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Utility of a novel point-of-care test for albuminuria in communities at high risk for chronic kidney disease in Thailand

Somkanya Tungsanga ,[1,2] Rungrawee Nantanawijit,[3] Patcharakorn Kiatamornrak,[4,5] Win Kulvichit,[6] Umphan Ngoensawat,[4,5] Sasipa Tachaboon,[4,5] Janejira Dinhuzen,[4,5] Watchadaporn Chaisuriyong,[4,5] Kittinan Komolpis,[5,7] Sadudee Peerapornratana,[4,6] Kearkiat Praditpornsilpa,[8] Kriang Tungsanga,[5] Aminu K Bello,[9] Nattachai Srisawat[10]

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For numbered affiliations see end of article.

Correspondence to
Dr Nattachai Srisawat; drnattachai@yahoo.com

ABSTRACT

Introduction Chronic kidney disease (CKD) is a major public health concern, and early detection is crucial to prevent adverse outcomes. Albuminuria is an early marker and key prognostic marker in CKD, but reliable tools for its detection are limited particularly in low resource settings. We tested the utility of a novel, affordable point-of-care test (POCT) for albuminuria among high-risk individuals for CKD.

Methods This is a community-based cross-sectional study covering 17 primary subdistrict healthcare units in Ban Phaeo District, Samut Sakhon Province, Thailand. The inclusion criteria were asymptomatic adult participants diagnosed with hypertension, diabetes and/or aged over 60 years. We measured serum creatinine and quantitative urine albumin–creatinine ratio (UACR) and administered POCT urine albumin strip test (Albii, K. BioSciences, Bangkok, Thailand) and urine dipstick test for protein. Participants with albuminuria or estimated glomerular filtration rate (eGFR) by CKD-EPI 2009 equation <60 mL/min/1.73 m^2 were considered to have suspected CKD. We evaluated diagnostic performance of POCT urine albumin strip.

Results Among 2307 participants, 489 (20.3%) participants had reduced eGFR and/or albuminuria. The median eGFR was 93.23 (87.82, 98.73) mL/min/m^2, and the median UACR was 9.15 (5.09, 20.96) mg/g. The POCT urine albumin strip showed a sensitivity of 0.70, specificity of 0.97 and accuracy of 0.92 compared with the quantitative UACR. Conversely, the POCT urine dipstick for protein had poor sensitivity, positive predictive value and accuracy.

Conclusion The urine albumin test strip is a highly effective tool to conduct point-of-care identification for early CKD among high-risk populations. Given the test's diagnostic performance and ease of use, such test should be incorporated into health policy.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Albuminuria is a key marker of chronic kidney disease (CKD) status (definition and staging) and important prognostic marker for adverse outcomes in people living with CKD. Existing guideline recommendations include testing for albuminuria and estimated glomerular filtration rate for identification and risk stratification of CKD.

⇒ Quantitative tests for albuminuria (urine albumin–creatinine ratio; UACR) are not universally available and affordable particularly in low-resource settings.

⇒ Point-of-care urine dipstick tests for protein are generally available but less accurate compared with UACR for disease detection and risk stratification in CKD.

BACKGROUND

It has been well established that chronic kidney disease (CKD) is a significant public health issue. Early detection and management are essential to decrease the adverse health consequences associated with CKD. The presence of albuminuria is one of the most sensitive indicators for early-stage CKD, and important prognostic marker for adverse outcomes.[1 2]

With the increasing prevalence of non-communicable diseases, the Ministry of Public Health of Thailand, responsible for healthcare administration nationwide, mandates that healthcare units at all levels screen citizens over the age of 35 years for diabetes and hypertension. In 2022, approximately 85% of Thai citizens in this age group were screened for these conditions.[3] While screening using kidney measures of serum creatinine and estimated glomerular filtration rate (eGFR) is mandatory under Thai health legislation for individuals with hypertension and/or diabetes, there is no definite requirement for urine albumin screening in Thailand. Reliable testing tools for albuminuria and

WHAT THIS STUDY ADDS

⇒ The utility of locally developed tool for albuminuria detection at community level and demonstrated efficacy for usage in early CKD detection.

⇒ The tool is easy to use, accessible and affordable in communities outside of large cities in Thailand, creating opportunities for development of CKD detection programmes in primary care.

⇒ The diagnostic performance of the novel urine albumin strip in identifying albuminuria at the point of care is superior to the use of simple urine dipstick, and performance compatible with the standard laboratory measures.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The novel tool can facilitate the development of community-based prevention programmes for testing albuminuria as an early marker of CKD and cardiovascular disease in Thailand and similar jurisdictions in Asia.

⇒ The portability, accessibility and affordability of the new tool is an opportunity for early CKD detection and CV-risk reduction at community levels in Thailand as primary care professionals can be easily trained on its application.

⇒ Further assessing its cost-effectiveness as a tool for preventing CKD and reduction of CV risk can potentially inform the decisions on adoption, scalability and sustainability of its integration into primary care programmes.

eGFR recommended by the Kidney Disease Improving Global Outcomes as a global panel for CKD screening are essential for early detection.[4 5] However, they are often unaffordable and unavailable in low to middle-income countries, especially in the level of subdistrict health office (SDHO).[6–8] Routine screening for all high-risk populations can be economically burdensome.[9–11] Although urine dipstick tests for protein are cheaper and do not require specialised measurement equipment, they have poor sensitivity and a high false-positive rate in detecting albuminuria.[12–14] Developing affordable testing kits is crucial for mitigating the rising global burden of kidney disease.

To improve accessibility and efficacy in detecting albuminuria, a urine albumin strip could be a viable solution as a point-of-care test (POCT). Our team developed a paper-based lateral flow immunochromatography test kit to detect albuminuria, which has undergone internal validation.[15] In this study, we present the results of a community-based early detection programme for CKD in Thailand using the locally developed POCT urine albumin strip and compare measurements to standard albuminuria measures.

METHODS

We conducted a community-based cross-sectional study in 17 SDHOs in Ban Phaeo District, Samut Sakhon Province, Thailand (online supplemental material 1), as a part of the Chulalongkorn University-Banphaeo General Hospital Collaborative CKD cohort. The study adhered to ethical principles of the Declaration of Helsinki and was approved by The Institutional Review Board committees of the Faculty of Medicine, Chulalongkorn University, Bangkok (IRB No. 543/60) and the Banphaeo General Hospital (IRB No. 004/64).

Setting of the primary public healthcare system of Thailand

The primary public healthcare system of Thailand has been established for decades. Each of the 76 provinces (excluding the Bangkok Metropolitan Area) has one tertiary-care hospital, a secondary-care hospital in each district and at least one SDHO for each subdistrict. There are approximately 11 000 SDHOs in the country, providing healthcare to 66 million Thai citizens.

Study population and recruitment

Community nurses in the various participating SDHO reviewed local medical record databases to identify eligible individuals for participation, specifically asymptomatic residents aged ≥18 years with at least one of the following risk factors: age ≥60 years, hypertension or diabetes as defined by the International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM diagnosis codes were selected for enrolment into the study).[16] Participants previously diagnosed with kidney disease of any type were excluded. The enrolment window was 1 February to 31 March 2022. Each individual was informed by mail about their potential risk for CKD and invited to participate in the study. A 1-month local media promotion was also conducted to identify additional eligible individuals who may not have been included in the community databases. The total population, populations at risk for CKD and number of enrolled participants from each SDHO are presented in online supplemental material 2.

Study procedures

Enrolled participants completed in-person surveys in their subdistrict areas after agreeing to participate and providing written informed consent. Community nurses collected demographic and clinical data (ie, age, gender, comorbidities, smoking and alcohol consumption) and documented oral responses to the EuroQol group-5 Dimensions-5 Levels (EQ-5D-5L) questionnaire (online supplemental material 3) to affirm participants' asymptomatic status by evaluating five levels of five dimensions of health-related quality of life.[17 18] The EQ-5D-5L score, calculated using the coefficients from the validated study in the Thai population, ranged from 0 to 1, with 0 indicating severely impaired health and 1 indicating complete health (online supplemental material 4).[19] The EQ-5D-5L score of 1 is interpreted as asymptomatic. SDHO staff took blood pressure measurements based on established standards (Omron HEM 7130, Omron, Tokyo, Japan), measured body weight and height using digital scale (Seca 703, IDS Medical Systems, Shatin, Hong Kong) and measured waist circumference using a measuring tape. A non-fasting blood sample was collected for serum creatinine measurement using an enzymatic

assay and eGFR was calculated using the 2009 CKD-EPI equation.[20] A spot morning midstream urine sample was collected for a urine albumin POCT. The remaining urine was dispensed in a sterile container and stored at −20°C for quantitative urine albumin analysis within 24 hours.

Assessment of the utility of the point-of-care urine albumin strip

The urine albumin strip (Albii, K. BioSciences, Pathum Thani, Thailand), the first home-based test in Thailand, is a lateral flow immunoassay (LFIA) kit approved by the Thai FDA. Each urine albumin strip consists of a sample pad, a conjugate pad, a nitrocellulose membrane and an absorbing pad. The conjugate pad is coated with a mixture of antialbumin monoclonal antibodies (MAb) and gold nanoparticles (GNP). The test and control lines were coated with albumin and goat-generated anti-mouse antibodies, respectively. In normal urine samples, the MAb-GNP conjugate binds to the coated albumin, revealing a red band on the test line, and is interpreted as a negative result. If albuminuria is present, the urine albumin competitively binds to the MAb-GNP conjugate, leaving coated albumin on the test line unbound, and is interpreted as a positive result. Both forms of the MAb-GNP conjugate bind to the goat-generated antimouse antibodies, revealing a red band on the control line. Notably, the strip test should be read at least 10 min after applying the urine sample on the sample pad, and the red band on the control line must appear for accurate interpretation (online supplemental material 5).[15]

Qualitative test for urine albumin

Qualitative tests for urine albumin were conducted using the novel urine albumin strip (Albii, K. BioSciences, Pathum Thani, Thailand) and urine dipstick test for protein (Combur-Test strip, Roche Diagnostics, Basel, Switzerland). The tests were administered at the point-of-care within an hour after spot urine collection using 100 µ of urine per strip.

Quantitative measurement of urine albumin

Automated chemical analysis (Beckman Coulter AU5810, California, USA) was used to perform quantitative measurements of urine albumin concentration (UAC) and creatinine. These measurements were subsequently used to calculate the urine albumin-creatinine ratio (UACR), which served as the standard reference according to established recommendations.[4] Albuminuria was defined as UACR of ≥30 mg/g.

Outcome measurements and follow-up

Participants with albuminuria regardless of eGFR or patients with eGFR <60 mL/min/1.73 m^2 were considered

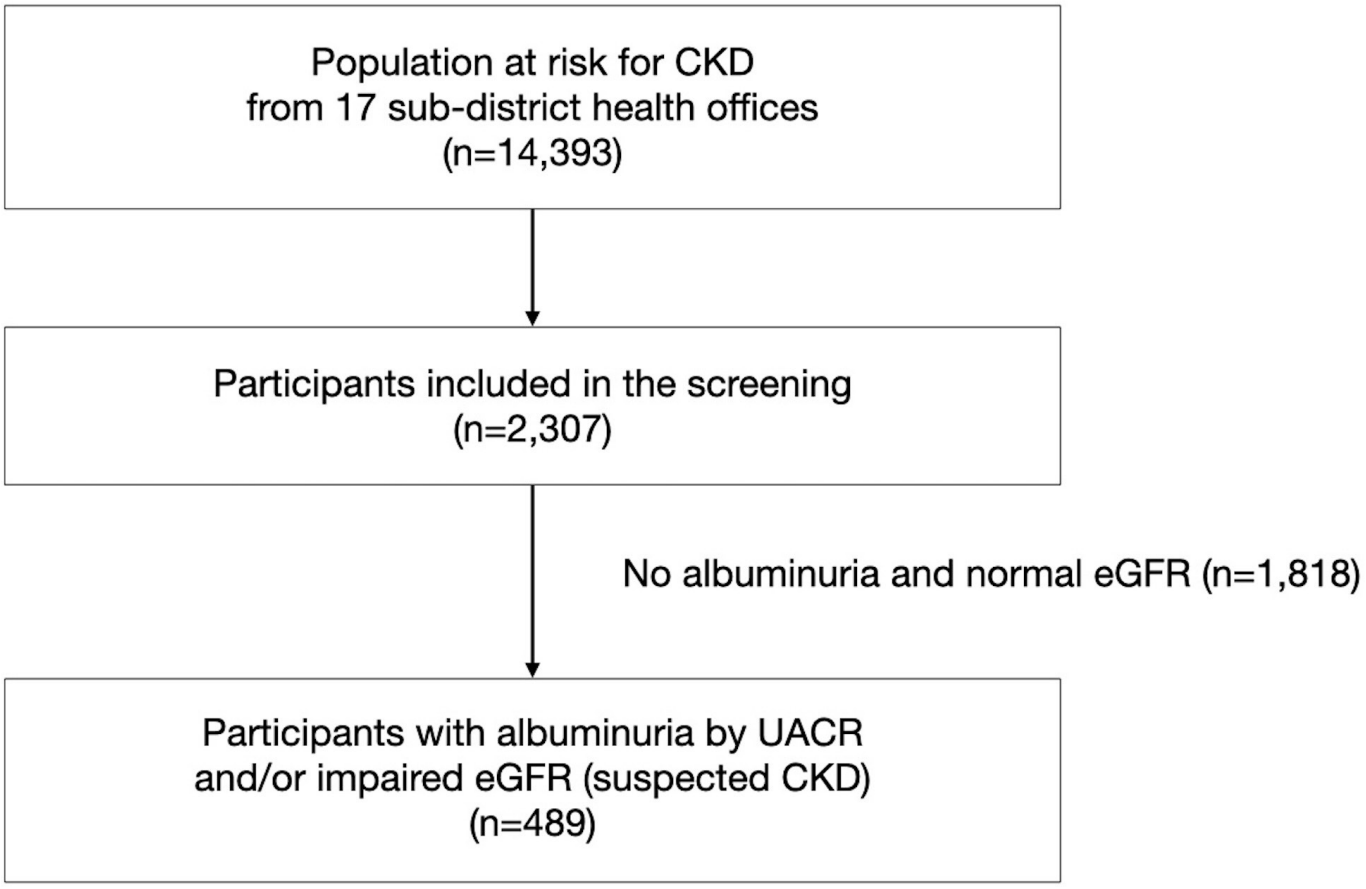

Figure 1 Study flowchart. CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; UACR, urine albumin-creatinine ratio.

as suspected CKD and received follow-up tests 3 months later to confirm the chronicity of abnormalities. The primary outcome was the prevalence of suspected CKD in the high-risk population, and the secondary outcome was the diagnostic performance of the novel POCT urine albumin strip.

The test results and interpretation, including diagnosis and severity of disease (if applicable), were mailed to each participant in a sealed envelope. Participants with persistent albuminuria or impaired eGFR were advised to attend the outpatient kidney clinic at the district hospital for appropriate management to slow CKD progression.

Patient public engagement

Patient public engagement was integrated into every phase of our study. We presented the study to the Community Hospital Advisory Committee for their input, ensuring that our methods were well-suited for the community. This community-based study involved an active camp survey, with significant involvement from SDOH nurses and staff. We promoted recruitment through local media channels. Participants received comprehensive information about their test results and were guided on appropriate follow-up actions. The implementation framework was also vetted for feasibility by the local working group.

Statistical analysis

A sample size of 1035 patients was calculated to provide a 5% width of a two-sided 95% CI for sensitivity and specificity given the estimated prevalence of 17.5% of CKD in our target high-risk population.[21 22] A sample size of 2307 samples included in our study would provide a 2.4% width of a two-sided 95% CI of sensitivity of this novel urine albumin strip. Descriptive statistics were calculated for patient characteristics. The central tendency for each variable is presented as mean±SD and median±IQR as appropriate. All statistical tests were two-sided, and $p<0.05$ was required to reject the null hypothesis. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy were calculated to evaluate the diagnostic performance characteristics of the novel test. Statistical analysis was performed using R Core Team (Vienna, Austria).

RESULTS

Among 14 393 individuals who met the eligibility criteria, 2307 (16%) agreed to attend the first screening event (figure 1). The mean age was 66±9.1 years, and 38.2% were men. The demographic characteristics of participants are shown in table 1. The most common pre-existing comorbidities were hypertension (62.7%), dyslipidaemia (58%) and diabetes mellitus (29.2%). The mean calculated EQ-5D-5L score was 0.981±0.04, reflecting asymptomatic status. The median eGFR was 93.2 (87.82, 98.73) mL/min/1.73 m^2, median serum creatinine was 0.67 (0.67, 0.67) g/dL and the median UACR was 9.15 (5.09, 20.96) mg/g (online supplemental material 6). Among the 489 participants with impaired eGFR and/or albuminuria, 406 (83%) had albuminuria with normal eGFR, 60 (12%) had impaired eGFR without albuminuria and 23 (5%) had both impaired eGFR and albuminuria (table 2). The median eGFR was 89.34 (72.26, 96.49) mL/min/m^2, median serum creatinine was 0.67 (0.67, 0.95) g/dL and the median UACR was 110.94 (52.71, 237.66) mg/g.

Urine albumin strip and dipstick for protein had a sensitivity of 0.70 and 0.51, specificity of 0.97 and 0.93, PPV of 0.84 and 0.64, NPV of 0.93 and 0.83 and accuracy of 0.92 and 0.86, respectively, in predicting UACR of ≥30 mg/g (table 3).

DISCUSSION

In this study, we have shown the prevalence of CKD in an asymptomatic high-risk population, predominantly characterised by albuminuria with normal eGFR. The urine albumin strip demonstrated significantly superior diagnostic performance compared with the urine dipstick for protein in detecting albuminuria at a point of care.

Table 1 Demographic characteristics of the participants

Characteristics	All participants (n=2307)	Participants with albuminuria and/or impaired eGFR (n=489)
Age, year (SD)	66.11 (9.1)	67.15 (9.84)
Gender, male (%)	881 (38.2)	190 (38.9)
Co-morbidities, n (%)		
Diabetes	673 (29.2)	215 (44.0)
Hypertension	1446 (62.7)	381 (77.9)
Dyslipidaemia	1338 (58.0)	313 (64.0)
Coronary artery disease	115 (5.0)	32 (6.5)
Cerebrovascular disease	42 (1.8)	13 (2.7)
No underlying disease	365 (15.8)	44 (9.0)
Unknown	87 (3.8)	9 (1.8)
Calculated EQ-5D-5L score, score (SD)	0.99 (0.04)	0.98 (0.04)
Smoking, n (%)	324 (14.1)	71 (14.5)
Alcohol use, n (%)	277 (12.0)	54 (11.1)
Analgesic use, n (%)	894 (38.9)	204 (41.8)
Body weight, kg (SD)	64.54 (21.1)	65.08 (12.9)
Body mass index, kg/m^2 (IQR)	24.91 (22.1, 27.9)	26.14 (23.2, 29.1)
Waist circumference, cm (SD)	87.68 (13.8)	90.43 (13.3)
Systolic blood pressure, mm Hg (SD)	144.32 (19.6)	147.51 (19.3)
Diastolic blood pressure, mmHg (SD)	82.32 (11.7)	83.15 (12.2)

eGFR, estimated glomerular filtration rate; EQ-5D-5L, EuroQol group-5 Dimensions-5 Levels.

The significance of these findings lies in the well-established understanding that albuminuria could reflect functional or structural defects of the kidneys, such as a breakdown of the glomerular barrier, insufficient albumin reabsorption and tubular endocytosis.[23] In patients with CKD, albuminuria occurs prior to the emergence of symptoms and before decreased eGFR or elevated serum creatinine can be detected.[5 24] It is also an independent predictor of CKD progression and cardiovascular mortality, especially in patients with diabetes.[25–28] Therefore, it is considered a sensitive marker in detecting early CKD and also CVD (as a marker of vascular endothelial damage).[29 30] There are various methods to detect albuminuria, such as the urine dipstick test for protein and quantitative analysis of either spot or 24-hour urine. However, the latter two methods require access to hospital laboratory facilities and might not be cost-effective for large-scale screening initiatives, especially in countries with limited resources as shown by the data from the International Society of Nephrology-Global Kidney Health Atlas.[8] Thus, a urine albumin strip test is more practical as a POCT health check in a primary healthcare setting.

The POCT strip we invented for detecting urine albumin is a GNP-based LFIA, which is accessible, simple to administer, less burdensome than other tests, and can be interpreted within 10 min. It has received validation in 100 urine samples from general outpatients, consisting of 54% with CKD, 10% with diabetes, 8% with acute kidney injury and 28% healthy controls.[15] Furthermore, as the urine samples included in the validation cohort mainly were collected from patients with low to high-grade albuminuria, the results of this study reaffirm that the urine albumin strip test detects albuminuria with high accuracy, even at low levels. As a POCT, the urine albumin strip performs better than the urine dipstick for protein. Findings from the present study confirm those of previous studies that although the urine dipstick test for protein is cheaper, it has lower sensitivity, particularly in detecting milder forms of albuminuria.[13 14 31–33] Among 429 individuals with albuminuria determined by UACR, the urine dipstick test for protein failed to detect albuminuria in 209 participants at the initial screening phase, a number higher than the cases of missed diagnoses when the urine albumin strip was applied (n=130). Previous studies showed the sensitivity and specificity of UACR as 0.87 and 0.88, and UAC as 0.85 and 0.88, respectively, compared with 24-hour urine albumin.[34] In our study, the sensitivity of the urine albumin strip was lower than that of random UACR (table 2) but is comparable to random UAC reported in previous studies (online supplemental material 7). This observation highlights the potential for further enhancement in the accuracy of the test, especially in cases where UACR is considered a more comprehensive measure.[35] To address this, future iterations of the urine albumin strip may benefit from the development of a urine strip for albumin–creatinine ratio. Since previous studies have shown that a urine sample from

Table 2 Number of study population by CKD staging and detection by POCT tests

	Albuminuria by UACR			
eGFR	A1	A2	A3	Detected by POCT tests
G1	7	44	26	Both tests
	30	118	5	Urine albumin strip only
	6	1	1	Urine dipstick only
	1221	72	1	Not detected by both test
G2	5	22	10	Both tests
	14	52	2	Urine albumin strip only
	5	1	0	Urine dipstick only
	550	49	2	Not detected by both test
G3a	0	2	3	Both tests
	1	6	0	Urine albumin strip only
	1	0	0	Urine dipstick only
	28	3	0	Not detected by both test
G3b	0	0	1	Both tests
	1	3	1	Urine albumin strip only
	0	0	0	Urine dipstick only
	8	0	0	Not detected by both test
G4	0	1	1	Both tests
	0	0	1	Urine albumin strip only
	0	0	0	Urine dipstick only
	0	0	0	Not detected by both test
G5	0	1	0	Both tests
	0	0	0	Urine albumin strip only
	0	0	0	Urine dipstick only
	0	0	0	Not detected by both test

CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; POCT, point-of-care testing; UACR, urine albumin-creatinine ratio.

Table 3 Diagnostic performance of the point-of-care urine albumin strip and random urine dipstick for protein, compared with the random urine albumin-creatinine ratio (UACR)

Diagnostic performance	Urine albumin strip* (95% CI)	Urine dipstick for protein* (95% CI)
Sensitivity	0.70 (0.65 to 0.74)	0.51 (0.46 to 0.56)
Specificity	0.97 (0.96 to 0.98)	0.93 (0.92 to 0.94)
Positive predictive value	0.84 (0.80 to 0.87)	0.64 (0.58 to 0.69)
Negative predictive value	0.93 (0.92 to 0.94)	0.83 (0.88 to 0.91)
Accuracy	0.92 (0.91 to 0.93)	0.86 (0.84 to 0.87)

*Compared with random UAC.

a mid-morning collection had the best correlation with 24-hour urine albumin,[36–38] we collected morning urine samples from enrolled participants. However, we recognise that while this approach enhances accuracy, it may be challenging to implement in real-world settings due to constraints of getting people attending screening appointments as per schedules.

The implication of our findings is the fact that developing affordable testing kits is crucial for mitigating the rising global burden of kidney disease. Although several different kidney health laboratory tests are widely available, costs vary substantially. A comparison of overall median reimbursement values reveals that serum creatinine (international dollar; Int$ 6.61) and urine dipstick tests for protein (Int$ 6.26) cost less than UACR tests (Int$ 17.72).[6] In Thailand, serum creatinine (THB 40=Int$ 1.15), UACR (THB 310=Int$ 8.94), and urine dipstick (THB 60=Int$ 1.73) are available. However, serum creatinine and UACR, which require measurement equipment, are restricted to tertiary-care and secondary-care hospitals. Laboratory testing is unavailable at the level of SDHO. The Towards Home-based Albuminuria Screening study, which evaluated home-based screening tools for albuminuria across a population, revealed a significant participation rate of 59.4% with urine collecting devices and 44.3% with a smartphone application using urine dipsticks.[39] A subsequent cost-effectiveness analysis using an individual-level simulation model indicated an incremental cost-effectiveness ratio of €9225 per quality-adjusted life year.[40] Scaling up local production of our urine albumin strip could greatly enhance cost-effectiveness, and we aim to conduct an implementation study in the future.

Despite these promising results, this study had some limitations. First, participants in this study were asymptomatic, and asymptomatic individuals in the general population might not participate in screening. Indeed, only 17% of 14393 eligible individuals participated in the initial screening. Of these, only 55% of participants with either albuminuria or decreased eGFR received a follow-up confirmatory testing, reflecting the rate of real-world practice in engaging with the standard care pathway. This highlights the challenges in transitioning from initial screening to follow-up care, underscoring the need to address these gaps through enhanced engagement with the healthcare system and supportive policies. Furthermore, we selected high-risk individuals for screening, and this might have led to a selection bias, as those who attended the screening programme may have had superior health literacy. Second, the urine albumin strip was developed as a diagnostic tool, not accurately designed for facilitating quantitative comparisons over time. Despite its integration into CKD detection recommendations,[5] it has not been incorporated in the recommendation for use as a follow-up test in CKD care. Third, similar to other methods for qualitative detection or quantitative measurement of urine albumin, some phenotypes of CKD, such as non-albuminuric CKD or non-albuminuric proteinuria, cannot be ruled out using the urine albumin strip test. Moreover, since this was a community field survey, we did not review the current medications taken by each participant. Some medications, such as angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, might decrease urinary protein.

All participants were asymptomatic and at high risk for CKD, and thus were members of the ideal target population that would benefit most from screening. Focusing the screening programme on the high-risk segment of the population would be the most cost-effective approach, as it maximises the impact of intervention measures to mitigate adverse health outcomes and related care

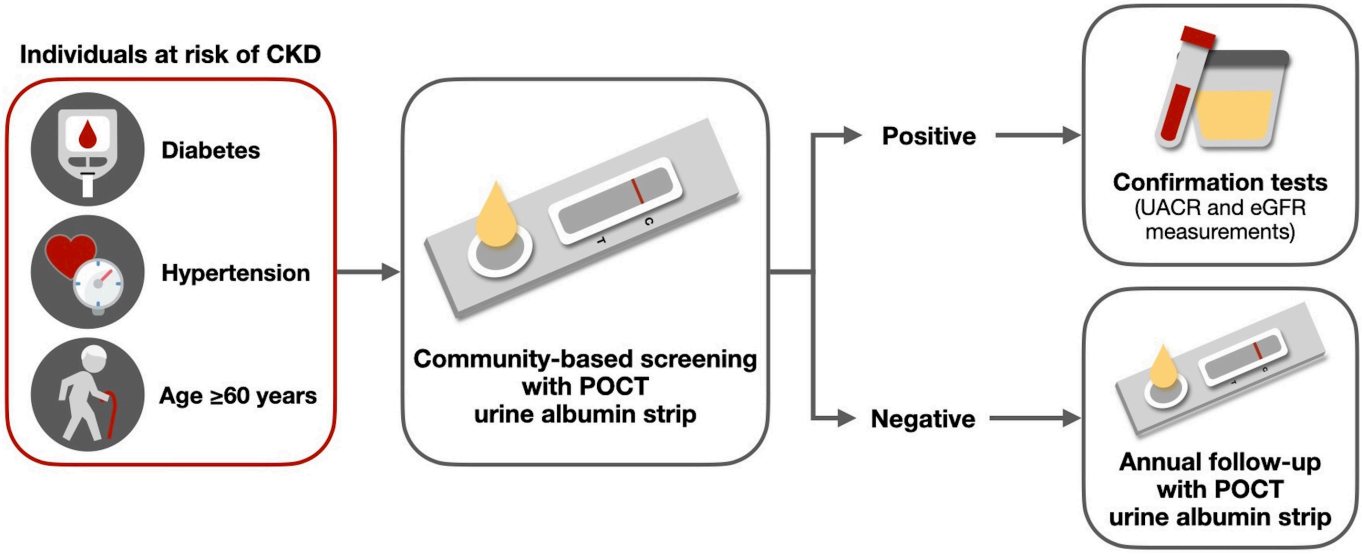

Figure 2 Proposed framework for implementation of urine albumin strip in community-based screening for CKD. CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; POCT, point-of-care testing; UACR, urine albumin-creatinine ratio.

costs.[5 10 41–43] Urine albumin strip tests could be widely used in practice for point-of-care CKD screening in the community setting. We outline a framework for implementing the POCT urine albumin strip, involving screening individuals at risk of CKD (figure 2). Positive results should prompt further confirmation tests for CKD identification, including UACR and eGFR measurement. Negative results should lead to annual follow-up screenings using the POCT urine albumin strip. To be the most beneficial to patients, the screening step should be followed by other comprehensive approaches to slow CKD progression, such as counselling on behaviour modification, weight reduction and/or appropriate medical treatment.[44]

CONCLUSION

A novel, locally produced urine albumin strip test is highly effective for use as a point-of-care screening test for early CKD among high-risk populations, with a comparable test performance to the standard UACR. This urine albumin strip test could be reliably and economically used for CKD screening on a larger scale.

Author affiliations
[1]Medicine, Chulalongkorn University, Bangkok, Thailand
[2]Medicine, University of Alberta, Edmonton, Alberta, Canada
[3]Banphaeo General Hospital, Samut Sakhon, Thailand
[4]Thai Red Cross Society, Bangkok, Thailand
[5]Chulalongkorn University, Bangkok, Thailand
[6]Department of Medicine, Chulalongkorn University, Bangkok, Thailand
[7]Research Unit of Chulalongkorn University, Bangkok, Thailand
[8]Division of Nephrology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand
[9]University of Alberta, Edmonton, Alberta, Canada
[10]Chulalongkorn University Faculty of Medicine, Bangkok, Thailand

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Contributors ST, PK and NS were responsible for research idea and study design; WC and KK for tool development and validation; ST, RN, PK, UN, ST and JD for data acquisition; ST and WK for data analysis; ST, RN, WK and NS for interpretation; ST, PK, WK and NS prepared the paper; SP, KP, KT and AKB revised the paper. NS accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by The Institutional Review Board committees of the Faculty of Medicine, Chulalongkorn University, Bangkok (IRB Number 543/60) and the Banphaeo General Hospital (IRB Number 004/64). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer-reviewed.

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ORCID iD
Somkanya Tungsanga http://orcid.org/0000-0002-2640-1131

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