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Original Research Article

Early detection of CKD using uACR screening in high-risk Indian Adults: A cross-sectional, real-world study using the Neodocs Kit

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Abstract

Background: Chronic kidney disease (CKD) is a growing global health concern, with diabetes and hypertension being its primary contributors. Early detection in high-risk populations is necessary to prevent end-stage renal disease (ESRD).

Aim and Objective: The present study aimed to assess CKD prevalence among high-risk individuals using a novel screening tool and to evaluate the impact of associated medical conditions, namely diabetes and hypertension, on CKD risk.

Materials and Methods: A prospective, cross-sectional study included 505 high-risk patients from various cities across India, where CKD screening was performed using the Point of Care, Neodocs Kidney Care Kit, a dipstick urinalysis tool that tests for multiple markers, including the urine albumin-to-creatinine ratio (uACR). Data was analyzed to check the feasibility of this screening, CKD prevalence, and its association with diabetes, hypertension.

Results: CKD prevalence was significantly higher in patients with diabetes (30.16%) compared to those without (18.42%, p = 0.0048). A non-significant trend toward higher CKD prevalence was observed in hypertensive patients (30.24% vs. 22.67%, p = 0.07). Patients with both diabetes and hypertension had the highest CKD prevalence (37.59%), significantly exceeding those with only diabetes (24.73%, p = 0.02), only hypertension (16.67%, p = 0.003), or neither condition (19.49%, p = 0.003). Although CKD incidence was highest among patients with diabetes duration over 10 years (36.4%), the difference was not statistically significant compared to those with shorter durations.

Conclusion: This study shows the high burden of CKD in patients with diabetes and hypertension, especially when both conditions coexist. Targeted screening could improve outcomes and reduce the burden of kidney disease in India.

Keywords: Chronic Kidney Disease (CKD), Hypertension, Diabetes Mellitus, Urine Albumin-to-Creatinine Ratio (uACR), Early CKD Detection, Dipstick Urinalysis, CKD Screening in India, Neodocs Kidney Care Kit.

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1. Introduction

Chronic Kidney Disease (CKD) has emerged as a major global health concern, ranking among the top 20 causes of death worldwide.[1] As per the latest data of Global Burden of Disease (GBD), the estimated global prevalence is approximately 13.4% (over 800 million people), with prevalence in India estimated to be around 15–17%, higher than the global average.[2-4] The burden has significantly increased in low- and middle-income countries (LMICs), including India.[5] WHO, in its Bulletin on CKD in India, has emphasized enhanced early screening interventions as a measure to significantly reduce the clinical burden and financial strain on both patients and the health system.[6] Diabetes & hypertension are the two leading causes of CKD. Chronic hyperglycemia in diabetes damages the kidney's microvasculature through oxidative stress, inflammation, and fibrosis, leading to albuminuria and progressive loss of filtration function. Hypertension exacerbates this damage by causing glomerular hyperfiltration and vascular injury, accelerating nephron loss and CKD progression.[7-8]

Early detection is critical, as interventions can slow disease progression and the risk of associated complications. Screening methods involve estimating the glomerular filtration rate (GFR) through serum creatinine measurements and detecting proteinuria via urine tests, including urine dipstick analysis. However, current CKD screening practices in LMICs are sparse and not systematically implemented.[9] The challenges and barriers to the implementation of universal screening include limited awareness and education, financial constraints, inadequate primary healthcare infrastructure, especially in rural and underserved areas, lack of National Screening Guidelines, diagnostic and laboratory limitations, and social stigma.[6,10]

Universal screening is not feasible in resource-limited settings; hence, targeted screening is recommended. A simple point-of-care screening strategy using non-invasive measures (e.g., urine dipstick tests) has been shown to effectively identify high-risk individuals in India.[2] Urinary Albumin-to-Creatinine Ratio (uACR) screening offers a non-invasive, cost-effective means to identify kidney dysfunction at its incipient stages. The present study aims to assess the feasibility of uACR screening, facilitated by Neodocs (ND) Healthcare Private Limited's Kidney Care Kit, in detecting CKD among populations at risk, particularly those with diabetes, hypertension, and cardiovascular diseases.(**Figure 1**)

2. Materials & Methods

2.1. Neodocs kidney care kit

The Neodocs Kidney Care Kit is a validated and CDSCO-approved point-of-care testing system that includes the Neodocs Test Card, which uses small urine samples (40–50 mL) for immediate analysis. Combining colorimetric test strips with AI-based image analysis via a smartphone app, the Neodocs Test Card can measure 14 different parameters, including urobilinogen, bilirubin, ketone, creatinine, blood, protein, micro-albumin, nitrite, leukocyte, glucose, specific gravity, pH, ascorbate, calcium, zinc, magnesium, uric acid, and salt. With albumin & creatinine measured, the uACR values get calculated and displayed via the smartphone application.(**Figure 2**) Moreover, this point-of-care device for rapid urine analysis has been validated by comparison to that of an established certified clinical-grade laboratory device named Acon Mission U120 urine analyser.[11]

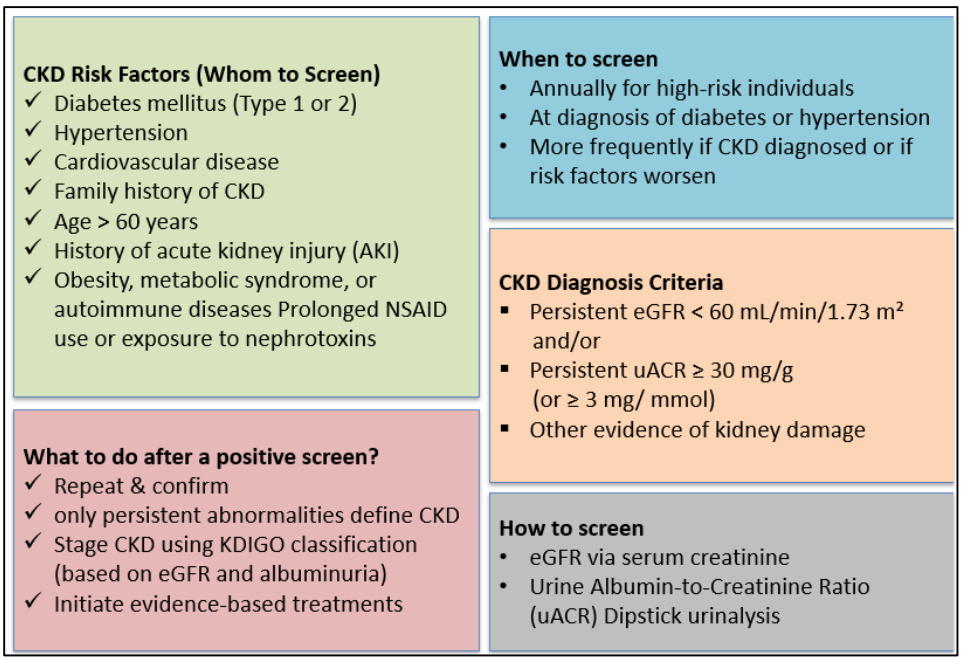

Figure 1: Criteria of screening**,** CKD risk factors, screening and diagnosis. uACR- urine albumin-to-creatinine ratio; CKD-chronic kidney disease; eGFR- estimated glomerular filtration rate

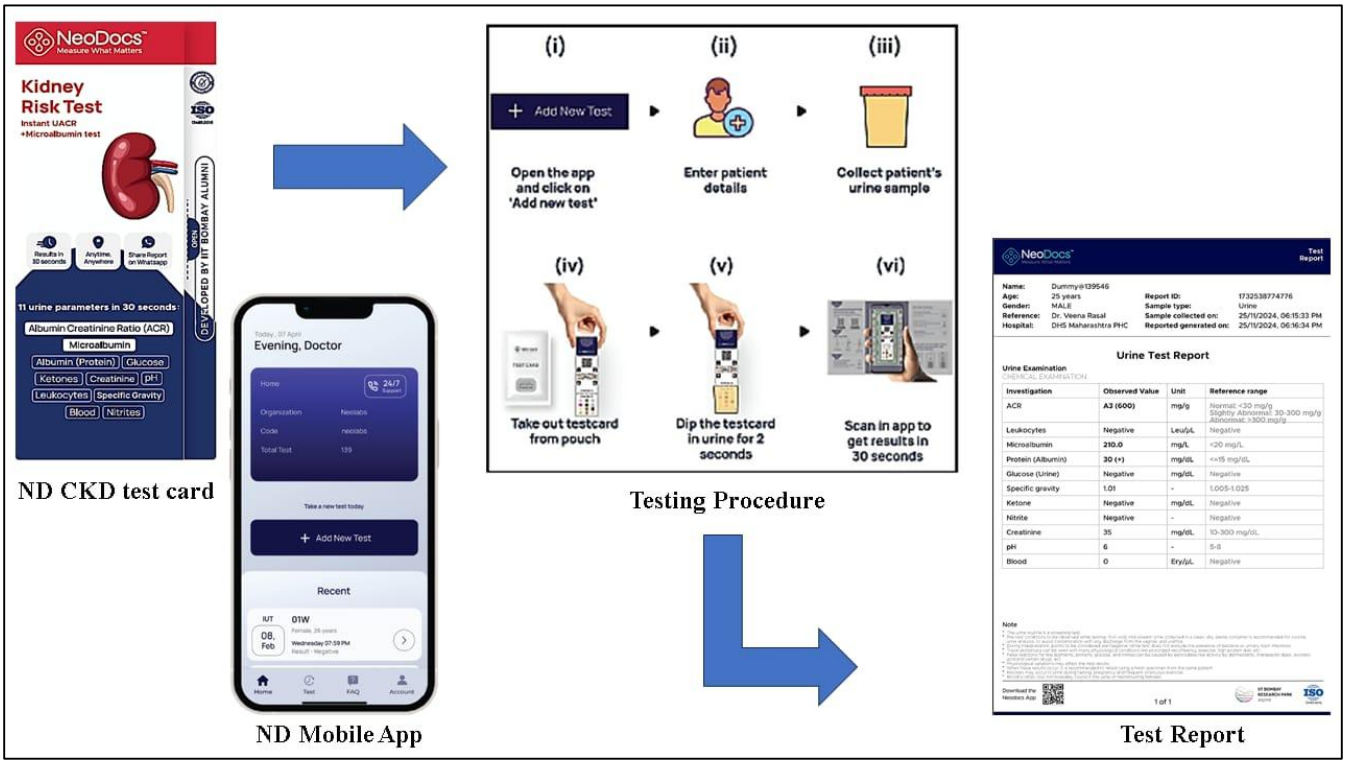

Figure 2: Flowchart representing the method of the Neodocs Kidney Care Kit; ND- Neodocs

2.2. Study design

The cross-sectional study was conducted at various clinics based in ten major cities of India, like Ahmedabad, Delhi, Hyderabad, Chennai, Jaipur, Kolkata, Mumbai, Indore, Bhopal and Chandigarh.

2.3. Study setting and participants

For recruiting the patients to this observational study, the inclusion & exclusion criteria were defined as follows:

2.3.1. Inclusion criteria

Demographics: Male, female, and other adults aged 18 years and older, Individuals with at least one of the following CKD risk factors:

1. Diabetes
2. Hypertension
3. Cardiovascular disease
4. Family history of CKD

2.3.2. Exclusion criteria

1. Pregnant or breastfeeding women
2. Menstruating women
3. Individuals with a known history of CKD
4. Active urinary tract infection

The patients who met the inclusion & exclusion criteria and gave their informed consent were asked to use the Neodocs Kidney Care Kit to determine the required uACR. Instructions for using the kit were provided to the participants along with a sterilized container to collect a 30ml urine sample. The test was performed using the Dr. Neodocs App at the doctor's clinic, and the results of the study were shared with the doctors participating in the study.

2.4. Data collection and outcome measures

The primary outcomes were to identify the uACR positive correlation with the associated medical history of diabetes and/or hypertension, glycemic control, and duration of diabetes. Data was collected at baseline, and the uACR values were recorded based on the risk stratification following the American Diabetes Association (ADA) and Kidney Disease Improving Global Outcomes (KDIGO) Guidelines. uACR categorization (A1, A2, A3) was available for all study patients.[12] However, uACR values (in mg/g) were missing for most patients, due to which no trend analysis of uACR values and HbA1c (%) was possible.(**Table 1**)

2.5. Sample size calculation

The sample size for frequency in a population was determined using OpenEpi, Version 3. The recommended sample size for 95% confidence interval was 384 patients. Considering 30% patients may not co-operate with the entire process and hence drop out, 505 patients were enrolled for the study.

2.6. Statistical methods

The study data were analyzed with the use of the Statistical Package for Social Sciences software (SPSS) version 19. Data analysis includes descriptive analysis of the frequency, percentage, mean, median, standard deviation, and inferential analysis, such as the relationship and the effect between variables in the study. Categorical data were compared by using the chi-square ($\chi 2$) test with a significant value ($p < 0.05$).

3. Results

A total of 505 patients participated in the study, and all these patients completed the study protocol. In order to minimize bias, the subjects were matched across key factors such as age and sex, the presence of co-morbid conditions, and their lifestyles. This ensured a balanced baseline for the study (**Table 2**).

Table 1: Persistent albuminuria categories, description & range used in CKD classification

Category	Description	uACR Range (mg/g)
A1	Normal to mildly increased	< 30 mg/g
A2	Moderately increased (microalbuminuria)	30–300 mg/g
A3	Severely increased (macroalbuminuria)	> 300 mg/g

Table 2: Baseline patient characteristics*

	Male (n - 272)	Female (n - 233)	Total (n - 505)
Age	53.05 ± 14.60	53.59 ± 13.17	53.28 ± 13.92
Cardiac issues			
Yes	36 (13.23%)	21 (9.01%)	57 (11.28%)
No	236 (86.76%)	211 (90.55%)	447 (88.51)
Don't Know		1 (0.42%)	1 (0.19)
Urinary tract infection			
Yes	5 (1.83%)	4 (1.71%)	9 (1.78%)
No	266 (97.79%)	229 (98.28%)	495 (98.01%)
Currently uses any medicine			
Yes	204 (75%)	190 (81.54%)	394 (78.01%)
No	68 (25%)	43 (18.45%)	111 (21.98%)
Diabetes			
Yes	158 (58.08%)	157 (67.38%)	315 (62.38%)
No	114 (41.91%)	76 (32.61%)	190 (37.62%)
Duration of diabetes			
0 – 1 years ago	31 (11.39%)	28 (12.02%)	59 (11.68%)
1 – 3 years ago	21 (7.72%)	23 (9.87%)	44 (8.71%)
3 – 5 years ago	26 (9.55%)	26 (11.15%)	52 (10.29%)
5 – 10 years ago	34 (12.50%)	27 (11.59%)	61 (12.08%)
Over 10 years ago	46 (16.91%)	53 (23.17%)	99 (19.60%)
Hypertension			
Yes	111 (40.80%)	94 (40.34%)	205 (40.59%)
No	161 (59.19%)	136 (58.36%)	297 (58.81%)
Diet			
Vegetarian	118 (43.38%)	107 (45.92%)	225 (44.55%)
Non-Vegetarian	151 (55.51%)	113 (48.49%)	264 (52.28%)
Eggetarian	3 (1.10%)	12 (5.15%)	15 (2.97%)
Exercise			
Regularly	84 (30.88%)	44 (18.88%)	128 (25.34%)
Sometimes	87 (31.98%)	63 (27.03%)	150 (29.70%)
Not at all	101 (37.13%)	126 (54.07%)	227 (44.95%)
Smoke			
Daily	13 (4.77%)	3 (1.28%)	16 (3.16%)
Few times a month	9 (3.30%)	1 (0.42%)	10 (1.98%)
Few times a week	13 (4.77%)		13 (2.57%)
Never	237 (87.13%)	229 (98.28%)	466 (92.27%)
Alcohol			
Regularly	5 (1.83%)	1 (0.42%)	6 (1.18%)
Rarely	26 (9.55%)	1 (0.42%)	27 (5.34%)

Socially	9 (3.30%)		9 (1.78%)
Never	232 (85.29%)	231 (99.14%)	463 (91.68%)
uACR done in last 3 months			
Yes	8 (2.94%)	17 (7.29%)	25 (4.95%)
No	264 (97.05%)	216 (92.70%)	480 (95.04%)
Serum Creatinine done in last 3 months			
Yes	35 (12.86%)	32 (13.73%)	67 (13.26%)
No	237 (87.13%)	201 (86.26%)	438 (86.73%)
eGFR done in last 3 months			
Yes	7 (2.57%)	11 (4.72%)	18 (3.56%)
No	265 (97.42%)	222 (95.27%)	487 (96.43%)
uACR category			
A-1	198 (72.79%)	177 (75.96%)	375 (74.26%)
A-2	52 (19.11%)	34 (14.95%)	86 (17.03%)
A-3	22 (8.08%)	22 (9.44%)	44 (8.71%)
HbA1c value	7.05 ± 1.77	7.11 ± 1.70	7.10 ± 1.75
*p-values were non-significant.			

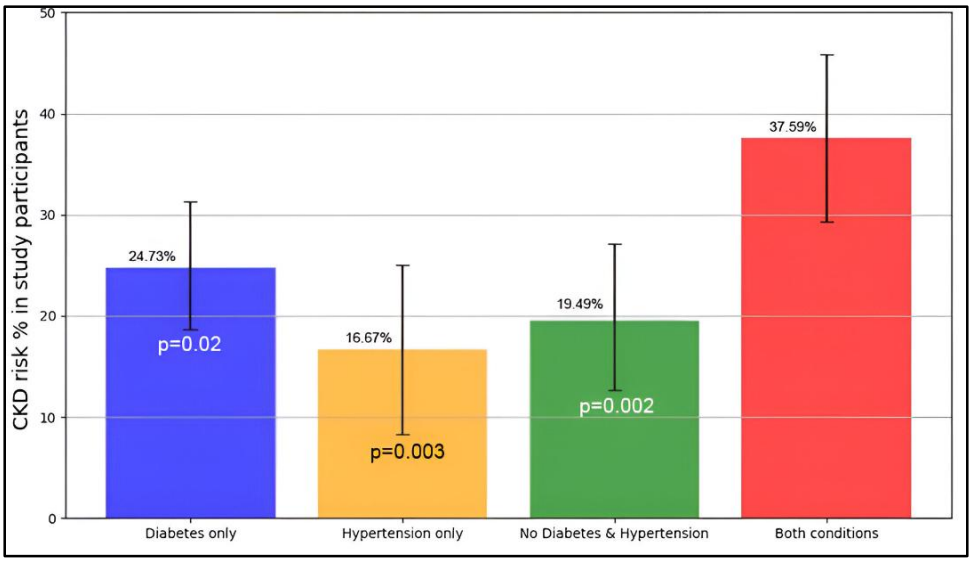

Figure 3: CKD risk comparison in patients with diabetes, hypertension & combination respectively

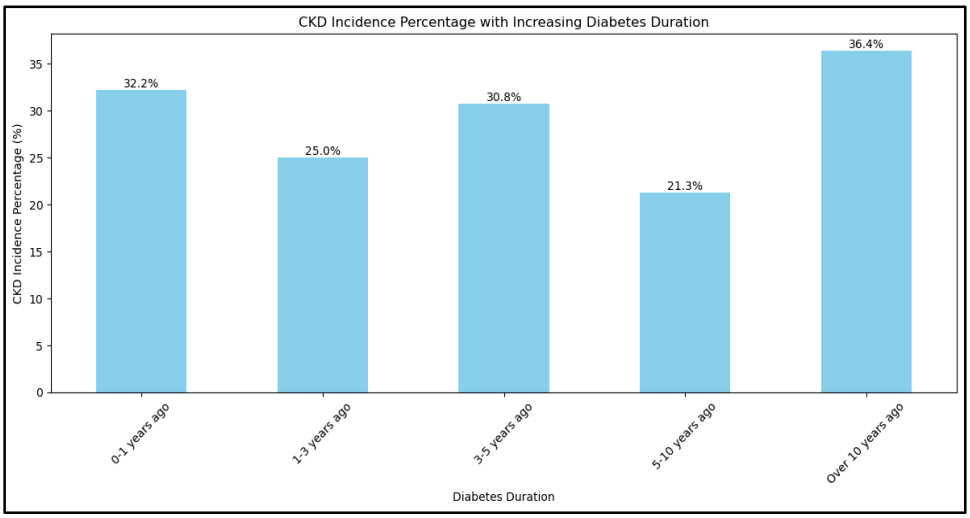

Figure 4: CKD Risk Comparison with increasing duration of diabetes

Patients with a history of diabetes had a significantly higher risk of CKD (30.16% vs 18.42%, p = 0.0048) than patients with no history of diabetes. Hypertension was also associated with a higher, though not statistically significant, risk of developing CKD (30.24% vs 22.67%, p = 0.07). Specifically, individuals with both diabetes and hypertension had a significantly higher risk of CKD compared to those with only diabetes, (37.59% vs 24.73%, p = 0.02) only hypertension (37.59% vs 16.67%, p = 0.003), or neither condition (37.59% vs 19.49%, p = 0.003).(**Figure 3**)

Refer to Diabetes patients were further stratified based on the duration of diabetes. This bar plot shows the percentage of CKD incidence with increasing diabetes duration. CKD incidence was highest in patients with diabetes duration over 10 years; however, there was no statistically significant difference in CKD risk between patients with diabetes over 10 years and those with shorter durations.(**Figure 4**)

Among patients with history of diabetes, 57% (180/315) presented with HbA1c> 7%, whereas 32.70% (103/315) patients had HBA1c > 8%.

4. Discussion

4.1. Clinical implications

Our cross-sectional screening of 505 high-risk adults across ten major Indian cities revealed a significant burden (25%) of undiagnosed chronic kidney disease (CKD), especially among individuals with diabetes and hypertension. This is consistent with global data showing that 20–40% of people with diabetes develop CKD,[13] making it the primary cause of end-stage renal disease (ESRD). Although CKD prevalence was also higher in patients with hypertension, the difference wasn't statistically significant; possibly due to overlapping comorbidities. Notably, individuals with both diabetes and hypertension had the highest CKD prevalence (37.59%), suggesting a synergistic effect in accelerating kidney damage. These findings support routine urine albumin-to-creatinine ratio (uACR) testing in patients with diabetes, hypertension, or other CKD risk factors.[14] Even a single elevated uACR (≥30 mg/g) warrants confirmation and close monitoring, as persistent albuminuria is an early CKD marker that allows timely intervention.

The study also highlights the need for better glycaemic control, as poor HbA1c levels were common. As per ADA guidelines, HbA1c < 7.0% is the primary target for most non-pregnant adults to reduce the risk of complications, while the less stringent target is <8.0%.[15] Evidence shows that every 1% reduction in HbA1c significantly lowers the risk of albuminuria and nephropathy.[16-18] Achieving HbA1c targets (<7% or individualized) and maintaining blood pressure below 130/80 mmHg are critical to slowing CKD progression and reducing cardiovascular mortality.[19] Finally, the study emphasizes comprehensive risk factor management. Treating diabetes or hypertension in isolation is insufficient. Patients with multiple risk factors need holistic care and education. Early screening and aggressive treatment can help detect CKD in its early stages and prevent irreversible damage.

4.2. Public health implications

From a public health perspective, the findings underscore a growing crisis in urban India, where lifestyle-related diseases like diabetes and hypertension are surging due to sedentary habits, poor diets, and rising obesity.[20,21] India already has one of the world's highest diabetes burdens, with 77 million adults affected in 2019- a number projected to exceed 130 million by 2045.[22] Hypertension affects about 30% of urban adults, often undiagnosed or poorly managed. These overlapping risk factors are fueling a hidden epidemic of CKD.[23] Our study revealed a high prevalence of albuminuria among high-risk individuals, indicating a large undiagnosed population on the path to CKD. In the SEEK-India study, only 7.9% of those with CKD were aware of their condition.[2] This highlights the urgent need for routine screening, such as annual urine albumin-to-creatinine ratio (uACR) tests for patients with diabetes, to detect early kidney damage. Early intervention is far more cost-effective than treating end-stage renal disease (ESRD).

Integrating CKD screening into India's existing non-communicable disease (NCD) programs is both feasible and essential. Urban clinics should be equipped to conduct basic kidney tests, and even point-of-care urine strips can be used in resource-limited settings. Public awareness campaigns must accompany these efforts, along with improved healthcare access. Lifestyle interventions including diet and exercise are imperative for prevention, as diabetes and hypertension often stem from modifiable behaviors.[24] Community-based programs offering dietary counselling can help manage these conditions and protect kidney health.

Finally, a patient centric multidisciplinary team approach would be required to address CKD. This would comprise of coordinated efforts from policymakers, healthcare providers, and public health authorities to implement screening, ensure medication access, and strengthen referral systems. Preventing CKD progression not only improves patient outcomes but also reduces the economic burden on families and the healthcare system.

5. Limitations

This study has several limitations that warrant consideration. First, the reliance on self-reported medical history for diabetes and hypertension may have introduced recall bias or misclassification, potentially affecting the accuracy of risk stratification. Second, uACR was measured only once, which limits the ability to confirm persistent albuminuria—a key criterion for chronic kidney disease (CKD) diagnosis.

Transient elevations due to factors like exercise or infection could have influenced results.

Moreover, uACR values (in mg/g) were missing for most patients due to which further analysis of uACR values with variables to generate further insights was not possible. Third, the study population was drawn exclusively from urban centers, introducing an urban bias that may not reflect the CKD burden in rural or semi-urban populations, where healthcare access and risk profiles differ. Lastly, the absence of a gold-standard comparator, such as laboratory-based uACR testing or eGFR measurements, limits the ability to validate the performance of the Neodocs kit against established diagnostic benchmarks.

6. Conclusion

This study highlights the urgent need for early CKD detection and integrated risk factor management in high-risk urban populations. Clinicians should routinely screen patients with diabetes and hypertension, who are most vulnerable to silent kidney damage. As India grapples with rising NCDs, embedding CKD screening into existing public health programs can prevent costly complications and improve long-term outcomes. Therefore, policymakers must act now to make CKD screening a standard component of diabetes and hypertension care nationwide.

7. Ethical Considerations

A cross-sectional analysis involving no clinical procedures, interventions, or collection of sensitive personal data. The patients' confidentiality was maintained using anonymized and de-identified data at the source level. Informed consent was obtained from all participants before data collection for conducting analyses for research purposes. As the study posed minimal risk to participants and involved anonymized data, formal ethics committee approval or waiver was not sought.

8. Conflict of Interest

None.

9. Source of Funding

Not applicable.

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