma | | | Serum (mM) | Plasma (mM) |
	Average (mM)	SD	No.	Average (mM)	SD	No.	Average (mM)	SD	No.	Average (mM)	SD	No.		
1	4.58	0.32	12	4.62	0.23	4	4.75	0.33	6	4.59	0.23	6	4.8	4.6
2	3.62	0.30	5	3.47	0.29	6	3.83	0.30	6	3.56	0.19	6	3.5	3.5
3	5.57	0.29	9	5.58	0.15	6	5.23	0.39	6	5.39	0.18	5	5.5	5.4
4	4.46	0.20	10	4.57	0.23	5	5.03	0.27	6	4.22	0.19	6	4.7	4.5
5	4.68	0.25	11	4.17	0.30	6	4.91	0.13	6	4.95	0.17	6	4.8	4.6
6	4.88	0.35	6	4.93	0.15	6	5.11	0.29	6	4.88	0.19	6	5.3	5.0
7	4.27	0.33	11	4.21	0.12	6	5.13	0.15	6	4.77	0.22	5	5.1	4.7
8	4.11	0.26	12	4.47	0.16	6	5.01	0.40	6	5.00	0.27	6	4.9	4.7
9	4.59	0.44	12	4.74	0.35	6	5.64	0.29	8	5.10	0.36	8	4.9	4.6
10	5.01	0.63	8	5.12	0.40	6	5.70	0.37	8	5.49	0.12	7	5.1	5.0
11	5.21	0.28	9	5.18	0.41	6	5.57	0.24	9	5.67	0.23	9	5.4	5.4
12	5.86	0.37	10	5.60	0.15	6	7.04	0.59	4	5.34	0.24	9	6.3	5.4
13	3.99	0.31	12	3.96	0.24	5	3.81	0.25	9	3.87	0.34	9	4.0	3.8
14	4.73	0.28	12	4.13	0.13	6	4.69	0.24	6	4.90	0.29	8	4.5	4.5
15	5.62	0.22	8	5.76	0.36	6	7.16	0.26	7	6.26	0.25	8	7.1	6.1
16	5.21	0.43	9	6.16	0.25	6	6.12	0.15	8	5.90	0.30	8	5.6	5.4
17	3.74	0.27	11	3.79	0.16	5	4.20	0.19	8	3.49	0.19	6	4.3	3.9
18	5.59	0.23	5	5.24	0.35	6	5.69	0.34	8	5.35	0.38	9	5.8	5.5
19	4.16	0.24	11	4.01	0.25	6	4.42	0.45	7	4.31	0.25	9	4.6	4.3
20	3.71	0.07	4	3.59	0.13	5	4.02	0.33	8	3.94	0.37	8	3.8	3.5
21	5.13	0.32	11	4.82	0.15	6	5.18	0.27	9	4.90	0.18	9	4.7	4.5
22	3.45	0.38	11	3.44	0.21	6	4.58	0.22	9	3.35	0.15	9	4.3	3.5
23	5.52	0.32	12	4.80	0.32	6	6.66	0.17	8	5.37	0.22	7	5.6	5.1
24	4.34	0.28	11	4.17	0.31	6	4.87	0.23	9	4.62	0.29	9	4.3	4.4
25	3.72	0.27	14	3.23	0.22	6	4.13	0.13	9	3.59	0.12	9	3.8	3.3
26	3.71	0.32	4	3.47	0.10	6	3.82	0.12	9	3.60	0.22	9	4.0	3.6
27	5.02	0.38	11	4.77	0.37	6	5.39	0.40	8	5.10	0.53	9	4.9	4.6
28	3.20	0.19	12	3.48	0.19	6	4.56	0.18	9	3.72	0.28	9	4.2	3.6
29	3.68	0.13	6	3.71	0.18	6	4.58	0.27	9	3.62	0.15	9	4.0	3.6
30	3.17	0.39	12	2.89	0.19	6	3.44	0.31	9	3.15	0.21	9	3.2	3.3
31	4.46	0.12	11	3.18	0.17	6	4.87	0.16	9	3.47	0.17	9	4.7	3.2
32	4.17	0.29	11	4.41	0.23	6	4.81	0.27	9	4.32	0.36	9	4.2	3.9
33	4.25	0.21	6	3.76	0.18	6	4.15	0.21	9	4.05	0.21	9	3.8	3.7
34	3.55	0.18	12	3.18	0.22	6	3.86	0.16	9	3.56	0.26	8	3.8	3.5
35	4.60	0.51	10	3.96	0.12	6	5.13	0.13	6	4.38	0.11	7	4.1	3.8
36	4.46	0.38	8	3.75	0.22	6	4.40	0.26	8	4.60	0.20	4	3.8	3.7
37	4.48	0.46	8	4.31	0.61	6	4.63	0.22	7	4.14	0.25	9	4.3	4.2
38	4.60	0.27	6	4.41	0.28	6	4.87	0.16	8	4.22	0.15	9	4.5	4.2
39	4.14	0.10	6	4.02	0.28	6	5.47	0.14	9	4.61	0.26	9	4.8	4.2
40	3.63	0.40	6	3.26	0.16	6	3.80	0.16	8	3.29	0.07	9	3.6	3.3

K-POCT, point-of-care testing using disposable test strip for potassium.

To assess the correlation between potassium levels measured by POCT using disposable test strips for potassium (K-POCT) and a single potassium concentration determined by central laboratory equipment, Passing-Bablok regression and Bland-Altman analysis were used. As the data were not normally distributed for the Bland-Altman analysis, we adopted nonparametric methods under the statistician's consultation. In addition, we conducted the correlation analysis using the first potassium concentrations measured by K-POCT and the potassium level obtained from conventional measurement to explore the utility of K-POCT in a clinical setting. Since the data of the first potassium levels measured by K-POCT were normally distributed for the Bland-Altman analysis, we performed the analysis with parametric methods.

To verify the accuracy of potassium concentrations measured by disposable test strip, we also analyzed the frequency of measurement errors (potassium level in capillary blood [K-POCT]—potassium level in serum or plasma [central laboratory]) <-1.0 or -0.5 mM or >0.5 or 1.0 mM.

Data were analyzed using R, version 4.5.0 (R Foundation for Statistical Computing, Vienna, Austria), and GraphPad Prism, version 8.0 (GraphPad Software, San Diego, CA).

Results

Baseline Characteristics

The baseline characteristics of the 40 participants according to sex are presented in Table 1. The median age was 63 (interquartile range [IQR], 55–74) years, and 53% of the participants were male. Diabetic kidney disease was the main cause of ESKD (45%), and the mean dialysis vintage was 5.5 (SD, 8.0) years.
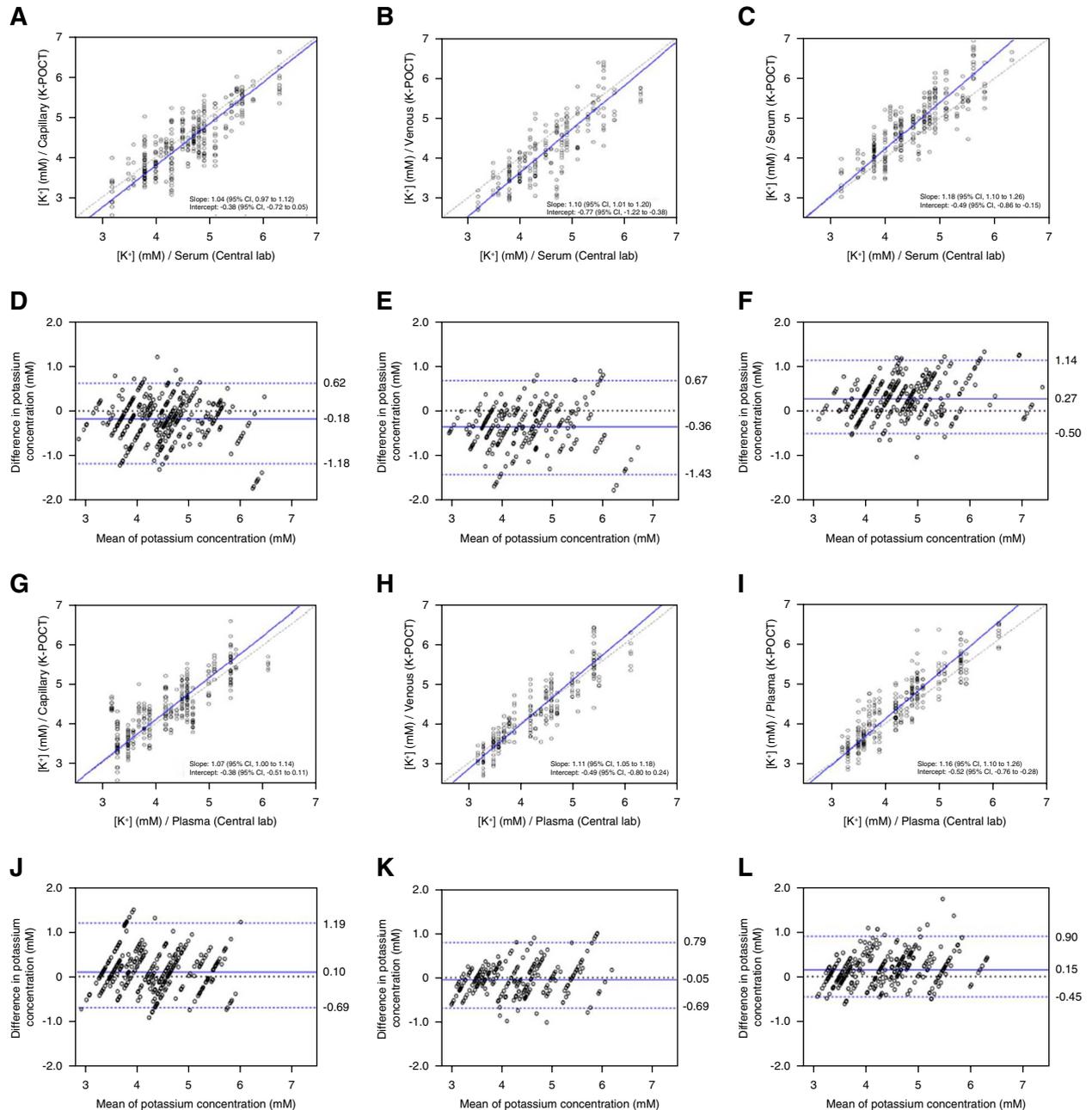
Figure 3. Comparison of potassium concentrations measured by disposable test strip for potassium concentration with potassium concentrations measured by central laboratory equipment. Passing-Bablok regression analysis between potassium concentrations measured by K-POCT (capillary blood [A], venous blood [B], and serum [C]) and central laboratory equipment (serum). Bland-Altman plot between potassium concentrations measured by K-POCT (capillary blood [D], venous blood [E], and serum [F]) and central laboratory equipment (serum). Passing-Bablok regression analysis between potassium concentrations measured by K-POCT (capillary blood [G], venous blood [H], and plasma [I]) and central laboratory equipment (plasma). Bland-Altman plot between potassium concentrations measured by K-POCT (capillary blood [J], venous blood [K], and plasma [L]) and central laboratory equipment (plasma). CI, confidence interval. Figure 3 can be viewed in color online at www.cjasn.org.

Performance of Disposable Test Strip for Potassium Concentration Measurement

Figure 2 shows the performance of the disposable test strip for potassium level measurement. The Nernstian potential, achieved by disposable test strips using a broad range of potassium concentrations from 10 μM to 1 M, demonstrated a high degree of linearity with potassium levels, showing an R value of 0.99 (Figure 2A). The ideal Nernstian sensitivity for monovalent ions, such as potassium, is 59.16 mV/decade at 25°C and 1 atm. On evaluating the sensitivity of 40 individual test strips for potassium level, all strips exhibited values within the range of 57–62 mV/decade, confirming high and consistent sensitivity levels (Figure 2B). Figure 2C presents the selectivity

Table 3. Relationship between potassium concentrations according to measurement methods (Passing-Bablok regression)

Measurement		No.	Slope (95% CI)	Intercept (95% CI)
Central Laboratory	K-POCT			
Serum	Capillary	375	1.04 (0.97 to 1.12)	−0.38 (−0.72 to 0.05)
	Venous blood	234	1.10 (1.01 to 1.20)	−0.77 (−1.22 to −0.38)
	Serum	308	1.18 (1.10 to 1.26)	−0.49 (−0.86 to 0.15)
Plasma	Capillary	375	1.07 (1.00 to 1.14)	−0.19 (−0.51 to 0.11)
	Venous blood	231	1.11 (1.05 to 1.18)	−0.49 (−0.80 to 0.24)
	Plasma	314	1.16 (1.10 to 1.26)	−0.52 (−0.76 to −0.28)

CI, confidence interval; K-POCT, point-of-care testing using disposable test strip for potassium.

of the test strip. The test strip showed a selective response to potassium, whereas it did not respond to interfering ions, such as calcium ion, magnesium ion, lithium ion, and sodium ion, confirming the high selectivity of the strip toward potassium ion. Furthermore, we assessed whether the presence of interfering ions in the sample solution may influence the measured potassium ion concentrations. As shown in Figure 2D, the measured potassium levels were largely consistent, despite the presence of interfering ions. To verify the accuracy of disposable test strip, we compared the potassium levels measured in standard potassium solution using the strip with those obtained using ICP-AES. The potassium concentrations measured by the disposable test strip showed strong agreement with those obtained using ICP-AES (Figure 2E). In addition, we tested the CV to substantiate the reliability of the test strip using 32 replicates for each potassium concentration in standard potassium solution ranging from 2 to 9 mM. The CV remained below 5% across all concentrations (Figure 2F).

Validation of Disposable Test Strip for Potassium Concentration Measurement in Patients Treated with Maintenance Hemodialysis

Table 2 summarizes the potassium concentrations of various samples from patients treated with maintenance hemodialysis. The potassium concentrations were measured by K-POCT and equipment in the central laboratory. The ranges for the number of measurement replicates were 4–14, 4–6, 4–9, and 4–9 for capillary blood, venous blood, serum, and plasma, respectively, due to variations in sample volumes. The ranges of mean potassium levels obtained by K-POCT were 3.17–5.86, 3.18–6.16, 3.44–7.16, and 3.15–6.26 mM for respective sample types, while the

ranges of potassium concentrations determined by central laboratory equipment were 3.2–7.1 and 3.2–6.1 mM using serum and plasma, respectively. Overall, potassium levels were comparable across measurements.

We examined the agreement between potassium concentrations measured by K-POCT and those obtained from the central laboratory using Passing-Bablock regression and Bland-Altman analysis. The potassium concentrations of capillary blood, venous blood, and serum obtained from K-POCT largely showed accordance with serum potassium levels measured using central laboratory equipment (Figure 3, A–C). The corresponding slopes were 1.04 (95% confidence interval [CI], 0.97 to 1.12), 1.10 (95% CI, 1.01 to 1.20), and 1.18 (95% CI, 1.10 to 1.26), for potassium concentrations obtained from capillary blood, venous blood, and serum, respectively (Table 3). The concordance between potassium levels measured by two methods was verified further using Bland-Altman analysis (Figure 3, D–F). The biases were −0.18 (95% CI, −0.24 to −0.13), −0.36 (95% CI, −0.41 to −0.30), and 0.27 (95% CI, 0.20 to 0.35) in the respective sample types (Table 4). The lower limit of agreement and upper limit of agreement ranged from −1.43 (95% CI, −1.67 to −1.18) to −0.50 (95% CI, −0.58 to −0.42) and 0.62 (95% CI, 0.52 to 0.72) to 1.14 (95% CI, 0.99 to 1.21), respectively (Table 4). The agreement between potassium levels from various samples (capillary blood, venous blood, and plasma) measured by K-POCT and plasma potassium concentrations determined by equipment in the central laboratory showed similar results (Figure 3, G–L and Tables 3 and 4).

In the repeated analysis comparing the potassium levels obtained by the first test strip with those measured by

Table 4. Relationship between potassium concentrations according to measurement methods (Bland-Altman analysis)

Measurement		Bias (95% CI)	Lower Limit of Agreement (95% CI)	Upper Limit of Agreement (95% CI)
Central Laboratory	K-POCT			
Serum	Capillary	−0.18 (−0.24 to −0.13)	−1.18 (−1.53 to −1.00)	0.62 (0.52 to 0.72)
	Venous blood	−0.36 (−0.41 to −0.30)	−1.43 (−1.67 to −1.18)	0.67 (0.37 to 0.80)
	Serum	0.27 (0.20 to 0.35)	−0.50 (−0.58 to −0.31)	1.14 (0.99 to 1.21)
Plasma	Capillary	0.10 (0.06 to 0.16)	−0.69 (−0.78 to −0.60)	1.19 (0.90 to 1.31)
	Venous blood	−0.05 (−0.09 to 0.02)	−0.69 (−0.86 to −0.56)	0.79 (0.60 to 0.93)
	Plasma	0.15 (0.10 to 0.20)	−0.45 (−0.50 to −0.38)	0.90 (0.78 to 1.07)

CI, confidence interval; K-POCT, point-of-care testing using disposable test strip for potassium.

Table 5. Frequency of measurement errors in potassium concentrations obtained by point-of-care testing using disposable test strip for potassium (capillary blood) referenced by potassium concentration determined by central laboratory equipment (serum)

Patient	Measurement Error (mM)	Frequency of Measurement Error (%)				No.
		≤−1.0 mEq/L	≤−0.5 mEq/L	≥0.5 mEq/L	≥1.0 mEq/L	
1	−0.19 (−0.38 to 0.01)	25	25	0	0	12
2	0.10 (−0.04 to 0.34)	0	0	0	0	5
3	0.15 (−0.14 to 0.21)	0	0	11	0	9
4	−0.27 (−0.33 to −0.11)	0	10	0	0	10
5	−0.11 (−0.28 to 0.03)	0	9	0	0	11
6	−0.54 (−0.58 to −0.30)	0	67	0	0	6
7	−0.86 (−1.04 to −0.63)	36	55	0	0	11
8	−0.85 (−0.91 to −0.80)	83	75	0	0	12
9	−0.24 (−0.56 to −0.05)	33	25	0	0	12
10	0.02 (−0.38 to 0.23)	13	13	13	13	8
11	−0.13 (−0.28 to −0.05)	0	11	0	0	9
12	−0.53 (−0.66 to −0.28)	0	50	0	0	10
13	−0.10 (−0.16 to 0.19)	0	8	8	0	12
14	0.20 (0.10–0.41)	0	0	17	0	12
15	−1.54 (−1.62 to −1.35)	100	100	0	0	8
16	−0.05 (−0.54 to 0.04)	0	33	0	0	9
17	−0.58 (−0.75 to −0.44)	0	64	0	0	11
18	−0.36 (−0.38 to −0.02)	0	0	0	0	5
19	−0.41 (−0.59 to −0.28)	0	27	0	0	11
20	−0.10 (−0.14 to −0.05)	0	0	0	0	4
21	0.41 (0.28–0.61)	0	0	36	0	11
22	−0.85 (−1.12 to −0.78)	46	91	0	0	11
23	−0.18 (−0.23 to 0.00)	0	0	8	0	12
24	−0.05 (−0.15 to 0.05)	0	0	18	0	11
25	−0.11 (−0.29 to 0.14)	0	7	0	0	14
26	−0.33 (−0.53 to −0.10)	0	50	0	0	4
27	0.24 (−0.20 to 0.38)	0	0	0	0	11
28	−1.08 (−1.13 to −0.90)	67	100	0	0	12
29	−0.29 (−0.42 to −0.22)	0	17	0	0	6
30	0.01 (−0.31 to 0.20)	0	8	8	0	12
31	−0.28 (−0.32 to −0.17)	0	0	0	0	11
32	0.03 (−0.08 to 0.13)	0	9	0	0	11
33	0.49 (0.34–0.58)	0	0	50	0	6
34	−0.28 (−0.35 to −0.13)	0	8	0	0	12
35	0.37 (0.16–0.68)	0	0	40	10	10
36	0.61 (0.49–0.78)	0	0	75	25	8
37	−0.09 (−0.36 to 0.17)	0	0	50	0	8
38	0.07 (−0.09 to 0.32)	17	17	0	0	6
39	−0.67 (−0.67 to −0.67)	0	83	0	0	6
40	−0.13 (−0.24 to − 0.18)	0	0	17	0	6
Overall	−0.13 (−0.37 to 0.03)	12	24	9	1	375

Data are presented as medians (interquartile range) or percentages.

central laboratory equipment, agreement between potassium levels from various sample types measured by K-POCT and those yielded from conventional measurement was maintained (Supplemental Figure 3 and Supplemental Tables 1 and 2).

Performance of Disposable Test Strip for Potassium Concentration Measurement in Patients Treated with Maintenance Hemodialysis

Tables 5 and 6 present the degree of measurement errors and frequency of differences between measured potassium levels using K-POCT with capillary blood and central laboratory equipment with serum or plasma, respectively, >0.5 and 1.0 mM. The median measurement error between potassium levels obtained by K-POCT and those of serum measured by central laboratory equipment was −0.13 (IQR, −0.37 to −0.03) mM and the frequencies of measurement error <−1.0 and −0.5 mM and >0.5 and

1.0 mM were 12%, 24%, 9%, and 1%, respectively. The median measurement error between potassium levels measured by K-POCT and those of plasma acquired using central laboratory equipment was 0.10 (IQR, −0.08 to 0.32) mM, and the respective frequencies of measurement error were 3%, 14%, 11%, and 2%, respectively.

Discussion

In this study for validation and clinical evaluation of K-POCT, the disposable strip for potassium concentration measurement yielded excellent performance with selectivity for potassium, accuracy, and reliability. In addition, potassium concentrations measured by K-POCT in various sample types obtained from patients undergoing maintenance hemodialysis, including capillary blood, venous blood, and serum (or plasma), showed acceptable agreement with potassium levels in their serum (or plasma) as

Table 6. Frequency of measurement errors in potassium concentrations obtained by point-of-care testing using disposable test strip for potassium (capillary blood) referenced by potassium concentration determined by central laboratory equipment (plasma)

Patient	Measurement Error (mM)	Frequency of Measurement Error (%)				No.
		≤−1.0 mEq/L	≤−0.5 mEq/L	≥0.5 mEq/L	≥1.0 mEq/L	
1	0.01 (−0.18 to 0.21)	0	8	0	0	12
2	0.10 (−0.04 to 0.34)	0	0	0	0	5
3	0.25 (−0.04 to 0.31)	0	0	11	0	9
4	−0.07 (−0.13 to 0.09)	0	0	0	0	10
5	0.09 (−0.08 to 0.23)	0	0	9	0	11
6	−0.24 (−0.28 to 0.00)	0	0	0	0	6
7	−0.46 (−0.64 to −0.23)	0	36	0	0	11
8	−0.65 (−0.71 to −0.60)	0	83	0	0	12
9	0.06 (−0.26 to 0.25)	8	17	0	0	12
10	0.12 (−0.28 to 0.33)	25	25	0	0	8
11	−0.13 (−0.28 to −0.05)	0	11	0	0	9
12	0.37 (0.24–0.62)	10	40	0	0	10
13	0.10 (0.04–0.39)	0	0	25	0	12
14	0.20 (0.10–0.41)	0	0	17	0	12
15	−0.54 (−0.62 to −0.35)	0	63	0	0	8
16	0.15 (−0.34 to 0.24)	0	0	0	0	9
17	−0.18 (−0.35 to −0.04)	0	9	0	0	11
18	−0.06 (−0.08 to 0.28)	0	0	0	0	5
19	−0.11 (−0.29 to 0.02)	0	9	0	0	11
20	0.20 (0.16–0.25)	0	0	0	0	4
21	0.61 (0.48–0.81)	0	0	73	18	11
22	−0.05 (−0.32 to 0.02)	0	0	9	0	11
23	0.32 (0.27–0.50)	0	0	25	8	12
24	−0.15 (−0.22 to 0.05)	0	0	0	0	11
25	0.39 (0.21–0.64)	0	0	43	0	14
26	0.07 (−0.53 to −0.10)	0	50	0	0	4
27	0.54 (−0.20 to 0.38)	0	0	18	0	11
28	−0.48 (−1.13 to −0.90)	67	100	0	0	12
29	0.11 (−0.42 to −0.22)	0	17	0	0	6
30	−0.09 (−0.42 to −0.22)	0	8	8	0	12
31	1.22 (−0.32 to −0.17)	0	0	0	0	11
32	0.33 (−0.08 to 0.13)	0	9	0	0	11
33	0.59 (0.34–0.58)	0	0	50	0	6
34	0.02 (−0.35 to −0.13)	0	8	0	0	12
35	0.67 (0.16–0.68))	0	0	40	10	10
36	0.71 (0.47–0.78)	0	0	75	25	8
37	0.01 (−0.36 to 0.17)	0	0	50	0	8
38	0.37 (−0.09 to 0.32)	17	17	0	0	6
39	−0.07 (−0.67 to −0.67)	0	83	0	0	6
40	0.17 (−0.24 to 0.18)	0	0	17	0	6
Overall	0.10 (−0.08 to 0.32)	3	14	11	2	375

Data are presented as medians (interquartile range) or percentages.

determined using central laboratory equipment. Therefore, our findings suggest that the K-POCT could be used for self-monitoring of potassium levels to improve patient care and enhance timely intervention for dyskalemia, especially hyperkalemia, which frequently threatens patients with advanced CKD or treated with dialysis.

Hyperkalemia increases the risk of life-threatening cardiac dysrhythmias and mortality in patients with advanced CKD and dependent on dialysis.[19–21] Hence, regular monitoring and proper management of potassium levels, including dietary education and prescribing medications to lower potassium concentration, is an important issue in clinical practice for patients at the highest risk for hyperkalemia.[14–16] However, appropriate potassium level monitoring is often not feasible in a primary care setting, since potassium concentration measurements require blood draw and a time lag between the blood sampling and result reporting frequently exists.[17] Hence, a facile potassium concentration measurement using POCT has been expected to overcome those limitations. Although notable advances have been achieved in POCT and self-monitoring measurement technologies, such as devices for potassium level measurement using venous blood, devices for home blood collection and remote measurement, and wearable potassium sensors in various tissue fluids, a brief and accurate device for potassium concentration measurement using capillary blood obtained by fingerstick blood draw is not practically available to date.[17,22–25]

Therefore, the findings of our study are significant. We tested the accuracy and reliability of the disposable test strip for potassium measurement by comparing potassium levels measured by ICP-AES with those obtained using the device. Furthermore, we verified the agreement of potassium

concentrations between K-POCT and central laboratory equipment across various blood samples, including capillary blood, venous blood, serum, and plasma. Our results showed that the disposable test strip for potassium measurement yielded excellent performance, and potassium levels obtained using K-POCT were revealed to have satisfactory agreement with those measured by central laboratory equipment, regardless of various sample types. Furthermore, measurement errors in potassium levels acquired using K-POCT were revealed to be acceptable. Specifically, the frequencies of differences between potassium levels measured by K-POCT and those of serum and plasma using central laboratory equipment exceeding 1 mM were 13% and 5%, respectively. Notably, the frequency for the measurement errors of < -0.5 mM was higher when potassium levels measured by K-POCT were referenced to serum than when they were referenced to plasma. This may be partly attributed to the issue of clotting, which occurs during the serum preparation.[26,27] Considering that serum potassium levels are usually higher compared to plasma potassium levels to some extent (0.3–0.4 mM), as reported in the previous literature,[28–30] and plasma potassium levels can be used to differentiate between true hyperkalemia and pseudohyperkalemia,[28–30] these results imply that K-POCT is a relatively accurate laboratory test measuring potassium level. It should also be noted that the K-POCT requires a minimum blood volume of 10 μl, minimizing the concern for the need of finger squeezing to obtain enough blood volume. As reviewed by Hutter *et al.*, the existing point-of care devices, such as Abbott i-STAT and Siemens Epoc, capable of measuring potassium levels using capillary blood, usually require a minimum blood volume of over 60–90 μl.[17] The relatively large blood volume required by such devices inevitably results in hemolysis and is therefore unsuitable for reporting reliable potassium levels.[31,32] As such, those devices are usually implemented in measuring potassium levels using venous samples in real-world practice, while the K-POCT could measure potassium levels using capillary blood acquired from a brief process.[17] Furthermore, the existing portable point-of-care devices are not approved for home or self-monitoring by patients, and the cost of the devices and the single-use cartridges is high, whereas the cost of the paper-based disposable test strips used in this study is relatively inexpensive.[17] Hence, the disposable test strip for potassium measurement in this study has the potential utility in clinical practice for the management of patients who are at risk of hyperkalemia, as well as patients treated with maintenance hemodialysis, although it needs a calibration process before measurement.

Our study had several limitations. First, the validity of this study can be challenged as this study involved only 40 patients. To minimize this issue, we repeated measurement and compared potassium levels across various sample types. Second, calibration process should be conducted just before the potassium level measurement. This process could be burdensome if this device used in home/self-monitoring by patients. However, the calibration process and potassium level measurement procedure are relatively simple and could be easily performed by patients with brief instructions or a user manual. In addition, the implementation of auto-calibration, which is under investigation, could improve patients' convenience. Third, the number of observed clinically extreme potassium values in the study population was limited. Hence, the accuracy of the disposable test strip for potassium concentration cannot be guaranteed at extreme potassium levels. Fourth, the issue of hemolysis cannot be excluded, although the disposable test strip for potassium measurement requires minimal volume of blood. Finally, this study exclusively included patients treated with maintenance hemodialysis, which may limit the validity of the device to the population or patients other than those receiving hemodialysis.

In conclusion, this study evaluated the clinical efficacy of the disposable test strip for determining potassium levels using blood samples, including capillary blood in patients undergoing maintenance hemodialysis and showed excellent performance of the disposable test strip. Our findings suggest that this device could be employed for self-monitoring of blood potassium levels in patients at high risk of hyperkalemia, including patients with advanced CKD and those with heart failure, who are being treated with medications inhibiting renal potassium excretion, as well as in a primary care or emergency care setting, to improve patient outcomes.

Author Contributions

Conceptualization: Chaeeun Kim, Chaehyung Kim, Yujoon Kim, Cheol Ho Park, Tae-Hyun Yoo.
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Writing – review & editing: Kangwon Lee, Cheol Ho Park, Tae-Hyun Yoo.

Declarative Statements

This study includes clinical experimentation and received Institutional Review Board or Ethics Committee approval. All patients provided written informed consent. This study includes clinical experimentation and complies with the Declaration of Helsinki.

Data Availability Statements

All original data, including deidentified patient-level data or individual laboratory data measurements, are included in the manuscript and/or supplemental material.

Supplemental Material

This article contains the following supplemental material online at http://links.lww.com/CJN/C557.

Supplemental Table 1. Relationship between potassium concentrations according to measurement methods (Passing-Bablok regression).

Supplemental Table 2. Relationship between potassium concentrations according to measurement methods (Bland-Altman analysis).

Supplemental Figure 1. Interoperator variability of potassium levels measured by K-POCT.

Supplemental Figure 2. Photographs of a disposable test strip and a portable electrochemical meter and diagrams for calibration procedure and potassium level measurement.

Supplemental Figure 3. Comparison of potassium concentrations measured by the first disposable test strip for potassium concentration with potassium concentrations measured by central laboratory equipment.

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