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Research Article

A CROSS-SECTIONAL STUDY TO FIND OUT THE SIGNIFICANT PREVALENCE OF CHRONIC KIDNEY DISEASE IN TYPE 2 DIABETICS IN EASTERN INDIA

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ABSTRACT

Objectives: Diabetes mellitus (DM) is a metabolic syndrome clinically presenting hyperglycemia with underlying absolute or relative insulin deficiency. Type 2 DM (T2DM) presently comprises about 90% of the diabetic population of the World. Diabetes leads to many complications. One major complication of long-term poorly controlled diabetes is diabetic nephropathy which usually leads to end-stage renal disease (ESRD). There are mainly two crucial markers to assess renal impairment– (1) Glomerular filtration rate (GFR) and (2) Microalbuminuria. The objective of our study is to find out the prevalence of chronic kidney disease (CKD) in T2DM patients.

Methods: We measured glycated hemoglobin (HbA1c), serum creatinine, urinary ACR, and estimated GFR (eGFR) (by Modification of Diet in Renal Disease formula) in selected 105 T2DM patients aged 40–70 years (mean duration of diabetes is 10.01±3.46 years). We analyzed the data by appropriate statistical software and assessed the prevalence of CKD (with Urinary ACR and eGFR) in T2DM patients (with fasting blood glucose, 2-h OGTT, and HbA1c).

Results: This study shows that 30 out of 105 diabetic patients were suffering from CKD, with a prevalence of 28.57%.

Discussion: In our study; out of 105 T2DM patients, 30 (28.57%) patients had some stages of CKD. Nineteen (63.33%) out of these 30 CKD patients had albuminuria (both micro and macroalbuminuria), and 11 (36.67%) out of 30 CKD patients had normoalbuminuria (ACR <30 mg/g).

Conclusion: There is a high prevalence (28.57%) of CKD in T2DM patients, and early detection and treatment of diabetic nephropathy, along with tight glycemic control, helps prevent ESRD.

Keywords: Fasting plasma glucose, 2 Hr OGTT, glycated hemoglobin, Urinary ACR, Estimated glomerular filtration rate, Type 2 diabetes mellitus, Diabetic nephropathy, Microalbuminuria, Modification of diet in renal disease formula.

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INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic and endocrinal disorders that are characterized by the body's inability to produce or respond to insulin, which results in elevated levels of glucose in the blood over a prolonged period. It occurs due to the abnormal metabolism of carbohydrates [1]. Among many types of diabetes; two clinically important types are: Type 1 DM or insulin dependent DM (IDDM) and Type 2 DM (T2DM) or non-IDDM. Now, Type 2 diabetes comprises about 90% of diabetic patients in the World.

In 2021, International Diabetes Federation found that 537 million people [2] (8.3% of the adult population [3]) had diabetes worldwide, of which about 90% cases are T2DM. There are similar rates both in men and women [4]. Asian and African low- and middle-income countries suffer more than 80% of diabetic deaths [5]. The researchers anticipate that the worldwide load of diabetes will rise to 592 million by 2035 [6].

In India, currently, there are more than 62 million diabetic individuals, and diabetes is going to be a potential epidemic [7,8]. Wild *et al.* [9] predicted that the overall prevalence of diabetes will double from 171 million in 2000 to 366 million in 2030, with a maximum share from India. T2DM represents a significant global health problem. According to some sources, the disease takes a toll on six lives every minute worldwide, and soon that figure will make T2DM one of the world's most prevalent causes of preventable mortality [9]. That is why India is called the "diabetes capital of the world." [10] One of the major chronic complications of poorly controlled diabetes is diabetic nephropathy, and it may lead to end-stage renal disease (ESRD).

In the Western countries and the United States, now diabetic nephropathy is the leading cause of chronic kidney disease (CKD). In the United States, diabetes is the cause of 30–40% of all ESRD cases. In India, the estimated overall incidence rate of CKD and ESRD is 800 per million population (pmp) and 150–200 per million population, respectively [11,12]. It was found that DM is the cause of CKD in 31.2% of patients. Estimation of glycated hemoglobin (HbA1c) is the best parameter to monitor the long-term control of diabetes.

Two crucial markers – glomerular filtration rate (GFR) and microalbuminuria (MA) assess renal impairment (RI) best. Spot urine albumin-creatinine ratio (Urinary ACR) reflects MA better. eGFR or estimated GFR is calculated by some formula, among them, Modification of Diet in Renal Disease (MDRD) study equation is the most used one.

In 2002, the Kidney Disease Outcomes Quality Initiative (KDOQI) of the National Kidney Foundation (NKF) defined and classified CKD [13]. The guidelines were updated by KDOQI and the international guideline group – Kidney Disease Improving Global Outcomes [14]. In the different parts of the World, better communication among the doctors was possible due to these guidelines. They have improved the medical interventions at the various stages of CKD.

The guidelines have defined CKD as either renal damage or a GFR <60 ml/min/1.73 m^2 body surface area for at least 3 months.

In other words, CKD can be defined as:-
An eGFR value below 60 ml/min/1.73 m^2 in a period equal to or more than 3 months or the presence of renal lesion with or without reduced GFR in a period equal to or more than 3 months.

Staging of CKD: The stages of CKD are classified as follows [13,14]:
- Stage 1: Kidney damage with normal or increased GFR (>90 ml/min/1.73 m^2)
- Stage 2: Mild reduction in GFR (60–89 ml/min/1.73 m^2)
- Stage 3a: Moderate reduction in GFR (45–59 ml/min/1.73 m^2)
- Stage 3b: Moderate reduction in GFR (30–44 ml/min/1.73 m^2)
- Stage 4: Severe reduction in GFR (15–29 ml/min/1.73 m^2)
- Stage 5: Kidney failure (GFR <15 ml/min/1.73 m^2 or dialysis).

In the early stages of CKD (Stage 1 and Stage 2), decreased GFR alone is not sufficient to clinch the diagnosis. In these stages, the GFR is either normal or borderline normal. The presence of one or more of the following markers of renal damage can establish the diagnosis in such cases [13].
- Albuminuria (albumin excretion >30 mg/24 h or albumin: creatinine ratio >30 mg/g [>3 mg/mmol])
- Electrolyte abnormalities
- Urine sediment abnormalities
- Histologic abnormalities
- Structural abnormalities detected by imaging
- History of kidney transplantation in such cases.

High blood pressure is a frequent and prevalent sign; but is not a reliable marker of CKD. Hypertension (HTN) is also common among people without CKD.

The NKF, in a recent update, advised that GFR and albuminuria should be used together, rather than separately, to improve the accuracy of prognosis in the assessment of CKD [13,15]. More specifically, the guidelines recommended the inclusion of estimated GFR (eGFR) and albuminuria levels to evaluate the risks for overall mortality, cardiovascular disease, the progression of CKD, acute kidney injury, and end-stage kidney failure. The recommendation was that a referral should be given to a nephrologist for patients with a very low GFR (<15 ml/min/1.73 m^2) or very high albuminuria (>300 mg/24 h) [13,15].

Patients with Stages 1–3 CKD are generally asymptomatic. Clinical manifestations with decreased renal functions typically appear in Stages 4–5. The term chronic renal failure applies to a continuous significant irreversible reduction in the number of nephrons and typically corresponds to the Stages 3–5 of CKD. The term ESRD represents the stage of CKD, where the accumulation of fluid, electrolytes, and toxins usually excreted by the kidneys, resulting in the uremic syndrome. This syndrome can lead to the death of the patients unless the toxins are removed by renal replacement therapy, using dialysis, or kidney transplantation.

Regular monitoring for blood sugar control, screening for MA, and early diagnosis of CKD have become the standard care for diabetic patients globally. Our present research aims to see the prevalence of CKD in Type 2 DM patients, with the two critical markers of RIs; urinary ACR (which reflects MA), and eGFR (a marker of creatinine clearance rate) [16].

In this hospital-based cross-sectional study, we measured HbA1c, serum creatinine, urinary ACR [17], and eGFR (by MDRD formula) in selected 105 Type 2 diabetic patients in the 40–70 years age group (mean years of duration of diabetes is 10.01±3.46), at a private medical college hospital in West Bengal, India. We analyzed the data by appropriate statistical software and got the prevalence of CKD in T2DM patients [16].

METHODS [16]

Study area
This study was conducted Type 2 diabetic patients in out-patient clinic of Department of Medicine and Diabetes clinic in a Private Medical College and Tertiary Care Hospital, in West Bengal.

Study population
The study population was Type 2 diabetic individuals irrespective of family history of diabetes and coexistence of HTN.

Study period
The research was done over 1 year from inception (July 2020–July 2021) to completion.

Study design
It was a cross-sectional, descriptive, and observational research work with diabetic patients in the Indian reference population.

Sample size
Initially, 126 patients with Type 2 diabetes were selected, but due to incomplete data and unclear history, we had to exclude 21 patients from the study. Hence, 105 patients with Type 2 diabetes (who met all the inclusion criteria of this study) were taken irrespective of gender, nutritional status, and socioeconomic status.

Inclusion criteria [16]
The following criteria were included in the study:
1. T2DM patients, with or without a family history of diabetes
2. T2DM patients irrespective of blood pressure status
3. Both known cases and newly diagnosed cases of T2DM
4. T2DM patients, with or without treatment
5. T2DM patients aged ≥40 years and ≤70 years.

Exclusion criteria [16]
The following criteria were excluded from the study:
1. Acute myocardial infarction
2. Acute renal failure
3. Severe trauma
4. Hyperglycemic crisis (e.g. DKA, HONK)
5. Type 1 DM, Gestational DM, and other rare types of DM
6. Those suffering from hypertensive crisis, hypertensive emergencies
7. Stage 5 CKD patients (eGFR<15 mL/min/1.73m^2 or on Dialysis)
8. Patients with acute infection or sepsis
9. Age <40 years and Age >70 years.

Data collection [16]
We submitted the study protocol, informed consent, and case record forms to the Ethical Committee of Medical College and Hospital for approval.

We took informed consent from all participants before inclusion in the study in a language of their mother tongue. The subjects who were not able to sign had given their left-thumb impressions instead of a signature.

Institutional Ethics Committee had given the necessary clearances.

After getting permission from the Head of the Departments of Medicine and Biochemistry and appropriate authority, we started the data collection using a pre-designed and pre-tested schedule, interviewing the participants, performing clinical examinations, laboratory investigations, and record analysis. In this way, we included all the eligible subjects.

Study technique [16]
A. Detailed assessment of the history of the patients under the study
B. Thorough general physical examination
C. Biochemical Estimations
   a. Sample collection and storage: We collected 10 mL of fasting venous blood from the antecubital vein of each study subject. 5 mL taken in a clotted vial for estimation of serum creatinine, 2 mL in ethylene diamine tetraacetic acid vial for estimation of HbA1c by high-performance liquid chromatography (HPLC), and 3 mL in fluoride vial for estimation of fasting plasma glucose (FPG)

We took a written consent from each patient before the procedure and counseled each patient separately about the process and purpose of

the study. We collected 20 mL morning urine samples from each study subject to estimate spot urine ACR.

b. We estimated FPG in mg/dL by glucose oxidase-peroxidase method [15]
c. We estimated the HbA1c using the HPLC technique [18], and the result is expressed as "percentage" (%)
d. We estimated urinary microalbumin (Immunoturbidimetric method) and urinary creatinine (Modified Jaffe's method [19,20]) by Mindray Autoanalyser using respective reagent kit, and their ratio, that is, urinary ACR was calculated and expressed in mg/g (µg/mg) unit [21,22]
e. eGFR is calculated using the MDRD formula. The equation does not require the patient's weight

MDRD formula→eGFR(mL/min/1.73m^2)=186×(S.cr)$^{-1.154}$×(Age)$^{-0.203}$×(0.742 if female)×(1.212 if African American) [23].

(Here, we have used the multiplier 186 instead of 175, because serum creatinine is not IDMS traceable.)

Here, the results are normalized to 1.73 m^2 body surface area (a well-accepted average body surface area for adults) [23], so, the equation does not require weight or height variables.

The equation is extensively validated in African American and Caucasian populations in subjects with impaired kidney function (eGFR< 60 ml/min/1.73 m^2), aged 18–70 years. The equation has shown good performance for patients with all common kidney diseases [23]. For patients older than 70 years, the equation is not validated. However, an MDRD-derived eGFR value may still be a valuable tool for health-care providers in managing patients more than 70 years of age. However, the MDRD underestimates the measured GFR at levels above 60 ml/min/1.73 m^2.

Recently, there are many atypical presentations of diabetic nephropathy where there is a dissociation of proteinuria from the reduced renal function. MA always does not predict diabetic nephropathy [24]. However, a majority of the cases of diabetic nephropathy present with proteinuria, which progressively gets worse with the disease progression and is almost uniformly associated with elevated blood pressure.

Statistical methods [16]

We arranged the data in a master chart and analyzed it using R-Studio Software. "Shapiro–Wilk" normality test was done for the normal distribution of data. We found a normal distribution of all data here. We calculated the statistical mean and standard deviation of the parameters under the study and obtained their respective p-values from the Unpaired Student's t-test by running a logistic regression in R-Studio software to know the level of significance. $p<0.05$ is the level of significance. We used scatter plots for the graphical representation of HbA1c, FBG, ACR, and eGFR. We also calculated the prevalence of CKD among T2DM patients.

RESULTS

We presented the results in the form of tables and graphs and discussed the significance of the results.

Nineteen (18.10%) patients out of 105 Type 2 diabetic patients have albuminuria.

Analysis

The total sample size or the number of patients/subjects is 105 (n=105). All selected patients under study were known Type 2 diabetic patients. It is a hospital-based cross-sectional study.

Table 1 shows the basic characteristics of the study subjects:

My study included 105 known Type 2 diabetic patients aged 50–70 years. All the patients under the study are selected at random and fulfill the inclusion criteria. The mean age (in years) of the subjects is 58.71±7.59 (mean and standard deviation, SD). Out of 105 patients, 53 are male and 52 are female. The mean duration of diabetes in years (DOD) is 10.01±3.46; mean FPG (mg/dl) is 122.05±21.32; mean HbA1c (%) is 7.68±1.31; mean serum creatinine (mg/dl) is 1.07±0.40; mean eGFR (ml/minute/1.73m^2) is 72.77±20.60, and mean urinary ACR or UACR expressed in mg/g or µg/mg is 54.48±90.16.

Table 2 shows that in Stage 1 (eGFR ≥90 ml/min/1.73 m^2) CKD patients; 26 patients (24.76%), 3 patients (2.86%), and 1 patient (0.95%) are normo, micro, and macroalbuminuric, respectively. (percentage was done out of 105 study subjects.)

In Stage 2 (eGFR: 60–89.9) CKD patients; 49 patients (46.67%), 5 patients (4.76%), and 1 patient (0.95%) have normo, micro, and macroalbuminuria.

(We did not include the patients with eGFR ≥ 60 and with normoalbuminuria as CKD patients as per definition.)

In Stage 3a (eGFR: 45–59.9%) CKD patients; 8 patients (7.62%), 3 patients (2.86%), and 1 patient (0.95%) have normo, micro, and macroalbuminuria, respectively.

In Stage 3b (eGFR: 30–44.9) CKD patients; 3 patients (2.86%), 2 patients (1.90%), and 1 patient (0.95%) have normo, micro, and macroalbuminuria, respectively.

In Stage 4 (eGFR: 15–29.9) CKD patients; zero patient (0.00%), 1 patient (0.95%), and 1 patient (0.95%) have normo, micro, and macroalbuminuria, respectively.

(Note: We have excluded Stage 5 CKD patients and the above percentage was done out of 105 study subjects.)

Table 3 shows the prevalence of CKD in different stages. In our research, the overall prevalence of CKD in Type 2 diabetes patients was 28.57% (30 CKD patients out of 105 Type 2 diabetic patients), and the CKD prevalence was classified into the following stages**:**

Stage 1=3.81%, Stage 2=5.71%, Stage 3=17.14% (Stage 3a=11.43% & Stage 3b=5.71%), and Stage 4=1.90% and non-CKD patients=71.43%. (Age range of study subjects is ≥40–≤70 years.)

Table 3a shows, that among the 105 patients with Type 2 diabetes, 10 (9.52%) patients have CKD despite eGFR value ≥60 ml/min/1.73 m^2 due to the presence of albuminuria; whereas 20 (19.04%) patients have CKD with eGFR<60 ml/min/1.73m^2.

Table 3b shows that, among the total 30 patients with both CKD and T2 DM, 20 patients (66.67%) have eGFR <60, and 10 patients (33.33%) patients have eGFR value ≥60 ml/min/1.73 m^2.

Table 3c shows that, among the total 105 T2 DM patients, 86 patients (81.90%), 14 patients (13.33%), and 5 patients (4.76%) patients

Table 1: Basic characteristics of the study subjects [16]. (n=105)

Parameters	Mean value (±SD)	p-value
Age (range- 40–70 years)	58.88 (±7.71)	0.965
Male (age in years)	61.38 (±7.10)	NA
Female in (age in years)	56.19 (±7.22)	NA
Duration of diabetes in years	10.01 (±3.46)	0.967
Fasting plasma glucose (mg/dL)	122.05 (±21.32)	0.070
Glycated hemoglobin (%)	7.68 (±1.31)	0.155
Serum creatinine (mg/dL)	1.07 (±0.40)	0.945
eGFR (mL/min/1.73 sq. m)	72.77 (±20.60)	0.120
Urinary ACR (mg/g)	54.48 (±90.16)	0.063

*At 95% confidence interval. We obtained the P values by running a logistic regression. All data are typically distributed. NA: Not applicable

Table 2: eGFR and ACR wise distribution of Type 2 diabetic patients under study

Sample size=105				
Stages of CKD	**eGFR Range (ml/min/1.73 m²)**	**Normoalbuminuria (%)**	**Microalbuminuria (%)**	**Macroalbuminuria (%)**
		ACR<30 mg/g (µg/mg)	**ACR 30–299 mg/g (µg/mg)**	**ACR≥300 mg/g (µg/mg)**
Stage 1	≥90	26 (24.76)	3 (2.86)	1 (0.95)
Stage 2	60–89.9	49 (46.67)	5 (4.76)	1 (0.95)
Stage 3a	45–59.9	8 (7.62)	3 (2.86)	1 (0.95)
Stage 3b	30–44.9	3 (2.86)	2 (1.90)	1 (0.95)
Stage 4	15–29.9	0 (0.00)	1 (0.95)	1 (0.95)

Table 3: Number of CKD patients among Type 2 diabetic patients: Sample size (n)=105

Stages of CKD	eGFR and urinary ACR	No. of subjects (%)
Stage 1	eGFR≥90 and ACR≥30	4 (3.81)
Stage 2	eGFR 60–89.9 and ACR≥30	6 (5.71)
Stage 3a	eGFR 45–59.9 irrespective of ACR value	12 (11.43)
Stage 3b	eGFR 30–44.9 irrespective of ACR value	6 (5.71)
Stage 4	eGFR 15–29.9 irrespective of ACR value	2 (1.90)
Non-CKD		75 (71.43)

Total number of CKD patients (of any stage) among 105 Type 2 diabetic patients (n=105)=30 (28.57%)
eGFR is expressed as ml/min/1.73m² body surface area and urinary ACR as mg/g

Table 3a: Total study subjects (Type 2 diabetes patient); n=105

eGFR Range	eGFR≥60 ml/min/1.73 m²	eGFR<60 ml/min/1.73 m²	Any type of CKD
Number of CKD Patients	10 (9.52%)	20 (19.04%)	30 (28.57%)

Table 3b: Total number of patients with Type 2 DM and CKD=30

eGFR ranges	eGFR<60 ml/min/1.73 m²	eGFR≥60 ml/min/1.73 m²
Number of CKD patients	20 (66.67%)	10 (33.33%)

Table 3c: Total number of subjects (n)=105

Normoalbuminuria ACR<30 mg/g	Microalbuminuria ACR 30–299 mg/g	Macroalbuminuria ACR≥300 mg/g
86 (81.90%)	14 (13.33%)	5 (4.76%)

Table 3d: Total number of patients with T2DM and CKD=30

Normoalbuminuria ACR<30 mg/g	Albuminuria (both micro and macro) ACR≥30 mg/g
11 (36.67%)	19 (63.33%)

have normo, micro, and macroalbuminuria, respectively. Moreover, a total of 19 patients (18.10%) have albuminuria (both micro and macroalbuminuria) out of 105 Type 2 diabetic patients.

Table 3d shows that, among 30 patients with both CKD and Type 2 diabetes, 11 patients (36.67%) are normoalbuminuric and 19 patients (63.33%) are albuminuric.

Fig. 1 shows the percentage-wise distribution of albuminuria across eGFR ranges (n=105) by bar diagram representation.

Fig. 2 shows the percentage-wise distribution of CKD in Type 2 diabetic patients by a pie chart.

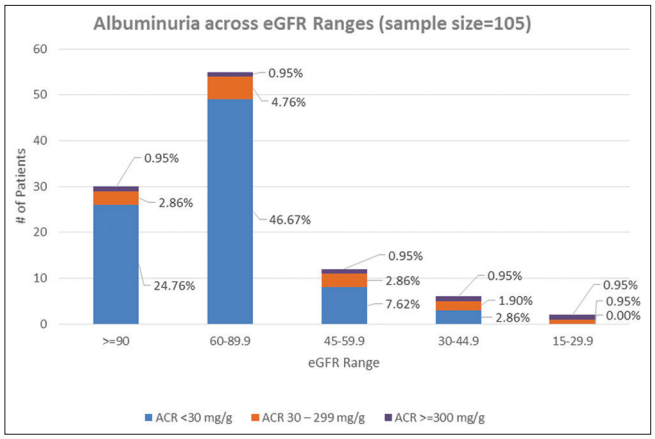

Fig. 1: Cases with albuminuria across eGFR Ranges

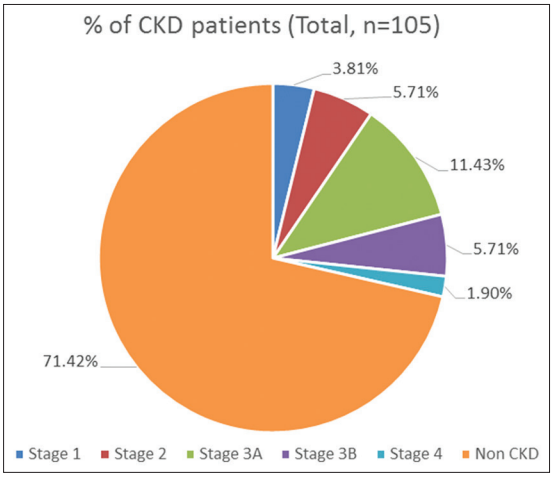

Fig. 2: Distribution of CKD patients in stages

(normoalbuminuria, MA, and macroalbuminuria mean urinary ACR value <30 mg/g, 30–299 mg/g, and ≥ 30 mg/g, respectively.)

There are 53 male and 52 female out of 105 Type 2 diabetic patients in our study. (Age range in years is ≥40–≤70) (Tables 4a, b and 5a, b).

Among the 53 male study subjects, 3 (5.66%), 2 (3.77%), 7 (13.21%), 4 (7.55%), and 1 (1.89%) patients have Stage 1, Stage 2, Stage 3a, Stage 3b, and Stage 4 CKD, respectively. Thirty-six patients (67.92%) are in the non-CKD group out of 53 male Type 2 diabetic patients.

Among the 105 study subjects, 17 (16.19%) male patients have CKD. Fig. 3 shows the percentage-wise distribution of albuminuria across eGFR ranges by bar diagram representation in the case of total male study subjects (n=53).

Among the 52 female study subjects, 1(1.92%), 4 (7.69%), 5 (9.62%), 2 (3.85%), and 1 (1.92%) patients have Stage 1, Stage 2, Stage 3a,

Stage 3b, and Stage 4 CKD, respectively. Thirty-nine patients (75%) are in the non-CKD group out of 52 female diabetics (Type 2).

Among the total 105 study subjects, 13 (12.38%) female patients have CKD.

Table 6 shows the age-wise distribution of CKD patients in the total study subjects (n=105).

In the age range (in years) of 40–50: 17 (16.91%), 1 (0.95%), 1 (0.95%), 0 (0.00%), 0 (0.00%), and 0 (0.00%) patients are in non-CKD, Stage 1, 2, 3a, 3b, and 4 CKD group, respectively.

In the age range (in years) of 51–60: 32 (30.48%), 1 (0.95%), 3 (2.86%), 4 (3.81%), 0 (0.00%) and 0 (0.00%) patients are in non-CKD, Stage 1, 2, 3a, 3b, and 4 CKD group, respectively.

In the age range (in years) of 61–70: 26 (24.76%), 3 (2.86%), 2 (1.90%), 7 (6.67%), 6 (5.71%), and 2 (1.90%) patients are in non-CKD, Stage 1, 2, 3a, 3b, and 4 CKD group, respectively.

Fig. 3 – This bar diagram shows the age-wise distribution of CKD patients.

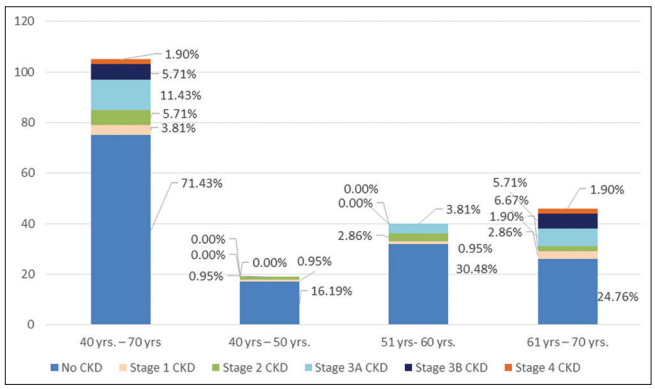

Fig. 3: Age group versus CKD

Table 4a: Number of CKD patients among Type 2 diabetic male patients

Stages of CKD	eGFR and Urinary ACR	No. of subjects (%)
Stage 1	eGFR≥90 and ACR≥30	3 (5.66)
Stage 2	eGFR 60–89.9 and ACR≥30	2 (3.77)
Stage 3a	eGFR 45–59.9 irrespective of ACR value	7 (13.21)
Stage 3b	eGFR 30–44.9 irrespective of ACR value	4 (7.55)
Stage 4	eGFR 15–29.9 irrespective of ACR value	1 (1.89)
Non-CKD		36 (67.92%)

eGFR is expressed as ml/min/1.73 m^2 body surface area and urinary ACR as mg/g

Table 4b: Number of CKD patients among Type 2 diabetic female patients

Stages of CKD	eGFR and Urinary ACR	No. of subjects (%)
Stage 1	eGFR≥90 and ACR≥30	1 (1.92)
Stage 2	eGFR 60–89.9 and ACR≥30	4 (7.69)
Stage 3A	eGFR 45–59.9 irrespective of ACR value	5 (9.62)
Stage 3B	eGFR 30–44.9 irrespective of ACR value	2 (3.85)
Stage 4	eGFR 15-29.9 irrespective of ACR value	1 (1.92)
Non-CKD		39 (75.00)

Total number of females in the study, n=52

DISCUSSION

Nephropathy is a major chronic complication of uncontrolled Type 1 and Type 2 diabetes. There are several steps in the progression of CKD, which progress from hyperfiltration to micro to macroalbuminuria and finally renal failure [16,25].

In the early stage of renal disease, classical markers such as serum creatinine and serum urea may be normal. Early changes such as glomerular basement membrane thickening, renal mesangial deposition of the matrix materials, and nodular deposits with resultant MA occur in the early stage [16]. At this stage, judicial use of pharmacological drugs may revert pathological changes in the kidney [1]. That is why both newly detected and known T2DM patients need strict monitoring of HbA1c, with simultaneous monitoring of GFR and MA [26].

In this hospital-based cross-sectional study, there are 105 T2DM patients aged between 40 and 70 years (with a mean age of 58.88±7.71) and mean duration of diabetes (in years) is 10.01±3.36 [16].

Tables 2 and 3 show the prevalence of the different types of CKD. Prevalence of CKD in patients was 28.57% and the CKD prevalence was classified into the following stages: Stage 1=3.81%, Stage 2=5.71%, Stage 3=17.14% (Stage 3a=11.43% and Stage 3b=5.71%), and Stage 4=1.90% and non-CKD patients=71.43%.

The result is quite similar to results found in the study PERCEDIME2 [26] study, where the overall prevalence of CKD (of any stage) was 27.9% (whereas the prevalence was 28.57% in my research). CKD prevalence was classified into the following stages in the PERCEDIME2 study**:** 3.5% with Stage 1, 6.4% with Stage 2, 16.8% with Stage 3 including 11.6% with Stage 3a, and 5.2% with Stage 3b, with 1.2% with Stage 4 and 5. Non-CKD patients were 72.14% in their study.

Two significant differences with our study are – In PERCEDIME2, they had included 1145 patients in their research, and they had included Stages 4 and 5 together whereas, in our research, a total number of study subjects is only 105 (smaller sample size). We excluded Stage 5 CKD patients.

In our research, RI (eGFR <60) was found in 20 patients (19.04%) out of 105 study subjects (Tables 2, 3, 3a and b) and 11 patients (55%) out of 20 had normoalbuminuria (ACR <30 mg/g) and 10 (9.52%) CKD patients (out of 105 study subjects) had albuminuria (ACR ≥30 mg/g) who had eGFR ≥60 ml/min/1.73 m^2. Nineteen patients (18.10%) out of 105 T2DM patients had albuminuria (ACR ≥30 mg/g).

In our research, out of 105 T2DM patients, 30 (28.57%) patients had some stages of CKD, 19 (63.33%) out of these 30 CKD patients had albuminuria (both micro and macroalbuminuria), and 11 patients (36.67%) out of 30 CKD patients had normoalbuminuria (ACR <30 mg/g).

In PERCEDIME2 [26] study, RI (eGFR <60) was found in 18% of patients and among them (eGFR <60) 69.4% had normoalbuminuria (ACR <30 mg/g). In patients with eGFR ≥60 ml/min/1.73 m^2, 9.9% had albuminuria (ACR ≥30 mg/g) in my study where this value is 9.52%. Overall % of albuminuria (micro and macro both) was 15.4% out of the total study subjects.

There are other studies, some of which show similar findings to our research, and some are showing slightly different statistics about the prevalence of CKD in Type 2 diabetes. These studies are discussed below in brief:

The study which was done by Lou Arnal *et al.* [27] showed 34.5% of T2DM patients presented some stages of CKD, 16.1% of DM2 patients

Table 5a: For male – Sex (gender) and ACR-wise distribution of CKD

Stages of CKD	eGFR range	Normalalbuminuria (%)	Microalbuminuria (%)	Macroalbuminuria (%)
		ACR<30 mg/g	ACR 30–299 mg/g	ACR≥300 mg/g
Stage 1	≥90	8 (15.09)	2 (3.77)	1 (1.89)
Stage 2	60–89.9	28 (52.83)	2 (3.77)	0 (0.00)
Stage 3a	45–59.9	5 (9.43)	1 (1.89)	1 (1.89)
Stage 3b	30–44.9	2 (3.77)	1 (1.89)	1 (1.89)
Stage 4	15–29.9	0 (0.00)	0 (0.00)	1 (1.89)

eGFR is expressed as ml/min/1.73 m^2 body surface area and urinary ACR as mg/g
Total number of males in the study, n=53

Table 5b: For female – Sex (gender) and ACR-wise distribution of CKD

Stages of CKD	eGFR Range	Normoalbuminuria (%)	Microalbuminuria (%)	Macroalbuminuria (%)
		ACR<30 mg/g	ACR 30–299 mg/g	ACR≥300 mg/g
Stage 1	≥90	18 (34.62)	1 (1.92)	0 (0.00)
Stage 2	60–89.9	21 (40.38)	3 (5.77)	1 (1.92)
Stage 3a	45–59.9	3 (5.77)	2 (3.85)	0 (0.00)
Stage 3b	30–44.9	1 (1.92)	1 (1.92)	0 (0.00)
Stage 4	15–29.9	0 (0.00)	1 (1.92)	0 (0.00)

eGFR is expressed as ml/min/1.73 m^2 body surface area and urinary ACR as mg/g
Total number of females in the study, n=52

Table 6: Age-wise distribution of CKD in the study

Age (range in years)	No CKD (%)	Stage 1 CKD (%)	Stage 2 CKD (%)	Stage 3a CKD (%)	Stage 3b CKD (%)	Stage 4 CKD (%)
40–70	75 (71.43)	4 (3.81)	6 (5.71)	12 (11.43)	6 (5.71)	2 (1.90)
40–50	17 (16.19)	1 (0.95)	1 (0.95)	0 (0.00)	0 (0.00)	0 (0.00)
51–60	32 (30.48)	1 (0.95)	3 (2.86)	4 (3.81)	0 (0.00)	0 (0.00)
61–70	26 (24.76)	3 (2.86)	2 (1.90)	7 (6.67)	6 (5.71)	2 (1.90)

had albuminuria (14.3% micro and 1.8% macroalbuminuria, and 9.4% of the patients, who had eGFR ≥60 ml/min/1.73 m^2 had albuminuria).

Vinagre *et al*. [28] had found a prevalence of 20% for RI and 16.7% for albuminuria. In another study in Spain [29], the prevalence of different types of renal disease in T2DM was: 34.1% with any stages of CKD, 22.9% with RI, and 19.5 % with albuminuria.

In another study performed in primary care centers in the Netherlands, Van der Meer *et al*. [30] observed that 27.6% of T2DM patients had CKD, and 13.6 % of these T2DM patients had albuminuria.

Another study performed in the United Kingdom [31] revealed that 31% of the diabetic patients had an eGFR <60 ml/min/1.73 m^2, and 37% had albuminuria.

In another study, Penno *et al*. [32] observed that, in patients with renal impairment (RI) (as identified by an eGFR <60 ml/min/1.73 m^2), 56.6 % were normoalbuminuric, 30.8% were microalbuminuric, and 12.6% were macroalbuminuric.

In the United States, Plantinga *et al*. [33] found that 32.9% of the American population had CKD, and 19.4% of these patients had albuminuria.

In another study performed in Australia, Thomas *et al*. [34] observed that 23.1% of Type 2 diabetic patients had an eGFR <60, and 34.6 % had albuminuria (27.3% had micro and 7.3% patients had macroalbuminuria).

In a Japanese study, Ohta *et al*. [35] estimated that 46% of Type 2 diabetes patients had CKD and 36.1% of T2DM patients had albuminuria, and they reported that 25.2% of these patients had an eGFR below 60 ml/min/1.73 m^2.

A study performed in Thailand [36] showed that 37.2% of Type 2 diabetic patients in primary care centers had albuminuria, (26% MA and 11.2% macroalbuminuria).

In Shanghai, Jia *et al*. [37] found that 29.6% of Type 2 diabetes patients had CKD, and 26.2% had albuminuria (22.8% MA and 3.4% macroalbuminuria).

In India, in the "Chennai Urban Rural Epidemiology Study," the statistics showed the prevalence of overt nephropathy and MA was 2.2% and 26.9%, respectively, in the urban citizens who have diabetes [38]. According to this study, the estimated incidence rate of CKD in India is 800 per million population [16] (pmp), and that of the ESRD is 150–200 per million population [39,40].

Indian CKD registry, established under the banner of the Indian Society of Nephrology, had observed that DM was the cause of CKD in 31.2% of patients [41]. They conducted this study on 38,193 patients collected from 154 centers, including 38 centers from the Indian Society of Paediatric Nephrology.

Different prevalence of RI and albuminuria among studies may be due to the different methodology of the studies, different sample sizes, the differences in geographical regions, and differences in human races.

As the MDRD study, equation for estimation of eGFR is valid up to 70 years of age, and Type 2 diabetes is comparatively rare before the age of 40 years; so we had included patients of Type 2 patients in the age range ≥40–≤70 years.

As the serum creatinine is not IDMS traceable in the laboratory of our working hospital; so the MDRD equation is multiplied by 186 instead of 175, and we had used the MDRD study equation of non-African-American type for the calculation of eGFR.

Chart 1: Grand chart for Data collection

Age	Sex	FPG	HbA1c	S.Cr.	eGFR	U.mA	U.Cr	ACR	Duration
54	M	114	6.5	1	83	14	81.6	17.15	10
68	M	144	8.2	1.4	54	23	82.1	28.01	16
60	M	98	6.8	0.9	91	28	159.4	17.57	8
66	F	129	9.5	1.25	46	19	72.6	26.17	12
62	M	133	7.4	0.82	101	21	48.2	43.57	10
65	M	138	6.0	1	80	29	151.6	19.13	9.5
59	F	146	5.7	0.86	72	19	128.2	14.82	9
64	M	124	7.7	1.34	57	44	158.5	27.76	10
41	F	141	6.7	1	63	36	125.4	28.7	6.5
55	F	127	7.3	0.68	95	31	70.7	43.85	8
48	M	128	7.1	0.92	93	17	58.2	29.21	7
42	F	95	7.2	0.75	90	19	79.1	24.02	6
58	M	152	9.6	1.62	47	46	158.9	28.95	10
56	M	132	6.7	1	82	19	72.3	26.28	8
63	F	112	8.3	1.12	52	33	125.8	26.23	13
51	F	124	6.8	0.91	69	42	155.3	27	9
62	M	139	6.9	1.2	65	23	81.7	28.15	12
56	M	162	6.4	1.1	74	22	93.8	23.45	8
65	M	135	9.1	0.88	92	142	44.6	318.39	11
52	F	128	6.4	0.7	93	30	152.6	19.66	7
61	M	140	6.7	1.2	65	24	120.4	19.93	11
56	F	132	6.5	0.7	92	34	125.2	27.16	9
48	F	164	8.9	1.32	46	22	73.5	29.93	7.5
65	M	148	6.9	1.26	61	21	71.3	29.45	15
60	M	128	7.5	1.1	73	21	104.5	20.09	7
68	M	142	7.0	0.82	99	33	142.8	23.11	7
59	F	132	6.9	0.7	91	29	151.8	19.13	8
48	F	140	6.6	0.78	84	19	84.8	22.41	9
67	M	145	8.7	1.2	64	96	71.1	135.02	11
70	M	145	7.9	1.2	63	34	118.5	28.69	13
69	M	138	9.0	1.52	49	33	116.5	28.33	16
60	F	95	8.2	0.93	65	372	86.7	429.07	17
59	F	135	7.1	0.86	72	20	127.6	15.67	9
56	F	134	6.4	0.7	92	28	159.4	17.57	7
62	M	142	6.8	1.2	65	21	92.7	22.65	10
58	M	129	8.4	1.52	50	108	157.1	68.75	13
63	F	92	7.1	0.88	69	27	105	25.71	9
64	F	108	8.4	0.89	68	19	31.9	59.56	11
59	F	128	7.1	0.86	72	20	127.6	15.67	12
70	M	150	7.8	1.1	69.4	28	139.8	20.03	15
70	M	103	8.5	1	79	34	130.6	26.03	11
54	M	131	6.5	0.78	110	29	146.6	19.78	6
56	F	116	8.2	1.12	53	32	29.4	108.84	12.5
50	F	96	6.8	0.7	94	21	103.5	20.29	7
53	F	112	6.7	0.72	90	23	87.9	26.17	8
45	F	90	6.8	0.68	99	20	100.5	19.9	6
48	M	92	7.2	0.74	113	14	81.6	17.15	6.5
55	F	77	6.2	1.2	50	80	85.1	93.13	11
42	M	88	6.7	0.78	116	19	129.8	14.64	6
65	F	92	8.2	1.2	60	46	160.6	28.64	11
48	F	118	6.3	0.68	98	24	120.4	19.93	6
56	M	83	8.9	1.21	66	292	149.6	195.19	12
43	M	86	6.5	0.78	115	18	87.8	20.5	6
57	F	132	7.5	0.98	62	45	162.6	27.68	9
59	M	130	7.7	1.2	66	22	93.8	23.45	10
61	M	108	7.9	1.2	65	24	120.4	19.93	8
60	M	143	8.5	0.92	89	29	149.6	19.39	7
67	M	146	12.1	1.53	48	241	57.7	417.68	18
62	F	106	7.3	0.95	63	22	84.5	26.04	8
55	F	87	7.3	0.72	92	20	86.2	23.2	8
62	M	137	8.1	1.12	71	24	86.7	27.68	7
53	F	98	6.9	0.64	103	29	160.7	18.05	6
66	M	134	7.7	0.86	95	28	21.8	128.44	10
52	F	106	6.8	0.7	93	32	151.7	21.09	7
61	M	116	7.1	1.2	65	25	121.8	20.53	7
56	F	129	6.5	0.7	92	35	127.2	27.52	6
63	F	124	9.0	1	60	37	128.5	28.79	9
61	M	109	8.7	1.52	50	23	87.8	26.2	11
59	F	130	7.1	0.86	72	21	127.8	16.43	12

(Contd...)

Chart 1: Grand chart for Data collection *(Continued)*

Age	Sex	FPG	HbA1c	S. Cr.	eGFR	U.mA	U.Cr	ACR	Duration
69	M	88	9.1	1.18	65	29	138.7	20.91	13
70	M	118	8.1	1	79	33	128.5	25.68	15
54	M	98	7.0	0.78	110	28	145.9	19.19	7
63	F	128	11.2	2.24	23	49	21.5	227.91	16
67	M	140	9.9	3.2	21	382	88.6	431.15	21
70	F	92	7.9	0.84	71	19	86.4	21.99	12
65	M	138	6.0	1	80	29	151.6	19.13	9
59	F	130	5.9	0.86	72	19	128.2	14.82	8.5
68	M	154	10.5	2.12	33	23	78.2	29.41	16
69	F	139	7.9	0.91	65	47	162.8	28.87	11
49	M	85	7.3	1.1	76	27	149.7	18.03	9.5
70	F	138	9.6	1.68	32	44	158.8	28.24	17
50	F	96	6.8	0.7	94	21	103.5	20.29	7.5
53	F	112	6.7	0.72	90	23	87.9	26.17	6
45	F	90	6.8	0.68	99	20	100.5	19.9	5.5
69	M	142	9.8	1.25	61	23	77.6	29.64	11.5
50	F	129	8.3	1.02	61	24	90.5	26.52	11
69	M	142	11.6	2.02	35	85	52	163.46	15
65	F	92	8.2	1.2	60	46	160.6	28.64	11.5
48	F	118	6.3	0.68	98	24	120.4	19.93	6.5
49	M	150	8.8	1.26	65	43	155.3	27.69	10
58	F	89	7.6	0.79	79	45	62.3	72.23	11
66	M	110	12.4	2.14	33	760	163.6	464.55	22
65	M	148	6.9	1.26	61	21	71.3	29.45	10.5
55	F	100	6.3	0.77	86	16	73.9	21.65	6
66	M	133	7.2	1.05	75	20	85.8	23.31	8
59	F	132	6.9	0.7	91	29	151.8	19.13	7
48	F	140	6.6	0.78	84	19	84.8	22.41	7.5
68	F	98	7.8	1.7	32	48	22.3	215.25	18
69	M	153	9.8	1.72	42	45	163.1	27.59	13
60	F	115	6.8	0.9	68	29	144.5	20.07	8
57	F	132	7.5	0.98	62	45	162.6	27.68	9
59	M	130	7.7	1.2	66	22	93.8	23.45	6.5
61	M	108	7.9	1.2	65	24	120.4	19.93	8
60	M	143	8.5	0.92	89	29	149.6	19.39	10
45	F	78	6.6	0.82	80	32	29.4	108.84	9

Age in years; M: Male, F: Female, FPG: Fasting plasma glucose (mg/dl), HbA1c: Glycated haemoglobin (%), S. Cr.: Serum creatinine (mg/dl), ACR: Urinary albumin creatinine ratio (mg/g or µg/mg), U.mA: Urine microalbumin (mg/L), U. Cr.: Urine creatinine (mg/dl), Duration: Duration of diabetes (Type 2) in years

CONCLUSION

From this tertiary care hospital-based cross-sectional study, we made the following conclusions:

1. Prevalence of CKD (except Stage 5 of CKD) in Type 2 diabetes patients is 28.57% (age range [in years] is ≥40–≤70). Among these patients with Type 2 diabetes, 9.52% patients had CKD despite eGFR value ≥60 ml/min/1.73 m^2 due to the presence of albuminuria; whereas 19.04% of patients had CKD with an eGFR value <60 ml/min/1.73 m^2. (We excluded Stage 5 CKD patients from this research.)
2. Among the patients with both Type 2 diabetes and CKD, 33.33% patients had CKD with eGFR ≥60 ml/min/1.73 m^2 and 66.67% patients had CKD with eGFR value <60 ml/min/m^2
3. Among the Type 2 diabetic patients, the prevalence of albuminuria (both micro and macroalbuminuria) is 18.10%
4. About 63.33% of patients with Type 2 diabetes and CKD had albuminuria (both micro and macro), and 36.67% of patients with Type 2 diabetes and CKD had normoalbuminuria.

CONFLICT OF INTEREST

There is no conflict of interest between the authors or the study.

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