

Research Article

A study to assess the level of pruritus among Type 2 Diabetes Mellitus patients with and without Chronic Kidney Disease attending Out-patient department, Tertiary Care Hospital, Vellore.

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Abstract

Background: The Prevalence of pruritus has increased from nearly 10% to more than 12% over two decades. One of the key complications of Type 2 Diabetes Mellitus is chronic kidney disease (CKD). Thus, CKD is one of the major causes of morbidity, affecting 20%-40% of people with diabetes Aims and objectives: To assess the level of pruritus among patients with and without Chronic Kidney Disease in a Tertiary Care Hospital. Methodology: A quantitative research approach was adopted. The researcher adopted a cross-sectional research design for a period of 1 year. Total of 135 Type 2 Diabetes Mellitus patients were recruited using purposive sampling technique. (45 patients with chronic kidney disease patients and 90 without chronic kidney disease patients)

Results: Mean age of patients with CKD is 53.02 ±8.79 and without CKD is 52.97 ±8.78. Majority of patients in both groups were male (73.3%, 74.4%), studied upto high school 48.89, 61.1, employed 55.6, (60%) 64.44% were from rural area married (97.78%, 97.8%) and in joined family 55.56, 62.22%. Majority were Hindus (82.22% and 80.90%) and their family income was less than Rs. 20,000 per month. Grandparents had the history of CKD in both the group (88.9% and 98.89%).

Conclusion: Chronic kidney disease associated pruritus is a common and troubling symptom amongst patients that is associated with decreased quality of life, sleep impairment, and poor prognosis.

Keywords: Chronic kidney disease, Diabetes Mellitus, Pruritus

Introduction

The metabolic systemic multifactorial disease known as diabetes mellitus (DM) is characterized by the body's inability to use or create enough insulin to meet its needs.

90% of adults with diabetes mellitus worldwide have type 2 diabetes (T2DM), accounting for one in every five cases of the disease. The global increase in obesity, sedentary lifestyles, high-calorie meals, and population ageing are the primary causes of the T2DM epidemic, which has doubled the incidence and prevalence of T2DM. The estimated global prevalence of diabetes in

2015 was 415 million by 2040 it is expected to climb to 642 million, with higher increase in poor and medium income nations. The good news is that there is a chance to delay or possibly avoid type 2 diabetes.

Makar M et al (2021) done a study and revealed that people with diabetes had a higher risk of developing chronic kidney disease (CKD), which can lead to significant morbidity, low quality of life, and higher healthcare expenses.¹

Low estimated glomerular filtration rate based on serum creatinine measurements is a hallmark of chronic kidney disease, which is defined as abnormalities in kidney structure or function that have persisted for longer than three months. The frequency of chronic kidney disease (CKD) varies greatly across the globe because to differences in the environment, ethnicity, socioeconomic status, and rural-urban lifestyle. Numerous risk factors have been linked to HIV infection, smoking, heavy drinking, obesity, ageing, hypertension, diabetes mellitus, hyperlipidemia, use of nephrotoxic medications, family history of kidney disease, low hemoglobin, use of traditional medications, rapid urbanization, physical activity, and rapid population growth, according to research.² **Chung H et al 2023**

An uncomfortable feeling that causes intense scratching for at least six weeks is called chronic itch (CI). The International Forum for the Study of Itch (IFSI) divides the etiology of persistent itch into six groups.

1. Dermatological
2. Organized
3. Neurological
4. Psychosomatic or psychogenic
5. Incongruous
6. Alternatives

According to IFSI, itch in diabetes is defined as a systemic itch that appears on either normal-looking or non-inflammatory skin. Between 18.4% and 27.5% of people with diabetes mellitus experience itching.

Pruritus, or itch, is defined as “an unpleasant sensation associated with a desire to scratch” . Pruritus is a common complaint among patients with progressive kidney disease (uremic pruritus). In various studies, the reported prevalence of uremic pruritus varies between 18% and 97.8%, and an overall prevalence of 55%. It is linked to worry, sadness, and restless nights, all of which can lower one's quality of life. Usually, a visual analogue scale (VAS), numerical rating scale (NRS), or questionnaire is used to determine the intensity of pruritus. With so few alternatives for treatment, pruritus can be very hard to manage.³ **Fenta et al 2023**

A cross-sectional research on itching in 109 adult patients with type 2 diabetes was conducted by **Aleksandra A. Stefaniak et al (2019)** An itch's intensity was measured using a numerical rating scale. In 35.8% of adult patients with Type 2 Diabetes Mellitus, itching had occurred.⁴ In comparison to the non-itching populations, itchy patients had significantly higher Fasting Plasma Glucose levels ($p=0.01$).⁵ **Manish Kadam et al 2018**

Itching connected with chronic kidney disease is referred to as uremic pruritus, or chronic kidney disease-associated pruritus (CKD-aP). It is generally understood to mean experiencing itching on a daily or almost daily basis when there isn't a major dermatologic finding.⁶ **Fenta ET et al 2023**

According to a number of studies, the prevalence of uremic pruritus ranges from 18% to 97%, with a 55% overall frequency.⁷ **Hu.X(2018)**. Uremic pruritus affects both sexes equally, with no discernible gender preference, albeit it is less common in younger people. Uremic pruritus also develops in individuals on hemodialysis and those on peritoneal dialysis.

Hemodialysis (HD) patients from twelve different countries participated in a sizable worldwide dialysis outcome and practice pattern study (DOPPS) . With 17,034 patients in DOPSS I (1996–2001) and 12,839 patients in DOPPS II (2002–2004), it was finished in two phases. Moderate to severe pruritus affected 45% of participants in DOPPS I and 42% in DOPPS II.⁸ **Osakwe N et al 2023**

Japan carried undertaken a second sizable dialysis outcome and practice pattern study (DOPPS). JDOPSS I (1999–2001; 65 hospitals, 2757 patients), JDOPPS II (2002–2004; 60 facilities, 2286 patients), and JDOPPS III (2005–2008; 62 facilities, 2326 patients) were the three phases that it was completed. There were 44% of people with moderate to severe pruritus and 35% of people who were somewhat itchy.⁷ **Hu X (2018)**

60% of participants in a sizable American research had CKD-aP . 51.7% of individuals in a Chinese study of 382 patients were found to have CKD-aP; patients on HD had a greater frequency than those on PD.⁹ **Aresi G et al 2019**

A meta-analysis comprising 42 cross-sectional studies found that the prevalence of CKD-aP varied throughout the studies, ranging from 18% to 97.8%, with an overall frequency of 55%. Male and female pooled prevalence was comparable at 55%. Patients undergoing HD had pruritus at a comparable rate (55% vs. 56%) as those receiving PD . The prevalence among individuals with HD and PD was shown to vary depending on the type of dialysis used.¹⁰ **Inayat Ur Rehman et al 2018**

In a cross-sectional study from Korea, the prevalence of mild pruritus was higher in PD patients (62.5%) than in HD patients (48.3%). There were 223 PD and 425 HD patients enrolled in the study.¹¹**Puneet Agarwal et al 2021.**

A multicenter cross-sectional study was conducted by Inayat Ur Rahman et al. (2018) in a tertiary care hospital in Pakistan with 345 patients getting hemodialysis who had CKD for 1-2 years, with 84% of patients receiving hemodialysis. 74% of people reported having pruritus, and it was found that this condition is strongly linked to poor sleep quality.

Nephrologists frequently underestimate the prevalence of CKD-associated pruritus, despite its high prevalence. Medical directors underestimated the prevalence of pruritus in 69 facilities, according to a study that analyzed data from 268 medical directors and 6256 patients across 17 nations between 2012 and 2015. ^(8,9) (**Aresi G). Osakwe N et al (2023)**

Although uremic pruritus has a detrimental effect on clinical outcomes, patients typically neglect to inform their healthcare provider of this symptom. Some patients would rather concentrate on other concerns, while others are ignorant that the itching is connected to CKD. Given the importance of pruritus on patients' physical and mental health, it is critical to inform and encourage patients to discuss the condition with their healthcare team.

Hence the present study was carried out with the objective to study the severity of pruritus among patients with chronic kidney disease in Type 2 Diabetes mellitus.

Statement of the problem:

A study to assess the level of pruritus among Type 2 Diabetes Mellitus patients with CKD and without Chronic kidney Disease attending out- patient department, Tertiary Care Hospital, Vellore

Objective of the study:

To assess and compare the level of pruritus among Type 2 Diabetes Mellitus patients with Chronic kidney disease and without Chronic kidney disease

Operational definition:

Pruritus: Pruritus is an unpleasant skin sensation associated with the immediate desire to scratch as measured and Itch severity scale by interview method.

Patients with chronic kidney disease: refers to patients who are medically diagnosed to have Type II diabetes mellitus and chronic kidney disease more than 6 months by Nephrologist attending Nephrology OPD up to Stage –IV according to estimated Glomerular filtration rate.

Patients without Chronic kidney disease: refers to patients who are medically diagnosed with Diabetes mellitus without Chronic Kidney disease by Diabetologists and attending Endo-diabetic OPD.

Demographic variables: include age, gender, education, occupation, locality, marital status, religion, type of family, size of the family, family income, family history of CKD, habit, number of times food taken and physical activity.

Clinical variables: diagnosed when, serum creatinine, treatment, hospitalization, drugs used and co-morbidity.

Materials and Methods:

A quantitative research approach was adopted.

Study design: A cross sectional observational study.

Study setting: Study was conducted at Tertiary Care Hospital, Vellore.

Study period : Study was conducted for a period of 1 year from March 2020-Feb 2021.

Sample size: Total of 135 Type 2 Diabetes Mellitus patients with purposive sampling technique was used.45 patients with chronic kidney disease patients and 90 without chronic kidney disease patients were recruited from Tertiary Care Hospital, Vellore

Inclusion Criteria:

The inclusion criteria were patients medically diagnosed as chronic kidney disease with Type II Diabetes Mellitus, whose eGFR <90ml/min/1.72m², eighteen years and above, continues treatment as outpatient without dialysis, can read and comprehend and gave consent to participate in the study. . The inclusion criteria were patients medically diagnosed as Type 2 Diabetes Mellitus without chronic kidney disease, whose e-GFR is more than 90ml/min/1.73m², continues treatment as outpatient, eighteen years and above, can read and comprehend and gave consent to participate in the study.

Exclusion criteria:

The exclusion criteria for patients with and without chronic kidney disease were with cognitive, hearing and speech disabilities, with serious illness and unable to follow instructions, has history of dermatologic disease, unwilling to comply and became sick during study.

Methods:

Data collection Tool:

Data was collected by using Numerical Rating Scale and Itch Severity Scale consisting of 7 questions in English, Tamil and Hindi administered to the patients who had pruritus in Chronic kidney disease patients.

Data collection procedure:

The researcher obtained written informed consent from the Type 2 diabetes mellitus patients with and without chronic kidney disease. Ethical and institutional review board approval was obtained. Detailed explanation was given to the patients with and without chronic kidney disease. Confidentiality and privacy were maintained throughout the study. The participants were given full freedom to continue participating (or) withdraw from the study at any time. A convenient timing and day were chosen to conduct the study.

Researcher assessed the demographic, clinical variables among Type 2 diabetes mellitus patients with and without chronic kidney disease. Researcher assessed the pruritus with severity with Itch severity scale.

Data analysis:

The collected data was compiled in EXCEL sheet and Master sheet was prepared. For analysis of this data SPSS (Statistical Software for Social Science) software version 21 was used. Quantitative data was represented in form of frequencies and percentages. P<0.05 was considered statistically significant.

Results:

TABLE: 1: Distribution of Type 2 Diabetes Mellitus with CKD and without CKD according to their demographic variables. (N=135)

Demographic data	With CKD (n=45)		Without CKD (n=90)		Homogeneity test	
	Mean / f	SD/ %	Mean / f	SD/ %	χ ² /t value	p-value
1. Age in years	53.02	8.79	52.97	8.78	t=0.027	p=0.979 (NS)
31-40	5	11.1	10	11.1		
41-50	13	28.9	26	28.9		
51-60	18	40.0	35	38.9		
61-70	8	17.8	16	17.8		
71-80	1	2.2	3	3.3		
2. Gender					χ² =0.019	p=0.890 (NS)
Male	33	73.3	67	74.4		
Female	12	26.7	23	25.6		
3. Education					χ² =8.71	p=0.03* (S)
Primary	4	8.89	8	8.89		
High school	22	48.89	55	61.1		
Secondary	2	4.4	12	13.33		
Graduate	17	37.78	15	16.67		

Demographic data	With CKD (n=45)		Without CKD (n=90)		Homogeneity test	
	Mean / f	SD/ %	Mean / f	SD/ %	χ^2 /t value	p-value
4. Occupation: Unemployed / Retired Employed	20 25	44.4 55.6	36 54	40 60	$\chi^2 = 1.59$	p=0.45 (NS)
5. Locality Urban Rural	16 29	35.56 64.44	55 35	61.11 38.89	$\chi^2 = 7.85$	p=0.005 (HS)
6. Marital status Single /Widows/ Widower Married	1 44	2.22 97.78	2 88	2.22 97.78	$\chi^2 = 0.75$	p=0.687 (NS)
7. Type of family Joint Nuclear	25 20	55.56 44.44	56 34	62.22 37.78	$\chi^2 = 0.556$	p=0.456 (NS)
8. Size of family <2 2-4 4-6 >6	0 24 16 5	0 53.3 35.56 11.11	1 34 54 1	1.1 37.78 60 1.1	$\chi^2 = 12.39$	p=0.006 (HS)
9. Religion: Christian Hindu Muslim / Others	3 37 5	6.67 82.22 11.1	11 72 7	12.22 80.90 7.78	$\chi^2 = 2.95$	p=0.398 (NS)
10 .Family income <=20000 >20000	26688 25 20	21683 55.6 44.4	20316 51 39	10253 56.7 43.3	t=2.322	p=0.02* (S)
11. Family History of CKD Father Mother Sibling Nobody	1 2 2 40	2.2 4.4 4.4 88.9	1 0 0 89	1.1 0 0 98.89	$\chi^2 = 8.56$	p=0.036* (S)
12. Habit Smoking Alcohol Nil	6 3 36	13.3 6.7 80	17 3 70	18.89 3.33 77.78	$\chi^2 = 1.31$	p=0.519 (NS)
13. Food taken 2 Times 3 Times >3 Times	6 36 3	13.3 80 6.7	0 90 0	0 100 0	$\chi^2 = 19.28$	p<0.001*** (HS)
14. Physical activity Walking Yoga	45 0	100 0	90 0	100 0	$\chi^2 = 0$	p=1 (NS)

Mean age of patients with CKD is 53.02 ±8.79 and without CKD is 52.97 ±8.78. Majority of patients in both groups were male (73.3%, 74.4%). Both the group patients had studied upto high school (48.89%, 61.1%) and were employed (55.6%, 60%) 64.44% of patients with CKD were from rural whereas 61.11% of patients with CKD. Were from urban most of them were married (97.78%, 97.8%) and in joined family (55.56%, 62.22%) in both group between 2-4 members were there in both group families. Majority was Hindus (82.22% and 80.90%) and their family income was less than Rs. 20,000 per month. Grandparents had the history of CKD in both the group (88.9% and 98.89%). None of the patients in both groups are smoker or alcohol.

Majority of them took meals at three times and 100% of them were walking their physical activity in both groups.

TABLE 2: Distribution of Type 2 Diabetes Mellitus patients with CKD and Without CKD according to their clinical variables (N=135)

Demographic data	With CKD (n=45)		Without CKD (n=90)		Homogeneity test	
	Mean / f	SD/ %	Mean / f	SD/ %	χ^2 /t value	p-value
1.Duration of CKD	6.55	4.01	8.37	3.74	t=2.58	p=0.01* (S)
≤8	30	66.7	50	55.6		
>8	15	33.3	40	44.4		
2.Sr. Creatinine	2.97	1.89	0.75	0.158	t=10.96	p<0.001*** (HS)
≤0.85	1	2.2	69	76.7		
>0.85	44	97.8	21	23.3		
3.Treatment					$\chi^2 = 0$	p=1 (NS)
Allopathy	45	100	90	100		
4.Hospitalized:					$\chi^2 = 0.74$	p=0.389 (NS)
Yes	28	62.2	49	54.4		
No	17	37.8	41	45.6		
4a.IF yes, How many times					$\chi^2 = 1.76$	p=0.622 (NS)
1	23	82.14	35	71.43		
2	5	17.86	12	24.49		
3	0	0	1	2.04		
4	0	0	1	2.04		
5.Co-morbidity					$\chi^2 = 16.27$	p=0.039* (S)
Hypertension	30	66.7	62	68.89		
Heart Disease	0	0	1	1.11		
Viral Hepatitis	0	0	1	1.11		
Dyslipidemia	0	0	1	1.11		
Hypertension and heart disease	1	2.22	2	2.22		
Hypertension and Dyslipidemia	11	24.44	11	12.22		
Hypertension and UTI	2	4.44	0	0		
Hypertension ,HD and Dyslipidemia	1	2.22	0	0		
Nil	0	0	12	13.3		
6.Medicine taken					$\chi^2 = 40.21$	p<0.001*** (HS)
Regularly	1	2.22	53	58.89		
Irregularly	32	71.11	26	28.89		
No response	12	26.67	11	12.22		
7.Medicines					$\chi^2 = 65.91$	p<0.001*** (HS)
Nil	0	0	3	3.3		
Sugar tablet	0	0	13	14.4		
Blood pressure tables	18	40	0	0		
Sugar and BP Tablets	14	31.1	60	66.7		
Sugar and cholesterol	0	0	1	1.11		
Sugar and antibiotics	0	0	1	1.11		
Bp and cholesterol tablets	5	11.1	0	0		
Bp and antibiotics	1	2.2	0	0		
Bp and pain	1	2.2	0	0		
Sugar , BP and cholesterol	6	13.3	12	13.3		
8. Number of tablet					t=10.95	p<0.001*** (HS)
≤5	6.88	1.82	4.38	0.84		
	11	24.4	83	92.2		

Demographic data	With CKD (n=45)		Without CKD (n=90)		Homogeneity test	
	Mean / f	SD / %	Mean / f	SD / %	χ^2 /t value	p-value
5	34	75.6	7	7.8		
9.Itching					$\chi^2 = 2.06$	p=0.151 (NS)
Yes	45	100	86	95.56		
No	0	0	4	4.44		
10.Sleeplessness					$\chi^2 = 2.06$	p=0.151 (NS)
Yes	45	100	86	95.56		
No	0	0	4	4.44		

S=Significant NS=Not Significant HS=Highly Significant $p < 0.001$

Table 2 depicts the distribution of Type 2 Diabetes Mellitus patients with CKD and Without CKD according to their clinical variables

In CKD group 66.7% had ≤ 8 years of duration of CKD and 55.6% had \leq years of duration of Type 2 Diabetes Mellitus in without CKD group. 97.8% had > 0.85 of serum creatinine in CKD group and 76.7% had < 0.85 of serum creatinine. 100% in both the group were on allopathy treatment. 62.2% and 54.4% were hospitalized and one time 82.14% and 71.43% in CKD group and without CKD group respectively. In CKD group and without CKD group 66.7% and 68.89% were having hypertension in both group and 24.44% had HT and dyslipidaemia in CKD group and 12.22% had HT and UTI in without CKD group. 71.11% were irregular in taking medication and 58.89% were adherent to medication prescribed. 40% were in CKD group on medication for Diabetes mellitus and Hypertension and 66.7% were taking medication of Diabetes Mellitus and antibiotics in patient without CKD. More than 5 tablets per dose was taken by 75.6% in CKD patients and 92.2% we taking < 5 tablets per dose. 100% of patient had itching in CKD group and 95.56% of patients had itching in patients with CKD. There is statistically highly significant in serum creatinine ($p < 0.001$) medicine taken ($p < 0.001$) medicine ($p < 0.001$) number of patients ($p < 0.001$). It is statistically significant in duration of CKD ($p = 0.01$) comorbidity ($p = 0.039$) and statistically not significant in treatment taken ($p = 1$) hospitalization ($p = 0.38$) and number of times hospitalized, ($p = 0.622$), itching ($p = 0.15$), and sleeplessness ($p = 0.151$).

Table 3: Comparison of Itch severity scale on overall wise distribution among patients with CKD and Without CKD group.

	Max score	With CKD			Without CKD			Difference in Mean%
		Mean \pm SD	SE	Mean%	Mean \pm SD	SE	Mean%	
Overall	21	9.17 \pm 1.65	0.25	44	7.94 \pm 1.52	0.16	38	6

Table 3 depicts the Comparison of Pruritus-Itch severity scale on overall wise distribution among patients with CKD and Without CKD group

The overall mean score of Pruritus itch severity scale in CKD group was 9.17 (SD 1.65) and without CKD group was 7.94 (SD 1.52). The mean score difference was 6.

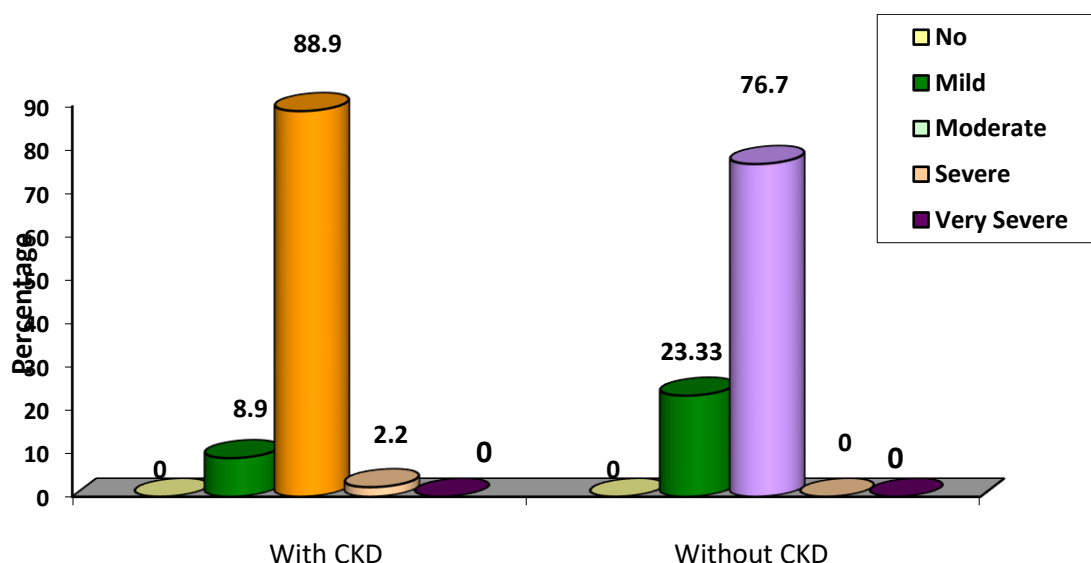
Table-4: Assessment and comparison of level of Pruritus -Itch severity scale (ISS)among patients with CKD and without CKD.

Level of Pruritus	With CKD n=45		Without CKD n=90		χ^2 -value	p-value
	f	%	f	%		
No	0	0	0	0	$\chi^2 =5.93$	p=0.05* (S)
Mild	4	8.9	21	23.33		
Moderate	40	88.9	69	76.7		
Severe	1	2.2	0	0		
Very severe	0	0	0	0		
Total	45	100	90	100		

S=Significant p<0.05%

Table 4 depicts the assessment and comparison of level of pruritus-Itch Severity scale among patients with CKD and Without CKD. In CKD group 8.9% had mild pruritus whereas in without CKD group it was 23.33%. Moderate pruritus was found among CKD group was 88.9% and 76.7% in without CKD group.

Fig.1



Discussion

The study is to assess the level of pruritus among Type 2 Diabetes Mellitus patients with and without Chronic Kidney Disease. In this study 11.1% were in the age group 31-40 years 28.9% were in the age group of 41-50 years, 40% among 51-60 years 17.8% between 61-70 years 2.2% above 70 years in CKD groups. It is in accordance to the study done by Rehman et al 2019 that 77.8% were in the age group 31-40 years, 73.7% were in the age group of 41-50 years 84.2% were in the age group 51-60 years and 84.2% were in the age group 61-70 years and 57.1% were in the age group 71-80 years. In this study the duration of CKD <8 years 90% and more than 8 years were 88.8% according to the study done by Rehman et al (2019). In this study 66.7% had co-morbidity of Hypertension and in another study it was 82.3% in CKD patients. According to Prasanna Kumar et al 2015 study it was found 43.7% had Hypertension as the Co-

morbidity in patients without CKD, Where as 68.89% had Hypertension as Co-morbidity in patients without CKD in our study.

Conclusion:

One common comorbidity that is linked to both chronic kidney disease and end-stage renal disease is pruritus. Treating physicians continue to underreport and undertreat it. Several risk variables that have been closely observed and managed may help these patients, who are already suffering from severe illnesses, live better lives. Limitation in slowing the progression of CKD may be due to inadequate knowledge, co-morbidities, inability to effectively communicate with health care providers and psychological aspects. To slow the progression of CKD support of multidisciplinary action along with interventions. Health education would enable the patients motivated to adhere to treatment regimen.

Institutional review Board statement:

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of Christian Medical College, Vellore

Informed consent statement:

Informed consent was obtained from all subjects involved in the study.

Data availability statement:

The data presented in this study are openly available

Conflict of Interest

The authors declare no conflict of interest.

Acknowledgement

The authors would like to acknowledge and thank the Physicians, Dr. Mahasampath Gowri, Mrs. Sowmi Joseph and patients who helped and participated in the study.

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Citation: Anandha Ruby Jacob, Thomas V Paul et.al., 2024. A study to assess the level of pruritus among Type 2 Diabetes Mellitus patients with and without Chronic kidney Disease attending Out-patient department, Tertiary Care Hospital, Vellore. *International Journal of Academic Research*, 11(2): 9-19.

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