

Original Article

Prevalence of impaired kidney function & its association with diabetes & hypertension in India: The ICMR–INDIAB study (ICMR-INDIAB-22)

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Background & objectives: Chronic kidney disease remains a leading cause of morbidity and mortality in developing nations like India. This study was conducted to assess the prevalence of impaired kidney function (IKF) and its association with type 2 diabetes(T2D) and systemic hypertension (HTN) in India.

Methods: A total of 25,408 individuals (with/without HTN and T2D), a nationally representative sample, were included from the Indian Council of Medical Research–India-DIABetes (ICMR-INDIAB) cross-sectional study. IKF was defined as estimated glomerular filtration rate eGFR <60 mL/min/1.73 m² (CKD-EPI-2009 equation-race free).

Results: The overall weighted prevalence of IKF was 3.2 per cent [95% confidence interval (CI): 2.9–3.5] with no significant differences between urban [3.3% (2.8–3.7)] and rural areas [3.2% (2.9–3.5)], but higher among males [3.8% (3.4–4.2)] compared to females [2.6% (2.3–2.9)]. Four States in the country had prevalence of IKF ≥ 6 per cent and another four States had prevalence ≥ 4 per cent. The decrease in eGFR for every year increase in age was around 1.0 ml/min/1.73 m²; this was greater in urban areas, females, and in those with both HTN and T2D. Presence of T2D alone was associated with significantly higher risk of IKF compared to HTN alone (Odds Ratio 3.2 vs. 2.4); however, the risk was six fold higher in individuals with both HTN and T2D.

Interpretation & conclusions: The burden of IKF is high across India and is likely to rise further owing to high prevalence of metabolic risk factors. T2D seems to confer higher risk of IKF compared to HTN in this population.

Key words Asian Indians - diabetes - hypertension - impaired kidney function - prevalence

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Globally, the burden of chronic kidney disease is rising, leading to ever increasing morbidity and mortality^{1,2}. Impaired kidney function (IKF), a broad term that encompasses various kidney dysfunctions or diseases, ranging from mild, asymptomatic changes in function to severe end-stage kidney disease (ESKD), is characterised by a low estimated glomerular filtration rate (eGFR)^{3,4}, which is a core indicator of kidney health. eGFR is used for detection, risk assessment, and management of kidney disease by longitudinal measurements. It is utilised for adjusting medication dosages. eGFR is also instrumental in estimating the prevalence and impact of kidney disease⁵. As determined by the global nephrology community and summarised in the 2012 and 2022 kidney disease: improving global outcomes (KDIGO) guidelines for the diagnosis and management of CKD, both eGFR along with albuminuria (as measured by urinary albumin-creatinine ratio) are required to ascertain kidney health.

A global systematic literature review⁶ of population-based studies which assessed the prevalence of IKF through eGFR among adults, reported prevalence of 1.7 per cent and 8.1 per cent in Chinese and US studies, respectively, with four other studies indicating an estimated prevalence of 3.2-5.6 per cent. Consequences of IKF include the development of kidney failure, cardiovascular disease, an increased propensity to develop infections, mineral and bone disorders, protein energy malnutrition, and impairment of physical and cognitive function^{7,8}.

Kidney disease is attributed largely to the growing burden of type 2 diabetes (T2D), systemic hypertension (HTN), and cardiovascular diseases (CVD)⁹. T2D and HTN have bidirectional link, both being a cause and a consequence of IKF^{10,11}. With around 101 million people having T2D and 315 million having HTN in India¹², IKF can be expected to become a major challenge for healthcare systems and the economy in the coming years.

Data are scarce in developing countries like India on the epidemiology of IKF in those with and without risk factors such as T2D and/or HTN. In this manuscript, we use nationally representative data from the Indian Council of Medical Research-India DIAbetes (ICMR-INDIAB) study to report on the prevalence of IKF, measured by serum creatine-based estimated eGFR in India, disaggregated State-wise, and in urban and rural areas. We also report associations of IKF with T2D and HTN and compare the change in eGFR for every year/decadal increase in age in individuals with and without T2D and HTN.

Materials & Methods

Sampling and study population: We utilised data from the national, cross-sectional, ICMR-INDIAB study, which is a population-based door-to-door survey conducted in adults aged ≥ 20 yr to assess diabetes and other metabolic disorders in India. The study methodology is published elsewhere^{12,13}. The study received approval from the Institutional Ethics Committee of Madras Diabetes Research Foundation. Written informed consent was obtained from all study participants.

The survey involved a phased sampling of 113,043 residents across 31 States and Union Territories (UTs) between the years 2008 and 2020, utilising a stratified multistage sampling approach¹². The study was conducted in different phases. Phase I, carried out between 2008 and 2010, included four regions representing different parts of India: Tamil Nadu (South), Chandigarh (North), Jharkhand (East), and Maharashtra (West). Between 2011 and 2020, the remaining States were surveyed as follows: Phase II (2012-2013) covered undivided Andhra Pradesh (later split into Andhra Pradesh and Telangana), Bihar, Gujarat, Karnataka, and Punjab, the North East Phase (2011-2017) included Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, and Tripura. Phase III (2017-2018) involved Delhi, Madhya Pradesh, Rajasthan, and Uttar Pradesh, Phase IV (2018-2019) focused on Kerala, Goa, Puducherry, Haryana, and Chhattisgarh and Phase V (2019-2020) included Himachal Pradesh, Uttarakhand, Odisha, and West Bengal. Further information on the sampling approach can be found in the Supplementary material (Supplementary Material; 1.1-1.5). A three-tier stratification approach was employed, taking into account the State's geography, population size, and socioeconomic status (SES) to ensure the study population was representative. Census enumeration blocks in urban and villages in rural areas were the main sampling units. A systematic approach was employed to select 24 households from urban in each census enumeration block, and 56 households in each village from the rural areas. A household-based survey was conducted, and one person was randomly selected from each household using the WHO Kish method¹⁴. This approach minimised selection bias related to sex and age. Capillary blood glucose (CBG) was measured in all 1,13,043 participants, and venous blood was drawn in one in five participants (maintaining the representativeness of the sample), and in all those with known and newly detected diabetes (n=25,649). Serum

creatinine and glycated haemoglobin were measured from the venous sample. Of the 25,649 participants, for whom serum creatinine measurements were available, 241 individuals were excluded due to lack of information on HTN or T2D. Thus, the present analysis included a total of 25,408 participants (Supplementary Material; Fig. 3.1). Among these participants, missing data was <1 per cent for all variables, except waist circumference (1.8%) and HbA1c (2.5%).

Data collection: A standardised, pre-tested questionnaire was used to gather information on demographic characteristics, socio-economic factors, physical activity, dietary patterns, medical history, family history of diabetes, smoking and alcohol consumption. Current smoking was defined as self-reported use of tobacco products either daily or on some days within the past six months and current alcohol consumption as any self-reported alcohol intake, regardless of the amount or duration. Standardised methodologies were used to measure the participant's weight (in kilograms), height (in centimetres), and waist circumference (in centimetres)^{12,15}. Body mass index was calculated using the standard formula¹². Blood pressure was recorded twice on the right arm 5 min apart, with the participant seated, using electronic monitors (Omron HEM-7101; Omron Corporation, Tokyo, Japan). The average of the two readings was taken as the final measurement. The inter and intra-observer coefficients of variation among field technicians were < 5 per cent. Consistency in equipment specifications was maintained throughout the study by utilising identical equipment to maintain quality assurance.

An oral glucose tolerance test (OGTT) was conducted using a One Touch Ultra glucose meter (Life Scan Johnson & Johnson, Milpitas, California) among those who had no previous history of diabetes after an overnight fast of at least 8 h. Individuals with known diabetes underwent a fasting capillary blood glucose (CBG) measurement. All biochemical assays were carried out using venous samples (drawn in a subset of individuals as mentioned above), which were centrifuged within an hour and the serum stored in labelled vials at -20°C prior to transportation to the centralised laboratory in Chennai. Using the Bio-Rad VariantTM II Turbo machine (Hercules, CA), HbA1c (glycated haemoglobin) was measured through high-pressure liquid chromatography, certified by the National Glycohemoglobin Standardisation Programme traceable to the Diabetes Control and Complications Trial (DCCT) standardised method¹⁶.

Serum cholesterol, HDL cholesterol and triglycerides were analysed using the CHOD-PAP, GPO-PAP and direct methods, respectively. LDL cholesterol concentrations were determined using the Friedewald equation. Serum creatinine was estimated by Jaffe's kinetic method using Beckman kits (Beckman Coulter AU2700, clinical chemistry analyser, Fullerton, CA, USA), isotope dilution mass spectrometry (IDMS)-traceable. The variability within and between assays for biochemical tests ranged from 3.1 to 7.6 per cent.

GFR was estimated using the 2009 chronic kidney disease epidemiology collaboration (CKD-EPI) equation (race free) = $141 * \min(S_{cr}/\kappa, 1)^{\alpha} * \max(S_{cr}/\kappa, 1)^{-1.209} * 0.993^{\text{Age}} * 1.018$ [if female], where S_{cr} is standardised serum creatinine (in mg/dL), κ is 0.7 for females and 0.9 for males, α is -0.329 for females and -0.411 for males, \min is the minimum of S_{cr}/κ or 1, and \max is the maximum of S_{cr}/κ or 1 and age is participants' age (in years)¹⁷. eGFR was also estimated using the new age and sex (AS) 2021 CKD-EPI equation¹⁸ and the European Kidney Function Consortium (EKFC) creatinine-based equation (race free) for sensitivity analysis¹⁹. Formulae used for sensitivity analysis are provided in the Supplementary material (Supplementary Material; 2.1).

Definitions: The table P²⁰⁻²³ present the operational definitions used in this study.

Statistical analysis: We used SAS statistical package (version 9.4; SAS Institute, Inc., Cary, NC). Summary statistics were presented as mean (SD) for continuous variables and as proportions with 95 per cent confidence intervals (CI) for categorical variables. The calculation of sample weights took into consideration sampling at various levels within each State¹². All statistical analyses were adjusted to reflect the complex survey structure, using appropriate survey weights and methods for estimating errors. For estimating population means, variance, and proportions, the State was taken into consideration as the stratum, the cluster as the primary sampling unit, and the normalised weight as the final study weight. Survey-adjusted linear regression and Wald χ^2 were used to compare the mean or percentage of variables between two groups (male and female, urban and rural).

A multiple linear regression analysis using eGFR as the dependent variable and age, study group and their interaction was used to assess the relationship between age and eGFR for the different study groups. Additionally, multiple logistic regression

Table I. Operational definitions used in the study

Source	Definition	Reference
World Health Organization (WHO)	Diabetes: Diagnosed if fasting CBG \geq 126 mg/dL (7.0 mmol/L), and/or 2 h after an oral glucose load CBG \geq 200 mg/dL(11.1mmol/L), and/or those who were on antidiabetic agents	20
Joint National Committee (JNC 8)	Systematic hypertension: Diagnosed in individuals who had systolic blood pressure 140 mmHg & above or diastolic blood pressure 90 mmHg or above or were on antihypertensive medication	21
Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group	Impaired kidney function: Characterised by an eGFR less than 60mL/min/1.73 m	22
WHO Asia Pacific guidelines	Generalised obesity: Defined as a BMI \geq 25kg/m ²	23
WHO Asia Pacific guidelines	Abdominal obesity: Defined as a waist circumference 90 cm or more for men & 80 cm or more for women	23

analysis was used to examine the association of various study groups with IKF, after adjusting for confounding variables. Age and sex-standardised IKF prevalence rate were derived using the World Health Organization (WHO) population estimates²⁴. For statistical significance, alpha was set at 0.05.

Results

Of the 25,408 individuals included in the study, 12,061 (47.5%) had neither HTN nor T2D, 5213 (20.2%) had HTN but no T2D, 3333 (13.1%) had T2D but no HTN and 4891(19.2%) had both HTN and T2D (Supplementary Material; Fig. 3.1). The study population’s clinical and biochemical traits are presented in supplementary material; table 3.1. Of those with only HTN, 28.5 per cent (n=1,486) had self-reported HTN with a median HTN duration of 2.0 (0.9 - 4.7) yr. Among those with only T2D, 48.8 per cent (n=1626) had self-reported diabetes with a mean diabetes duration of 6.2 \pm 5.8 yr. Among those who had both the conditions, 54 per cent (n=2646, mean duration of HTN: 6.0 \pm 6.6 yr) and 61.2 per cent (n=2992, mean duration of T2D: 7.2 \pm 6.4 yr) were already known to have HTN and T2D, respectively. The mean age was highest among those with both HTN and T2D and lowest among those with neither condition. The sex distribution was equal in all groups except the only HTN group, where there was a female preponderance (56.9%). Weight, waist circumference, BMI, generalised and abdominal obesity and fasting and 2 h CBG were significantly higher in those with T2D (with or without HTN) compared to only HTN and without HTN and T2D group ($P<0.001$). Blood pressure (systolic and diastolic), smoking and alcohol use were significantly higher in individuals with

only HTN compared to individuals with only T2D ($P<0.001$). Of all the three groups, the group with HTN and T2D had the worst metabolic (glycaemic and lipid) parameters. The mean eGFR was highest among those without HTN or T2D (113.7 mL/min/1.73 m²) and lowest in those with both HTN and T2D (94.3 mL/min/1.73 m²) (Supplementary Material; Table 3.1).

Overall, the weighted prevalence of IKF was 3.2 per cent (95% CI: 2.9–3.5). The prevalences of IKF by residence (urban/rural), gender disease condition (presence of HTN and/or T2M), and stage of disease (newly detected/self-reported) are shown in table II. The prevalence of IKF in urban and rural areas did not differ significantly while it was significantly higher among males compared to females. The WHO age-standardised overall prevalence rate of IKF was 2.7 per cent. When the prevalence of IKF was stratified based on the presence or absence of HTN and T2D, it was lowest among individuals without HTN and T2D and highest among those with both HTN and T2D. The prevalence of IKF was significantly higher among those with self-reported HTN and those with self-reported T2D compared to those who had newly detected HTN and T2D. When sensitivity analysis was done using 2021 new AS CKD-EPI 2021 equation (race free)¹⁸ the overall prevalence of IKF decreased to 2.7 per cent (95% CI: 2.4–2.9), while when the EKFC creatinine-based equation (race free)¹⁹ was used, the prevalence was nearly the same (3.3%; 95% CI: 3.0–3.5) (Supplementary Material; Table 3.2).

Figure 1 shows the State/Union Territory (UT) wise weighted prevalence of IKF in India. In the overall study population, the prevalence of IKF ranged from 0.6 per cent in Chandigarh to 7.4 per cent in Goa

Table II. Prevalence of impaired kidney function in the study population

	Total, n	Unweighted, n	Prevalence (%)	95% Confidence interval	P value
Overall [#]	25,408	844	3.2	2.9-3.5	
Area wise [#]					
Urban	8281	300	3.3	2.8-3.7	0.681
Rural	17127	544	3.2	2.8-3.5	
Sex wise [#]					
Females	12359	349	2.6	2.3-2.9	<0.001
Males	13049	495	3.8	3.4-4.2	
Overall [§]	25,088	773	2.7	1.5-3.8	
Sex wise [§]					
Females	12209	459	2.4	1.0-3.8	0.014
Males	12879	314	2.9	1.0-4.7	
Group wise [#]					
Individuals without hypertension/diabetes	12,061	147	1.2	1.0-1.4	
Individuals with hypertension	5,123	153	2.8	2.3-3.4	<0.001 [@]
Individuals with diabetes	3,333	119	3.7	3.0-4.5	
Individuals with diabetes & hypertension	4,891	425	8.1	7.2-9.0	
Individuals with hypertension					
Newly detected	5867	211	3.4	2.9-4.0	<0.001
Self-reported	4147	367	8.2	7.2-9.2	
Individuals with diabetes					
Newly detected	3403	131	3.9	3.1-4.6	<0.001
Self-reported	4821	413	8.1	7.3-9.0	

[@]Compared to individuals without hypertension/diabetes; [#] Weighted prevalence; [§]World Health Organization (WHO) age standardised prevalence

and Telangana. Four States/UT had IKF prevalence of ≥ 4 per cent and < 6 per cent (Himachal Pradesh, West Bengal, Tamil Nadu, Puducherry), while four States had prevalence of IKF ≥ 6 per cent (Goa, Telangana, Kerala, Odisha).

Supplementary Material; figures 3.2 and 3.3 provide the prevalence of IKF among those with self-reported HTN and self-reported T2D respectively, stratified based on duration of the disease. There was a significant increase in the prevalence of IKF with increase in duration of HTN in the HTN and both HTN and T2D groups. Among individuals with duration of HTN < 5 yr, the prevalence of IKF was 3.9 per cent and 8.6 per cent in the only HTN and both HTN and T2D groups, respectively; in those with duration of HTN ≥ 20 yr, the corresponding figures were 19.4 per cent and 23.0 per cent, respectively (trend $P < 0.001$). A similar trend was observed in the prevalence of IKF with increase in duration of T2D (Supplementary Material; Fig. 3.3). The prevalence of IKF was 2.2 per cent and 7.1 per cent in individuals with only T2D and

both HTN and T2D when the duration of T2D was < 5 yr, which increased to 13 per cent and 25.9 per cent in those with ≥ 20 yr of T2D duration, respectively ($P < 0.001$).

Figure 2 depicts the age-wise distribution of eGFR among the study groups. The fastest change in eGFR was observed in the group with both HTN and T2D, followed by those with only T2D, only HTN and the no HTN and T2D groups. The changes between groups were statistically significant. Supplementary material; figures 3.4 and 3.5 present the overall distribution of eGFR and density plots of eGFR by different age groups in the various study groups. The histogram of eGFR from the overall study participants indicates a left skewed distribution with mean eGFR of 106.4 ± 20.4 mL/min/1.73 m² (Supplementary Material; Fig. 3.4). There is a normal eGFR distribution among individuals without HTN and T2D and an increasing skewness to the left in the eGFR distributions among the other three groups in the advanced age groups (Supplementary Material; Fig. 3.5).

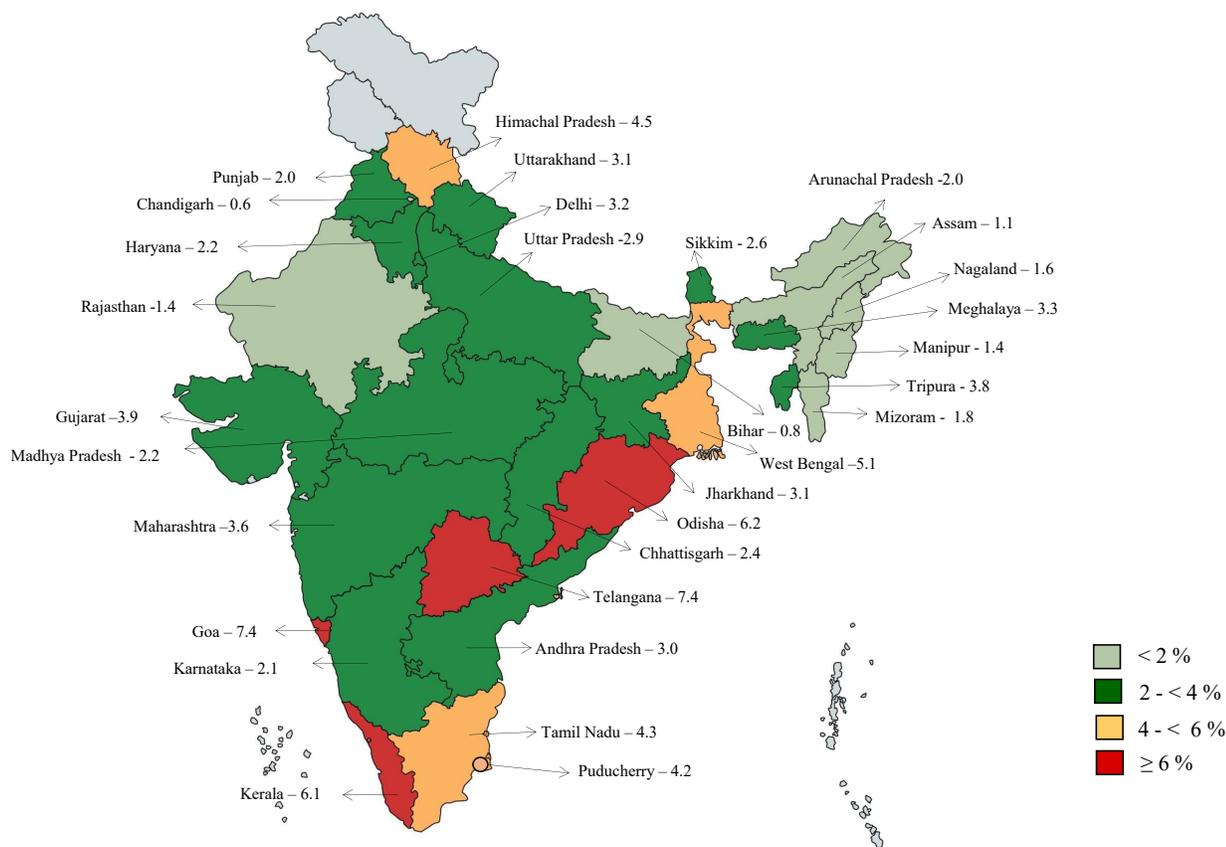


Fig. 1. Prevalence of impaired kidney function by individual state /UT (ICMR-INDIAB study: 31 States/Union territories) (Source: <https://www.mapchart.net/india.html>).

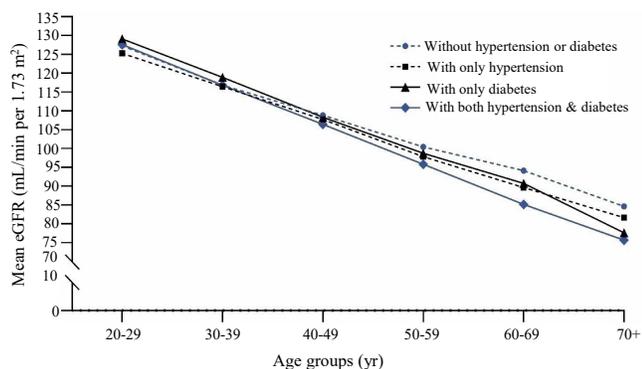


Fig. 2. Age wise eGFR in the study groups.

Table III shows the change in eGFR for every yearly/decadal increase in age, also stratified by urban/rural setting, and gender. Overall, a significant decadal decrease in eGFR with age was observed among both males and females by -9.10 and -9.49 ml/min/1.73 m², respectively and among both urban and rural residents by -9.51 and -9.22 ml/min/1.73 m², respectively. The highest annual change in eGFR was seen for those with both HTN and T2D, in males and in urban areas. Similar trends were seen for the

decadal decreases also. When sensitivity analysis was done among individuals with self-reported HTN and/or T2D (Supplementary Material; Table 3.3), a similar trend was observed.

The results of logistic regression analysis using IKF as dependent variable showed that individuals with HTN and T2D had six times higher odds for IKF compared to those without both the disorders, even after adjusting for age, sex, BMI, added salt intake and current smoking. Individuals with only T2D had a greater risk for IKF compared to those with only HTN. The risk for IKF was higher in urban areas and males (Table IV).

Discussion

We present national data on IKF in a population representative sample of over 25,000 adults from urban and rural areas of all 31 States/Union Territories of India. The weighted prevalence of IKF (as measured by eGFR) was 3.2 per cent with no significant difference in urban and rural areas, with higher prevalence among males compared to females. Four States/UT had

Table III. Change in eGFR for every year/decade increase in age among individuals in the study population

	Urban	Rural	Male	Female	Overall
	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)	β (95% CI)
Change in eGFR with yearly increase in age					
Overall					
Change in eGFR	-0.99 (-1.01 to -0.96)	-0.97 (-0.98 to -0.95)	-0.94 (-0.97 to -0.92)	-1.00 (-1.01 to -0.98)**	-0.97 (-0.99 to -0.96)
Individuals without hypertension or diabetes					
Change in eGFR	-0.92 (-0.96 to -0.87)	-0.87 (-0.90 to -0.85)	-0.82 (-0.85 to -0.80)	-0.95 (-0.97 to -0.92)*	-0.88 (-0.90 to -0.86)
Individuals with only hypertension					
Change in eGFR	-0.92 (-0.98 to -0.86)	-0.91 (-0.95 to -0.87)	-0.88 (-0.93 to -0.84)	-0.96 (-1.01 to -0.92)**	-0.91 (-0.94 to -0.88)
Individuals with only diabetes					
Change in eGFR	-1.01 (-1.08 to -0.95)	-1.02 (-1.08 to -0.96)	-0.99 (-1.06 to -0.92)	-1.01 (-1.07 to -0.96)	-1.02 (-1.06 to -0.98)
Individuals with hypertension and diabetes					
Change in eGFR	-1.09 (-1.17 to -1.01)	-1.04 (-1.10 to -0.99)	-1.11 (-1.17 to -1.05)	-1.02 (-1.09 to -0.95)	-1.06 (-1.11 to -1.02)
Change in eGFR with decadal increase in age					
Overall					
Change in eGFR	-9.51 (-9.82 to -9.20)	-9.22 (-9.40 to -9.05)	-9.10 (-9.31 to -8.89)	-9.49 (-9.70 to -9.27)**	-9.32 (-9.48 to -9.17)
Individuals without hypertension or diabetes					
Change in eGFR	-8.75 (-9.29 to -8.31)	-8.31 (-8.52 to -8.09)	-7.89 (-8.16 to -7.62)	-8.91 (-9.20 to -8.62)*	-8.40 (-8.86 to -8.20)
Individuals with only hypertension					
Change in eGFR	-8.83 (-9.45 to -8.20)	-8.61 (-8.96 to -8.25)	-8.49 (-8.91 to -8.07)	-9.0 (-9.43 to -8.56)	-8.66 (-8.96 to -8.35)
Individuals with only diabetes					
Change in eGFR	-9.62 (-10.29 to -8.94)	-9.56 (-10.12 to -9.00)	-9.33 (-10.01 to -8.65)	-9.55 (-10.11 to -9.00)	-9.62 (-10.05 to -9.19)
Individuals with hypertension and diabetes					
Change in eGFR	-10.28 (-11.00 to -9.56)	-9.73 (-10.27 to -9.18)	-10.51 (-11.11 to -9.90)	-9.48** (-10.11 to -8.85)	-9.98 (-10.42 to -9.54)

*P**<0.001, **<0.05 compared to male. CI, confidence interval; eGFR, estimated glomerular filtration rate

Table IV. Associations of impaired kidney function with hypertension/diabetes status

Hypertension/diabetes status	Adjusted Odds Ratio (95% CI)**				
	Urban*	Rural*	Male#	Female#	Overall*
Without hypertension or diabetes (Reference)					
Only hypertension	4.0 (1.7 - 9.6)	2.0 (1.4-3.0)	2.5 (1.6-3.9)	2.3 (1.3-3.8)	2.4 (1.7 - 3.4)
Only diabetes	3.0 (1.2 - 7.7)	3.5 (2.4 - 5.2)	4.3 (2.7-6.8)	1.8 (1.0-3.3)	3.2 (2.2 - 4.6)
With hypertension& diabetes	7.3 (3.2 - 16.4)	6.3 (4.4 - 8.9)	7.4 (4.9-11.0)	4.8 (2.9-7.7)	6.2 (4.5 - 8.6)

*Adjusted for age, sex, added salt intake, current smoking, BMI;#Adjusted for age, added salt intake, current smoking and BMI

prevalence of IKF ≥ 4 per cent and < 6 per cent and four States had prevalence of IKF ≥ 6 per cent. Individuals with T2D had a higher risk of IKF than those with HTN, even after adjusting for confounding factors.

Those with both HTN and T2D had the highest risk of IKF. The yearly decrease in eGFR was around 1.0 mL/min/1.73 m²; this was greater in urban areas, females and in the group with both HTN and T2D.

India has one of the largest numbers of people with HTN and T2D in the world. Therefore, the numeric burden of IKF in India is also likely to be high. A comprehensive review and meta-analysis of South Asian population-level studies on CKD prevalence, reported the prevalence of CKD in general population of India to be 16 per cent which varied from 6 per cent to 32 per cent²⁵. A cross-sectional study by the International Society of Nephrology's Kidney Disease Data Center reported an IKF prevalence of 2.5 per cent based on eGFR (CKD-EPI criteria)²⁶. Another population-based study conducted across India reported IKF prevalence of 13.1 per cent²⁷, while the screening and early evaluation of kidney disease (SEEK) study reported prevalence of 16.4 per cent using the CKD-EPI criteria²⁸. The SEEK-Andhra study reported IKF in 9.2 per cent, though these were camp-based and may have overrepresented individuals with known diseases²⁹. The center for cardiometabolic risk reduction in South Asia (CARRS) study, conducted in New Delhi and Chennai, found a crude IKF prevalence of 1.6 per cent, increasing to 2.6 per cent after age standardisation (based on 2012 KDIGO CKD guidelines)³⁰. A comparison between India (Punjab) and the USA showed a lower prevalence in India (2% vs. 3.8%)³¹. Our study reported an IKF prevalence of 3.2 per cent, aligning with earlier population-based findings^{26,30,31}.

In a study conducted in rural Andhra Pradesh, of the 403 participants who had CKD, 53.6 per cent were women³². The CARRS study also reported higher prevalence of CKD (Stage 3-5 defined as eGFR < 60 mL/min per 1.73 m²) among women³⁰. However, the SEEK study reported higher prevalence of CKD among males compared to females²⁸ which is similar to that observed in our study.

T2D and HTN are the major risk factors for kidney disease worldwide. Shrestha *et al*²⁵ reported CKD prevalence of 27 per cent in adults with hypertension and 31 per cent in those with diabetes in a meta-analysis of population-based studies South Asia. The multi-centre Start India study reported renal dysfunction in 22.6 per cent of individuals with T2D³³. A rural South India study found CKD in 11 per cent of people with diabetes, 14 per cent with hypertension, and 15 per cent with both³⁴, consistent with our findings. In contrast, a study of 12,500 individuals without diabetes or HTN across urban and rural areas of North (Delhi, Haryana) and South India (Andhra Pradesh, Tamil Nadu) found lower CKD prevalence – 1.4 per cent and 1.9 per cent in northern urban and rural areas, and 0.43 per cent

and 4.8 per cent in southern urban and rural areas – indicating lower IKF risk in the absence of these major risk factors³⁵.

Global data suggest HTN poses a greater IKF risk than diabetes, but Indian evidence suggests the converse. According to the Indian CKD registry, diabetic kidney disease is the leading cause of CKD nationwide (31.1%)³⁶. A study reported that South Asians with diabetes had a higher IKF risk than those with HTN (OR 2.25 vs. 1.57)²⁶. Individuals with both T2D and HTN have the highest odds of developing IKF (6-fold increased risk as per our findings), demonstrating the multiplicative effect of these risk factors.

The population-based CARRS study reported that the mean eGFR among healthy individuals was 108 mL/min/1.73 m², which was higher than what has been reported in other ethnic groups³⁷. Our study reports a similar finding with the eGFR among individuals without HTN and T2D being 113.7 mL/min/1.73 m². A community-based study conducted in Mexico reported the mean eGFR to be 109.4, 92.1, 95.4 and 85.5 mL/min/1.73 m² among individuals without T2D and HTN, with only HTN, with only T2D and with both the disorders, respectively³⁸. In our study, the mean eGFR was higher in all the groups, compared to the Mexican study. It needs to be pointed out, that the current GFR estimating equations overestimate GFR in Indians by 20-30 per cent, suggesting the true value is likely lower.

A change in eGFR with increasing age was observed in both urban and rural areas, in all the groups studied. This likely reflects the natural decline in eGFR. We report that 47.5 per cent of the variability in eGFR is due to age. An early study reported that starting in the third decade of life, eGFR decreases by approximately 1 mL/min/m² per year³⁹. Our study corroborates these findings. Thus, regular monitoring of eGFR and overall kidney function becomes increasingly important as people age so as to manage and potentially mitigate the impact of these age-related changes.

The wide variation in IKF prevalence across Indian States/UTs warrants further investigation. It is interesting to note that states with higher IKF rates were linked to poorer glycaemic control. Differences in healthcare infrastructure in different States, along with environmental factors like nephrotoxin exposure and extreme temperatures or humidity, may also play a role, as these have been associated with increased CKD burden in different parts of India^{40,41}.

In the current study, GFR was estimated using the 2009 CKD-EPI equation (race free). When we assessed the prevalence of IKF using 2021 new AS CKD-EPI 2021 equation (race free) we found that the overall prevalence of IKF decreased by 0.5 per cent compared to the prevalence reported using 2009 CKD-EPI equation (2.7% vs. 3.2%, respectively). Studies conducted in Asian Indians⁴², Chinese⁴³ and Korean and US Asian populations⁴⁴ have also reported similar observations, which resulted in significant reclassification among those originally classified as having IKF. However, when the EKFC creatinine-based equation (race free) was used in our study, there was not much difference in the prevalence of IKF compared to 2009 CKD-EPI equation (3.3% vs. 3.2%, respectively), while studies conducted in the Korean⁴⁵ and US population⁴⁶ comparing these two equations have reported an increase in the prevalence of CKD.

The study's key strength includes the fact that it is a truly representative national study based on a large sample size and careful study design, taking into account urban-rural and geographical diversity of all the States/UTs studied. The large sample size gives sufficient power to find significant results. The cross-sectional design of this study is one of the drawbacks; therefore, causal pathways underlying the reported relationships between risk factors such as T2D and systemic hypertension with IKF cannot be inferred. Secondly, serum creatinine data was available only on every 5th participant and those with diabetes, as this paper presents a sub analysis of research conducted as a component of a larger diabetes study in India. The third limitation was that even though the diagnosis of IKF requires persistently low eGFR over three months, we were constrained to use a single serum creatinine measurement, as it is challenging to do repeated measurements in large epidemiological studies. Thus, the use of a single eGFR measurement may lead to misclassification of IKD status, potentially resulting in overestimation of its prevalence. However, single cross-sectional measurements have been reported in epidemiological surveys globally^{47,48}. The fourth limitation was that our study did not assess albuminuria (for CKD diagnosis) because of difficulties in collecting urine samples in a study of this magnitude. The latter is of particular significance as albuminuria is often (but not always) the first manifestation to appear in individuals with diabetes who develop kidney disease. Future studies should address this gap. Another limitation is the use of the CKD-EPI 2009 creatinine-based (race-free) equation to estimate eGFR, which has not been specifically validated in the Indian population.

In the absence of a validated equation for this context, the KDIGO Work Group recommends using equations validated in similar geographic or ethnic populations. Furthermore, current guidelines advise reporting eGFRcr in adults using the 2009 CKD-EPI creatinine equation. The Work Group acknowledges that more accurate equations may be developed in the future and supports their adoption when available. Efforts are currently underway to develop an eGFR prediction equation tailored to the Indian population, which may improve accuracy in future studies⁴⁹.

In conclusion, IKF is a significant public health concern in India, particularly among those with T2D and/or HTN. Given the high burden of T2D, HTN, and other risk factors for IKF in the population, focusing on testing high-risk individuals is a practical and effective strategy. By identifying individuals at higher risk early, we can implement preventive measures and manage risk factors more effectively. Adding albuminuria testing to serum creatinine will make this program more comprehensive. In the Indian context, the integration of serum creatinine testing into existing National Programme for Prevention & Control of Non-Communicable Diseases (NP-NCD), which is already facilitating routine screening for major CKD risk factors such as diabetes and HTN, offers a feasible and potentially effective strategy for the early detection of IKF, particularly among high-risk individuals. Given the relatively low cost and wide availability of creatinine testing, such an approach is likely to be scalable within the public health system. Additionally, strengthening primary care infrastructure, enabling automated eGFR reporting in laboratories, and training healthcare providers in CKD risk assessment and management are essential system-level enhancements. Public awareness campaigns and community health worker engagement can further support uptake and adherence. Also, there are now effective evidence-based interventions available for reducing the progression and risk of adverse outcomes of IKF, particularly in T2D⁵⁰. Public health campaigns, regular screening programs, and improving access to healthcare are essential steps in addressing this issue. Educating people about lifestyle changes, such as managing blood pressure and blood glucose levels, maintaining a healthy diet, and avoiding nephrotoxins, can also play a key role in reducing the prevalence and impact of IKF.

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