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Original Research Article

PREVALENCE & CLINICAL PROFILE OF CKD OF UNKNOWN ETIOLOGY IN MARATHWADA REGION OF MAHARASHTRA STATE, INDIA

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ABSTRACT

Background: There were concerns raised regarding a high prevalence of chronic kidney disease (CKD) in Marathwada region. The present study was undertaken to ascertain the prevalence of CKD, disease characteristics, and risk factor profile in this area.

Materials and Methods: We selected 1300 subjects (age >18 years) using multistage sampling. After obtaining demographic and anthropometric data, urinary protein-creatinine ratio, serum creatinine, and blood glucose were measured in all the subjects. Glomerular filtration rate was estimated (eGFR) using the Modification of Diet in Renal Disease equation.

Results: Mean age of the subjects was 42.80 ± 14.25 years (range: 18–98), 43% were men and 55% were women. Mean eGFR of subjects was 94.3±33.4. Low eGFR (<60 ml/min per 1.73 m^2) was seen in 182 (13.98%) patients with a mean eGFR of 34.8 ±16.6. The prevalence of subjects having low eGFR and with proteinuria (CKD) was 18.23%. Major risk factors, such as diabetes, long-standing hypertension, and Significant proteinuria, were absent in 73% of patients with CKD, implying that a significant proportion of the population is afflicted with the entity "CKD of unknown etiology (CKDu).

Conclusion: The prevalence of CKD and CKDu in Marathwada region is much higher than other earlier studies in either rural or urban communities in India. We suggest that there is a dire need to review health policies and allocate resources for prevention and treatment of CKD in the Marathwada region.

Keywords: CKD, eGFR, Etiology

INTRODUCTION

Chronic kidney disease is a global public health problem associated with premature mortality, decreased quality of life. A trend towards an increase in its incidence and prevalence has been reported worldwide. Chronic kidney disease (CKD) is an irreversible deterioration of renal function, which results from diminished effective functioning renal tissue. Resultant damage of metabolic, excretory, and endocrine functions of the kidney indicates the progress of medical condition of uremia.

The first description resembling what would later become known as CKDu can be found in a 1993 report by Mani. He described chronic interstitial nephritis as the leading cause of chronic renal failure in patients presenting to a single hospital in Chennai. The overall prevalence of chronic interstitial nephritis in this report was 28%, increasing to 38% among lower income patients. Approximately 70% presented with advanced kidney failure.[1]

It is believed that the prevalence of CKD and CKDu is on the rise in India. Earlier studies in limited geographical areas in India have shown that the prevalence of CKD was less than 1%,[2] whereas in a recent study in rural parts of Karnataka, India, a growing prevalence of CKD of 6.8% was reported.[3] It also has been estimated that age-adjusted incidence of end-stage renal disease in India is 229 per million population,[4] however, there are no national reports establishing the prevalence of CKD across the country. In the first report of Indian CKD registry that published data from 52,273 adults, the most common cause of CKD was diabetes (31%).5 An interesting observation in this study was that a significant proportion (16%) had CKDu, and the patients were middle-aged, poor, and presented with advanced CKD.

In these circumstances, we have under- taken a systematic population study with the following objectives: to establish prevalence and the characteristics of CKD in the population of Marathwada region of Maharashtra state and examine whether CKD in Marathwada can be explained by traditional risk factors like diabetes and long-standing hypertension, or if this is CKDu. A study on the prevalence of CKD, identification of CKDu, and the associated risk factors will help in providing a basis for health care policy and planning preventive measures.

Chronic kidney disease is a preventable disease. In CKD u, we don't known exact etiology. If we will be able to know the cause then preventive action can be taken and incidence of CKD can be brought down. CKD is causing heavy burden on health system which can be reduced.

MATERIALS AND METHODS

Study Design and Sample Size

A Cross sectional observational study was conducted in the Western Region of Maharashtra State area on 1300 subjects, and the prevalence (p) of CKDu was found to be 14.50 % (188 cases)

Inclusion Criteria

1) All diagnosed chronic kidney disease patients.
2) Age 18 year and above.
3) Belonging to both genders.
4) Patient willing to participate in the study.

Exclusion Criteria

1) Patient with Diabetes Mellitus. Past history or current treatment for DM
2) Patient with Known Hypertension.
3) Known case of Nephritic or Nephrotic Syndrome.
4) Known case of Snake bite induced kidney injury.
5) Urological disease of known etiology.

Characteristics of the Subject Population and Sample Collection

All subjects were administered a structured questionnaire. Subjects were questioned about the presence or absence of symptoms suggestive of renal disease. Past medical history of diabetes mellitus, hypertension, ischemic heart disease, and stroke was elicited. Questions pertaining to tobacco smoking and alcohol consumption were asked. Blood pressure measurements were taken for the entire group using standard instruments, which were calibrated daily. Random midstream urine samples were taken from all individuals. Blood tests were done for all participants, after taking their informed consent.

For the purpose of data collection a detailed proforma will be prepared. The proforma will include demographic profile (Name, age, sex and BMI), analysis of water samples and laboratory investigation. Informed consent will be taken from the participants who will be satisfying inclusion and exclusion criteria of study. The data will be collected from the participate. The collected data will be into Ms-excel sheet.

Definitions and Evaluation Criteria

Blood samples were collected for creatinine and glucose. All samples were stored at 2 to 8 ◦C, using a cold pack placed in thermos containers. Urine samples were collected, labeled, and details of collection were recorded. Cold chain, the system of storing and transporting blood and urine samples at recommended temperatures from the place of collection to the point of analysis, was maintained and monitored. The blood and urine samples were sent to the core laboratory in Visakhapatnam and analyzed on the same day.

Hypertension

Hypertension was defined as blood pressure more than 140/90 mm Hg or if the patient was on medication for hypertension or had a positive self-reported history of hypertension. Hypertension of more than 5 years' duration was taken as long-standing hypertension.

Diabetes

Diabetes was defined as fasting blood glucose >126 mg/ dl or random blood glucose > 200 mg/dl or on any medication for diabetes.

Chronic Kidney Disease,[6]

Criteria for diagnosis of CKDu included

1. No previous history or present hypertension, diabetes mellitus, snake bites, urological ailment of recognized etiology or glomerulonephritis.
2. Normal glycosylated hemoglobin levels (HbA1C < 6.5%).
3. Blood pressure <160/100mmHg untreated or <140/90mmHg on up to 2 antihypertensive agent.

Statistical Analysis

Data analysis was carried out using SPSS version 26.0 was applied. For descriptive statistics, categorical variables were reported as a pro- portion, whereas continuous variables were reported as means and SDs, when distributions were considered approximately normal.

The outcome variable was eGFR. Exposure variables considered were age, gender, education, occupation (farmer/non-farmer), and exposure to

agrochemicals, tobacco smoking, alcohol intake, diabetes, hypertension, long-standing hypertension, and proteinuria. The unadjusted relationships between the exposure variables and the presence or absence of CKD were examined in univariate logistic regression analyses.

Simple logistic regression analysis was also applied taking CKDu as the dependent variable and age, gender, education, occupation (farmer/non-farmer), pesticide contact, tobacco smoking, and alcohol consumption as independent variables. Multivariate logistic regression analysis was performed to evaluate the simultaneous effects of various exposure variables, with adjustment for the potential confounding effects of other factors mentioned previously. All the potential risk factors in the initial logistic regression model were included. Covariates included in the initial model were age, education, occupation (farmer/non-farmer), direct exposure to agrochemicals (handling, spraying), tobacco smoking, alcohol consumption, diabetes, hypertension, and long-standing hypertension.

In the multiple logistic regression model, the variables included were those that were significant at the 20% ($P < 0.20$) level in the initial model to accommodate more explanatory variables and to reduce type II error.

The Backward Likelihood Ratio method was applied at the 10% level of significance to fit the model, and adjusted odds ratios were found. Confidence intervals from these analyses were based on SEs. In all the analyses, a $P < 0.05$ was considered significant.

RESULTS

Characteristics of CKD

In the present study, 1112 subjects had CKD. Of these, 634 (57 %) were women and 478 (43%) were men (1). Mean age of patients with CKD was 42.80 ± 14.25, whereas the mean age of the CKDU population was 37.77 ± 11.91, which is statistically significant ($P < 0.001$). The demographic, lifestyle, and clinical characteristics of patients with CKD are shown in Table 1`. Seventy percent of the patients with CKD were between 35 and 65 years old. Most patients with CKD (72%) were agricultural farmers and 51.6% did not have any education.

Table 1: Association of demographic, habitual, and health characteristics with CKD group (1112)

		Positive		Negative			
Variable	**Category**	***n***	**%**	***n***	**%**	**Crude OR (95% CI)**	***P***
Age, yr	>65	143	12.9	56	3.1	11 (6.4–18.9)	<0.001
	55–65	290	26.1	210	11.6	5.93 (3.7–9.3)	<0.001
	45–55	268	24.1	298	16.5	3.86 (2.4–6.1)	<0.001
	35–45	229	20.6	461	25.5	2.13 (1.3–3.4)	<0.001
	25–35	108	9.7	462	25.6	1 (0.6–1.6)	0.001
	18–25	74	6.7	320	17.7	Ref	
Gender	Women	634	53.6	1014	56.1	0.9 (0.7–1.1)	0.36
	Men	478	46.4	793	43.9		
Education	Educated	538	48.4	1080	59.8	0.63 (0.5–0.8)	<0.001
	Uneducated	574	51.6	727	40.2		
Occupation	Farmer	800	72	1151	63.7	1.46 (1.1–1.8)	0.002
	Non-farmer	312	28	656	36.3		
Farmers - Pesticide contact	Exposed to pesticides	190	17.1	257	14.2	1.25 (0.9–1.7)	0.14
	Not exposed to pesticides	922	82.9	1550	85.8		
Tobacco smoking	Yes	226	20.3	299	16.5	1.28 (0.9–1.7)	0.08
	No	886	79.7	1508	83.5		
Alcohol consumption	Yes	290	26.1	361	19.9	1.4 (1.1–1.8)	0.009
	No	822	73.9	1446	80.1		
Diabetes	Yes	157	14.1	100	5.6	2.75 (1.9–3.9)	<0.001
	No	955	85.9	1707	94.4		
Hypertension	Yes	367	33	236	13.1	3.28 (2.5–4.2)	<0.001
	No	745	67	1571	86.9		
Long-standing hypertension	Yes	152	13.6	87	4.8	3.12 (2.2–4.4)	<0.001

	No	960	86.4	1720	95.2		
Proteinuria	Yes	552	49.6	0	0	—	—
	No	560	50.4	1807	100		

CI, confidence interval; CKD, chronic kidney disease; OR, odds ratio.

Table 2: Clinical and biochemical characteristics of the subject population (study population, CKD and CKDu)

	CKD (1112)	CKDu (188)
	Mean ± SD	Mean ± SD
Age	42.8±14.25	37.77±11.9
Weight	54.3±11.5	53.3±11.1
Serum creatinine	3.00±2.7	2.2±1.8
Serum urea	75.2±52.8	40.3±35.4
Body mass index	22.3±4.6	21.8±4.9
eGFR	40.3±14.7	40.3±14.8
Systolic BP	137.2±28.3	127.5±25.7
Diastolic BP	85.8±16.8	84.3±15.8
Proteinuria (PCR)	1.5±0.9	0.3±0.1

BP, blood pressure; CKD, chronic kidney disease; CKDu, chronic kidney disease of unknown etiology; eGFR, estimated glomerular filtration rate; PCR, protein-creatinine ratio

Hypertension was found in 172 (33%). The duration of hypertension was less than 5 years in 101 (19.34%), whereas 71 (13.60%) had been hypertensive for more than 5 years (long-standing hypertension). The prevalence of diabetes and hypertension in subjects with CKD was found to be 14.1% and 33.0%, (Table 1). CKD due to long-standing hypertension as evidenced by left ventricular hypertrophy on electrocardiogram, was found in 43 (11.7%) of 172 hypertensive patients. As per National Kidney Foundation-K/DOQI stage wise classification of CKD, 13.2%, 10.7%, 29.8%, 17.4%, 18.6%, and 10.4% of patients were found in stages I, II, IIIA, IIIB, IV, and V, respectively.

On simple logistic regression analysis, there was significant relationship of CKD with age, education status, farming, alcohol consumption, diabetes, hypertension, and long-standing hypertension (Table 2); however, there was no statistically significant relationship of CKD with gender distribution, pesticide contact, and tobacco smoking.

Multiple Logistic Regression Analysis

Multiple logistic regression analysis of the study population for CKD showed significance for risk factors such as age, tobacco smoking, alcohol, education, diabetes, and long-standing hypertension (Table 5). Gender difference in the study population was not included in the multiple regression analysis because it did not have any association with CKD in univariate analysis even at a 20% significance level. Patients with chronic or long-standing hypertension were 2.1 times (95% confidence interval 0.7–2.8) more likely to get CKD than those without chronic hypertension.

Similarly, patients with diabetes were 1.65 times (95% confidence interval 0.7–4.8) more likely to get CKD compared with patients without diabetes. The adjusted odds ratio indicated that demographic characteristics, such as age, farming, and alcohol consumption, and clinical parameters, such as diabetes and long-standing hypertension, were found to be the risk factors for CKD in the western region of Maharashtra state area.

Characteristics of CKDu

Patients with CKD who did not have diabetes or long- standing hypertension were considered to have CKDu.15 A total of 78 (13%) of patients with CKD in the Marathwada region had CKDu. Their mean age was 50.9 ±12.3 (Table 3). There were 36 (46.3%) men and 42 (53.7%) women in the CKDu population (Table 3).

The mean eGFR was found to be 40.2 14.8. The mean systolic blood pressure was 128.0 ± 25.7 and diastolic blood pressure was 84.3 ±15.8 mm Hg. The mean blood pressure in both CKD and CKDu was normal, although a quarter of the patients were in advanced CKD stages IV and V.

As per National Kidney Foundation-K/DOQI stage wise classification of CKD, 16.0%, 9.5%, 32.7%,17.0%, 18.7%, and 6.1% of patients with CKDu were found in stages I, II, IIIA, IIIB, IV, and V, respectively.

Patients with CKDu did not have any symptoms even when they were in advanced stages IV and V of kidney failure. Sixty-nine percent of the CKDu population was between 35 and 65 years old. Most of the patients with CKDu were agricultural workers (73.1%), without even primary education (46.3%), non-smokers (81.6%), and non-alcoholics (75.5%).

On univariate analysis, it was observed that, except for age, no other parameter was statistically significant. Hence, multiple logistic regression analysis was not performed. The percentage of population distribution of both men and women was linear in CKD and CKDu groups.

Table 3: Association of demographic and habitual characteristics with CKDu

Variable	Category	Count	%	Crude OR (95% CI)	P
Age, yr	>65	18	9.9	0.048 (0.006–0.385)	0.004

	55–66	44	23.1	0.071 (0.009–0.542)	0.011
	45–55	45	24.1	0.1 (0.013–0.772)	0.027
	35–45	42	22.1	0.149 (0.019–1.18)	0.071
	25–35	27	11.9	0.337 (0.035–3.191)	0.343
	18–25	17	8.8	Ref	–
Gender	Women	101	53.7	1.083 (0.697–1.684)	0.723
	Men	87	46.3		
Education	Educated	87	46.3	0.729 (0.469–1.134)	0.161
	Uneducated	101	53.7		
Occupation	Farmer	138	73.1	1.234 (0.763–1.994)	0.391
	Nonfarmer	50	26.9		
Farmers - pesticides contact	Exposed to pesticides	40	21.1	0.853 (0.506–1.438)	0.551
	Not exposed to pesticides	148	78.9		
Tobacco smoking	Yes	35	18.4	0.651 (0.386–1.096)	0.106
	No	153	81.6		
Alcohol consumption	Yes	46	24.5	0.747 (0.459–1.216)	0.241
	No	142	75.5		

CI, confidence interval; CKDu, chronic kidney disease of unknown etiology; OR, odds rat

DISCUSSION

We undertook this study to determine the prevalence of CKD and associated risk factors among the rural population of Marathwada region. In our study, the prevalence of prevalence of CKDu was 14.5%. This uncanny high prevalence of CKD in a specific segment of the population is highly significant and is evidence pointing to an epidemic of CKD in this region. Although published data indicate an increasing prevalence of CKD in India, community-based studies are few and most of them were done in urban centers.

The prevalence of CKD in Marathwada region is at least 3 to 4 times higher than the prevalence reported in any of the previously mentioned studies. Several global epidemics of CKD have been reported, some with known etiology and in others the etiology remains unclear. In Sri Lanka, El Salvador, and Nicaragua, CKD is reported as a major public health problem causing significant mortality, and these regions are considered to be the hot- spots of CKD. The prevalence of CKD was between 13% and 18% in these 3 regions.[7,8]

Tatapudi et al9 found the prevalence of CKD at 18.3%, with 13% meeting the case definition of CKDu. This study was limited by a single time point estimate of the kidney function abnormalities and the use of unconventional definitions. The Study to Test and Operationalize Preventive Approaches for CKD of Undetermined etiology (STOP-CKDu) study recruited participants from 67 villages in the region and found the age-adjusted CKD prevalence to be 21.3% and 16.2% among males and females, respectively.

A recent report from a referral center at Puducherry10 reported on 2424 consecutive CKD patients — a disproportionate proportion (56%) of whom came from the districts of Villupuram and Cuddalore in Tamil Nadu. Approximately 52% were classified as CKDu. A subsequent community-based CKD screening program in those villages revealed a CKD prevalence of 19%. Referral patterns in major hospitals in Chennai and Pondicherry have shown a progressive increase in the number of patients presenting to the renal services with a short history, advanced kidney failure, no history of hypertension or proteinuria, and contracted kidneys.

Agarwal SK,[11] reported that the epidemiology of CKD in India is different from that in European and western world. Indian patients are younger and present with small kidneys and do not have known etiology of CKD. He concludes that a nationwide reporting system or registry is a necessary to determine the true incidence and prevalence.

Indian Society of Nephrology published the Indian CKD registry.[12] The data collected from 2005 showed that 16 % of the adult CKD patient had CKDu. These patients belong to low income group. CKDu was found to be the second biggest cause next to diabetes.

Ajay K. Sing et al,[13] Studied the epidemiology and risk factors of Chronic Kidney Disease in India. The results were published as SEEK study (Screening and Early Evaluation of Kidney Disease). This study included patients from urban area with high school diploma and from higher income group who were mostly over weight. The risk factors were hypertension 64.5 %, diabetes 31.6%. As this study was from urban area did not get cases of CKD of unknown origin due to bias.

The prevalence of diabetic kidney disease in our study was 14.6%, which is in stark contrast to the data from the Indian CKD registry in which diabetic nephropathy was the preeminent cause of CKD in 31% of patients.[5] We used similar criteria for identifying diabetic nephropathy. It is possible that some of these patients had non-diabetic kidney disease and more strict criteria for diagnosis of diabetic nephropathy could have further reduced the prevalence of diabetic kidney disease.

Among patients of chronic kidney disease, only 13.6% had long-standing hypertension. These results reveal that in a high proportion of patients with CKD, the 2 traditional etiological factors were strikingly absent.

In our study, pesticide contact and hypertension did not fit in the multiple logistic regression model

while evaluating the simultaneous effects of exposure variables. The reason that hypertension did not fit might be because of the covariance effect of long-standing hypertension. In studies of Meso-American nephropathy and Sri Lankan CKD, the prevalence of CKD varied conspicuously with age and occupation, such as agricultural works, sugarcane cutting, and mining, which are considered as heat stress occupations.[7] similarly we found the influence of occupation on the prevalence of CKD in Marathwada. CKD prevalence also varied with altitude and climatic conditions.[14]

The prevalence of CKD and CKDu was relatively high in Marathwada region. In our study, 188 (14.50%) patients with CKD did not have diabetes or long-standing hypertension. This type of CKD of unexplained etiology is strikingly common in the Marathwada region and to the best of our knowledge, has not been reported from any other parts of India.

A similar prevalence of more than 50% CKDu among patients with CKD was reported in cross-sectional studies from Nicaragua and Sri Lanka.[2]

Univariate regression analysis of our data did not show significant association of gender disparity, education, farming, and contact with pesticides, or habits such as tobacco smoking and alcohol consumption with CKDu in Marathwada. Our findings strongly indicate that both men and women are equally exposed to unknown factors that make them prone to CKD. The slow progress of disease, minimal urinary protein, and absence of chronic hypertension or diabetes strongly suggest that tubulo-interstitial nephritis is the pathology of CKD.

Strengths and Limitations of the Study

The strength of the study lies in its sampling methodology. We used multistage sampling, which covered a large area of investigation. We conducted house-to-house surveys with random sampling without bias for gender, occupation, literacy, or socioeconomic status. Questionnaires were administered and data were collected by medical graduates. This has ensured good compliance from the subjects and accuracy of the data. Biochemical tests were carried out in a single accredited reference laboratory.

There are a few limitations in the study. It was based on a single measurement of serum creatinine for each individual. However, because this is a large population-based study in a specific geographic area, high prevalence of low eGFR in a single spot determination is significant. In the second phase of our study, we have included Ground water analysis for establishing the type of kidney disease and possible etiological factors.

CONCLUSION

We report on prevalence and risk factors of CKDu in India. In this study, we report 14.50% prevalence of CKDu in a rural population in the Marathwada region of Maharashtra state of India. This study provides new evidence of high prevalence of CKD of epidemic proportions, which has emerged as a large public health threat involving consequent financial burden.

This form of CKDu appears to be unrelated to traditional risk factors, such as diabetes and chronic hypertension. 14.50 % of patients with CKDu in Marathwada region were identified as CKDu. This disease is similar to CKDu reported from Sri Lanka and rural Nicaragua; however, unlike CKDu in Sri Lanka or rural Nicaragua, we did not find any association with age, sex, education, employment in agricultural fields, or habits such as tobacco smoking and alcohol consumption.

Therefore, we propose that there might be a new etiological factor or multiple factors responsible for Marathwada region kidney disease. There is a compelling need for a cohort study for unravelling the etiology in early stages of CKD population.

In addition, it is important to make note of the existing disease burden, identify the population with early CKD, prevent progression of the disease, and establish treatment facilities for patients with advanced kidney disease so that morbidity and mortality can be contained.

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