

Research Article

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A Study to Assess the Medication Dherence 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: Due to the high prevalence of long-term health issues and the ageing population, medication non-adherence is a widespread issue worldwide. If a patient doesn't take their prescription as directed, they probably won't benefit from it to its fullest extent.

Aims and Objectives: To identify medication adherence among patients with CKD.

Methodology: A cross sectional research design for a period of 1 year A total of 45 patients with CKD were recruited using the consecutive sampling technique.

Results: The age group < 53 was 4.73 (SD 1.38) and > 53 age group 4 (SD 1.21) Majority of them lived in rural locality 4.46 (SD 1.44), Married 4.45 (SD 1.28). Employed 3.75 (SD 0.0), Joint family 4.86 (SD 1.32) and had primary education 4.25 (SD 2.28). 80% were non adherent to medication in CKD patients and 20% were adherent to medication in patients without CKD.

Conclusion: To slow the progression of CKD, support of multidisciplinary action along with practice health education would enable the patients motivated to adhere to treatment regimen.

Keywords: Medication Adherence, Chronic Kidney Disease, Type II Diabetes Mellitus

Introduction

Prolonged and frequently lifetime drug intake is necessary to improve patient survival and quality of life in chronic diseases. In low- and middle-income nations, the burden of chronic illness from noncommunicable diseases (NCDs) and HIV/ AIDS is among the highest. Less than half of these individuals, meanwhile, take their prescriptions as prescribed. Even though it's a global issue, nonadherence to medicine is thought to be a far greater issue in developing nations.

Drugs When a patient does not take their medications as prescribed by their doctor, it is an indication of non-adherence or non-compliance. As a result, patients are unable to fully benefit from the recommended course of care, therapeutic outcomes are worsened, the disease progresses and problems arise earlier, and hospital hospitalizations are more common. Preventing prescription non-adherence can save billions of dollars in preventable medical expenses, not to mention the indirect losses from decreased economic output.

pharmaceutical non-adherence is present when a prescribed pharmaceutical regimen is not followed, accepted, or executed incorrectly. The following categories might be used to further categorise medication non-adherence: Primary non-adherence refers to not starting prescribed prescriptions; secondary nonadherence is when prescribed medications are obtained through refills but are not used as directed. (3) Inadvertent noncompliance: this type of noncompliance occurs when a patient is unable to obtain refills because they are financially strapped or incapable

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According to, some patients believe that disclosing nonadherence is stigmatising because it suggests that they are disobeying their doctor's orders and are not concerned about their well-being. On the other hand, it has also been suggested that taking medication is an important health behaviour that the patient should be able to accurately self-report [1,2].

Medication adherence is an essential component of patient treatment and is required to meet clinical objectives. "Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatment," according to the WHO's 2003 study on medication adherence.

By opposition: Non-adherence results in subpar clinical outcomes, higher rates of morbidity and mortality, and needless medical expenses. Although noncommunicable and mental disorders are predicted to account for more than 65% of all diseases worldwide in 2020, between 50% and 60% of patients especially those with chronic illnesses do not take their prescribed medications as directed. Consequently, medication non-adherence accounts for almost 30% of hospital admissions connected to medications.

Medication adherence is even more important because the CDC reports that individuals with certain chronic diseases, such as diabetes, kidney disease, sickle cell disease, and chronic obstructive pulmonary disease, may be at increased risk of developing a serious illness from coronavirus disease 2019. Patients' health can be improved by overcoming medication adherence challenges and developing ways to address them.

- a. Individuals could not feel capable of managing their own health.
- b. Patients might not know about beneficial options or be unable to obtain drugs.
- c. Patients may be unable to comprehend and adhere to treatment programmes due to a lack of health literacy [1,2].

In the past 20 years, its prevalence has risen from about 10% to over 12% worldwide. Chronic kidney disease (CKD) is a major consequence of Type 2 Diabetes Mellitus (T2DM). Approximately 16% of the 697.5 million cases of chronic kidney disease (CKD) worldwide in 2017 occurred in India. Thus, CKD affects 20%-40% of diabetics and is one of the main causes of morbidity.

The increased mortality in individuals with type 2 diabetes was mostly explained by renal illness, according to data from the Third National Health and Nutrition Examination Survey (NHANES III), which assessed cumulative mortality by diabetes and kidney disease status in over 15,000 participants over a tenyear period. According to NHANES III, there was a greater absolute risk difference for death in those with both diabetes and kidney disease as compared to those without the condition. Thus, renal dysfunction is the reason for the higher death rate among T2DM patients. Along with hyperglycemia, hypertension, and cardiovascular disease, other factors that can raise the risk for CKD include age, gender, race/ethnicity, and family history. Increased blood pressure, unhealthful food choices, and the ensuing obesity are variables that exacerbate the course of chronic kidney disease (CKD).

According to a meta-analysis assessing the relationships between end-stage renal disease (ESRD) and mortality in diabetics, the inclusion of eGFR and the urine albumin-to-creatinine ratio (UACR) greatly enhanced the prognostication of outcome.

A study on 220 diabetic CKD patients without dialysis who were in the outpatient department of the largest tertiary care hospital in Thailand was carried out by Chairut [3]. Medication adherence was categorised as high-medium, poor, and 25%, respectively. After performing a multivariate analysis, it was determined that the only independent predictor of low adherence was late-stage CKD (stage IV-V) (odds ratio 5.54, 95% confidential interval 2.82-10.88), indicating that medicine taking behaviour was a common issue.

Conducted an inpatient cross-sectional study in an Eastern Asian tertiary care hospital's outpatient department. The majority of the 331 individuals (57.1%) who were questioned had a mean age of 53.40 (SD11.0) and were male. A 34.14% medication adherence rate was observed in the individuals. In binary logistic regression analysis, the odds of poor adherence were increased by 2.36 times, 1.88 times, and 2.35 times, respectively, for having any comorbidity, a positive family history of diabetes, and the habit of current alcohol consumption. For every additional day of unwell days, there was a 1.077-fold increase in poor medication adherence [4].

Carried out a cross-sectional study in a hospital setting at TASH's nephrology clinic. 256 patients in all were chosen by means of rigorous random sampling. Just 61.3% of the participants in the study followed their prescribed course of action. The main factor contributing to medication non-adherence was forgetfulness (79.8%). In comparison to patients with extremely low income, individuals with moderate and high monthly incomes were 4.14 (AOR 4.14, 95% CI 1.45-11.84 p=0.008) and 6.17 times (AOR =6.17, 95% CI 1.02-37.46 p=0.048) more likely to adhere. Compared to their peers, patients who received more than five prescriptions had a 0.46-times lower likelihood of adhering to their regimens [5].

Investigated the efficacy of the MEMR model (meal dose, education, monitoring, and referral) in slowing the progression of chronic renal disease in 68 diabetic patients with CKD 3-4 in Thailand using six members of a multidisciplinary team. Three phases of the research process were analysis, model creation, and evaluation. According to the results, 80.40% of patients were not taking their medications as prescribed, whereas only 46.09% of patients had slow-moving chronic kidney disease (CKD). The evaluation stage results showed that compared to before the development, there was a significant increase in the proportion of patients with medication adherence and those with delayed progression of CKD (p=<0.001). It was determined that the MEMR model's advantages included improved medication adherence and reduced CKD development [6].

Conducted a cross-sectional study at three basic healthcare facilities in Malaysia with 150 Type 2 Diabetes mellitus patients, ages 40 to 80, to find out how well these people understood diabetes and adhered to their prescription regimens. It was shown that there was a strong correlation between the knowledge and poor adherence. In comparison to patients with high knowledge adj 95% CI (1.92 - 10.69 p=0.001), it was shown that patients with low diabetic knowledge had an odds ratio of 4.53 for poor adherence [7].

A prospective study to assess the relationship between selfreported medication adherence and the development of chronic kidney disease (CKD) and all-cause mortality in US patients with CKD. 477 (15%), 570 (17%), and 2258 (68%) of the 3305 participants had low adherence, medium adherence, and good adherence, respectively. In all, 969 individuals experienced CKD development, and after a median follow-up of six years, 675 fatalities occurred. While the equivalent rates of all-cause death were 3.08, 2.97, and 3.99 per 100 person-years, respectively, the CKD progression event rate increased from high to medium to poor adherence (5.82, 6.48, and 9.52 per 100 person-years, respectively). The low-adherence group had a significantly higher risk of chronic kidney disease (CKD) development in comparison to the high-adherence group (adjusted hazard ratio 1.27; 95% confidence interval [CI] 1.05-1.54).

On the other hand, the medium-adherence group did not significantly increase in risk for unfavourable outcomes. Low drug adherence is an underappreciated but significant risk factor for the advancement of chronic kidney disease, the researchers concluded. The risk of chronic kidney disease (CKD) progression is enhanced by persistently elevated blood sugar and high blood pressure resulting from non-adherence to drug regimens. The non-pharmacological approach to managing diabetes and hypertension involves a balanced diet, regular exercise, giving up smoking, and abstaining from alcohol consumption. Increasing physical exercise can stop the progression of CKD on its own [1].

The researcher being specialized in Medical and Surgical nursing, during her experience in Medical wards had noticed that the patients with Chronic kidney disease have pruritus due to nonadherence to medication thus leading to poor sleep quality and quality of life. Health care professionals underestimate or neglect adherence to medication by patients. This gave intuition for the researcher to proceed for the study. The present study undertaken to evaluate the medication adherence among patients with and without chronic kidney disease.

Statement of the Problem

A study to assess the medication adherence among Type 2 Diabetes Mellitus patients with and without Chronic kidney Disease attending Out- patient department, Tertiary Care Hospital, Vellore

Objective of the Study

To assess and compare the medication adherence among Type 2 Diabetes Mellitus patients with and without Chronic kidney disease.

Operational Definition

Medication Adherence: It refers to the patient's response to the medication taking behavior as remembering to take medicine promptly without missing a single dose during any situation as measured by Malaysian Medication Adherence Scale.

Patients with Chronic Kidney Disease: refers to patients who are medically diagnosed to have Type 2 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 Endodiabetic 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 Malaysian Medication Adherence Scale consisting of 8 questions in English, Tamil and Hindi administered to the patients who had Chronic kidney disease and without 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 medication adherence with Malaysian Medication Adherence 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 patients with CKD and without CKD according to their demographic variables. (N=135)

Domographia data	With CKD (n=45)		Without CKD (n=90)		Homogeneity Test	
Demographic data	Mean / f	SD/ %	Mean / f	SD/ %	χ ^{2/t} value	p-value
1.Age in years	53.02	8.79	52.97	8.78		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	1-0.027	
61-70	8	17.8	16	17.8		
71-80	1	2.2	3	3.3		
2. Gender						
Male	33	73.3	67	74.4	$\chi^2 = 0.019$	p=0.890 (NS)
Female	12	26.7	23	25.6		
3. Education						
Primary	4	8.89	8	8.89		p=0.03* (S)
High school	22	48.89	55	61.1	$\chi^2 = 8.71$	
Secondary	2	4.4	12	13.33		
Graduate	17	37.78	15	16.67		
4. Occupation						
Unemployed / Retired	20	44.4	36	40	$\chi^2 = 1.59$	p=0.45 (NS)
Employed	25	55.6	54	60		
5. Locality						
Urban	16	35.56	55	61.11	$\chi^2 = 7.85$	p=0.005 (HS)
Rural	29	64.44	35	38.89		
6. Marital status						
Single /Widows/ Widower	1	2.22	2	2.22	$\chi^2 = 0.75$	p=0.687 (NS)
Married	44	97.78	88	97.78		
7. Type of family						
Joint	25	55.56	56	62.22	$\chi^2 = 0.556$	p=0.456 (NS)
Nuclear	20	44.44	34	37.78		
8. Size of family						
<2	0	0	1	1.1		p=0.006 (HS)
2-4	24	53.3	34	37.78	$\chi^2 = 12.39$	
4-6	16	35.56	54	60		
>6	5	11.11	1	1.1		

9. Religion						
Christian	3	6.67	11	12.22	$\chi^2 = 2.95$	p=0.398 (NS)
Hindu	37	82.22	72	80.90		
Muslim / Others	5	11.1	7	7.78		
10. Family income	26688	21683	20316	10253		
<=20000	25	55.6	51	56.7	t=2.322	p=0.02* (S)
>20000	20	44.4	39	43.3		
11. Family History of CKD						p=0.036* (S)
Father	1	2.2	1	1.1		
Mother	2	4.4	0	0	$\chi^2 = 8.56$	
Sibling	2	4.4	0	0		
Nobody	40	88.9	89	98.89		
12. Habit						
Smoking	6	13.3	17	18.89	$n^2 - 1 21$	n=0.510 (NS)
Alcohol	3	6.7	3	3.33	$\chi^{-1.51}$	p=0.319 (NS)
Nil	36	80	70	77.78		
13. Food taken						
2 Times	6	13.3	0	0	$\chi^2 = 19.28$	p<0.001*** (HS)
3 Times	36	80	90	100		
>3 Times	3	6.7	0	0		
14. Physical activity						
Walking		100	90	100	χ2 =0	p=1 (NS)
Yoga		0	0	0		

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.

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		
≤8	30	66.7	50	55.6	t=2.58	p=0.01* (S)
>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					w ² =0	n=1 (NIC)
Allopathy	45	100	90	100	$\chi^2 = 0$	p-1 (183)
4. Hospitalized						
Yes	28	62.2	49	54.4	$\chi^2 = 0.74$	p=0.389 (NS)
No	17	37.8	41	45.6		

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

4a. If yes, How many times						
1	23	82.14	35	71.43	$\chi^2 = 1.76$	p=0.622 (NS)
2	5	17.86	12	24.49		
3	0	0	1	2.04		
4	0	0	1	2.04		
5. Co-morbidity						
Hypertension	30	66.7	62	68.89		
Heart Disease	0	0	1	1.11		p=0.039* (S)
Viral Hepatitis	0	0	1	1.11		
Dyslipidemia	0	0	1	1.11		
Hypertension and heart disease	1	2.22	2		$\gamma^2 = 16.27$	
Hypertension and Dyslipidemia	11	24.44	11	2.22	~	1
Hypertension and UTI	2	4.44	0	12.22		
Hypertension, HD and Dyslipidemia	1	2.22	0	0		
Nil	0	0	12	0 13.3		
6. Medicine taken						
Regularly	1	2.22	53	58.89	2 40 21	p<0.001*** (HS)
Irregularly	32	71.11	26	28.89	$-\chi^2 = 40.21$	
No response	12	26.67	11	12.22		
7. Medicines						
Nil	0	0	3	3.3		p<0.001*** (HS)
Sugar tablet	0	0	13	14.4		
Blood pressure tables	18	40	0	0		
Sugar and BP Tablets	14		60			
Sugar and cholesterol	0	31.1	1	66.7	$\gamma^2 = 65.91$	
Sugar and antibiotics	0	0	1	1.11	λ 05.51	p (0.001 (115)
Bp and cholesterol tablets	5	0	0	1.1		
Bp and antibiotics	1	11.1	0	0		
Bp and pain	1	2.2	0	0		
Sugar, BP and cholesterol	6	2.2 13.3	12	0 13.3		
8. Number of tablet						
	6.88	1.82	4.38	0.84	t=10.95	p<0.001*** (HS)
<=5	11	24.4	83	92.2		
5	34	75.6	7	7.8		
9. Itching						
Yes	45	100	86	95.56	$\chi^2 = 2.06$	p=0.151 (NS)
No	0	0	4	4.44		
10. Sleeplessness						
Yes	45	100	86	95.56	$\chi^2 = 2.06$	p=0.151 (NS)
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 \leq 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: Distribution of Type 2 Diabetes Mellitus on Medication
 Adherence among patients with and without CKD

Level of medication	f With Without on CKD CKD		thout KD	χ²=value	p=value	
adherence	f	%	f	%		
Non-Adherence	36	80	80	88.9	$w^2 = 1.06$	P=0.162
Adherence	9	20	10	11.1	χ1.90	(NS)
Total	45	100	90	100		

NS=Not Significant p<0.001. Table 3 depicts the distribution of Type 2 Diabetes Mellitus patients with and without CKD according to the medication adherence..In patients with CKD 20% were adherent to prescribed medicine and 80% were nonadherent to medication. In patients without CKD 11.1% were adherent to the medication and 88.9% were non-adherent to the medicines prescribed. There is no statistically significant difference between these group p=0.162

Discussion

The study is to assess the medication adherence 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 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 [8]. In this study 66.7% had co-morbidity of Hypertension and in another study it was 82.3% in CKD patients. According to 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 [9].

In the present study findings 20% were adherent to prescribed medicine and 80% were nonadherent. In patients without CKD 11.1% were adherent to medication regime and 88.9% were not following the adherence to medication. The findings of this study was supported by that the n0n-adherent may be unable to access medication and unaware of helpful options and limitation to health literacy, Another study in supportive of this according to revealed that 34.4% were adherent to medication among CKD patients [4].

In contrast to this study reported that half of the participants among non-dialysis with diabetic CKD were adherent (50.9%). More than half of the patients (61.3%) were reported adherent to the prescribed medicines in the study done by. The main reason for the non-adherence to medication is forgetfulness [3-5].

Implications and Directions for Future Research

There are worldwide ongoing public health reforms to minimize unnecessary healthcare expenditure and maximize public health outcome. Improving medication adherence is a significant aspect in clinical practice and research. The lack of a universal guideline on medication adherence measures provides rooms for research on which measure, or which combination of measures, is the most appropriate for different target populations and health problems. Meanwhile, researches on improving the currently available measures and/or on the development of new ways to measure and uncover reasons behind medication nonadherence should also be further explored.

Conclusion

One common comorbidity that is linked to both chronic kidney disease and end-stage renal disease is non-adherence to medication. 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.

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