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Original Research Article

Evaluation of drug treatment awareness among caregivers and patients of chronic kidney disease: unexplored determinant in patient care

Raakhi K. Tripathi¹, Chaitali Pilliwar¹, Snehalata Gajbhiye¹,
Sujeet K. Bhilwade^{1*}, Tukaram Jamale²

¹Department of Pharmacology and Therapeutics, ²Department of Nephrology, Seth GS Medical College and KEM Hospital, Parel, Mumbai, Maharashtra, India

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***Correspondence:**

Dr. Sujeet K. Bhilwade,

Email: sujeetbhlwade@gmail.com

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ABSTRACT

Background: Chronic kidney disease (CKD) patients are prescribed multiple drugs to slow disease progression and prevent complications mandating adherence to therapy. Lack of awareness about drug treatment is one of the contributors to nonadherence. Hence the study was conducted to explore the awareness of patients and caregivers towards CKD treatment.

Methods: The study was a cross sectional questionnaire-based study conducted among 300 CKD patients (150 dialysis/150 non-dialysis) and 100 caregivers (50 of dialysis / 50 of non-dialysis patients) attending nephrology OPD at a tertiary care hospital. Patient /caregiver awareness about drug treatment was assessed using a prevalidated drug awareness questionnaire (8 items). The items were scored as correct response=2, no response=0 and incomplete response = -1, accounting the total awareness score as +20 to - 6

Results: The mean awareness score of patients / caregivers was 8.16±3.41 and 8.3±1.6 respectively. Majority (>70%) patients/ caregivers gave accurate responses for the items -specifying number of medicines, medication frequency and regular intake of drugs but awareness regarding action plan for skipped (27% patients, 11% caregivers) or missed doses (22% patients, 15% caregivers) and adverse effects (17% patients, 5% caregivers) was poor. Patients/ caregivers belonging to dialysis group had statistically better awareness than non-dialysis group.

Conclusions: Patient /caregiver awareness regarding drug treatment is less than 50% with strikingly low awareness about dose regimen, adverse effects, action plan for missed doses and co morbidities. Patient education programs to reinforce and retain this knowledge need to be implemented in CKD patients.

Keywords: Dialysis, Adherence, Adverse effects

INTRODUCTION

Chronic kidney disease (CKD) is defined as abnormalities of kidney structure and function evident as decreased glomerular filtration rate <60 ml/min per 1.73 m², or markers of kidney damage, or both, of at least 3 months duration, regardless of the underlying cause.¹

In 2017 with the global prevalence of 9.1%, 697.5 million cases of all stage CKD were recorded. The prevalence has

increased by 29% since 1990.² According to a systematic review and meta-analysis of observational studies which estimated CKD prevalence in 2016, as 13-4% for all 5 stages of CKD. Screening and Early Evaluation of Kidney Disease which is a community-based voluntary health screening program started in India published in 2013 reported that the prevalence of CKD was as high as 17.2% with nearly 6% having CKD stage 3 or worse.³ With the rising burden of CKD, the main goal of drug therapy is to slow disease progression and correct disease-associated

complications/co-morbidities. CKD patients are prescribed multiple drugs such as anti-hypertensives, anti-diabetics, phosphate binders. Adherence to medication is an important component of effective disease management in CKD patients.⁴ CKD patients have estimated non-adherence to medication varying from 17 to 74% and among patients on hemodialysis the non-adherence varies from 3 to 80%.⁴⁻⁶ One of the factors which can have impact on the medication adherence is CKD patient's awareness regarding the drug treatment. A study to analyze factors affecting adherence among hemodialysis patients was conducted in South India in 2018 which emphasized the need for the continued education to these patients for better understanding of the medications they use.⁷ Apart from inadequate awareness about drug therapy, there is variability in drug prescriptions too. A study on drug use pattern in CKD patients conducted in tertiary care hospital in Nagpur showed average number of medicines taken by each patient was 8.0±1.612/day and non-adherence to medication schedule was reported in 34% patients.⁸ Thus CKD patients are taking multiple drugs and awareness about the drug therapy (its essentiality, regimens, adverse effects) among the patient and their caregivers is essential to maintain adherence to therapy and subsequently better disease outcome. After thorough literature search there is dearth of published studies conducted in India assessing the drug therapy awareness in CKD patients though disease awareness studies are done in some countries. These studies did conclude that, to retard the progression of CKD, patient/ caregiver awareness and education towards disease and its treatment must be raised.⁹ Hence, the study was conducted to explore the awareness of patients and caregivers towards CKD treatment.

METHODS

The study was a cross-sectional questionnaire-based study conducted among 300 CKD patients (150 dialysis and 150 non-dialysis patients) and 100 caregivers (50 of dialysis and 50 of non-dialysis patients) attending nephrology OPD at a tertiary care hospital from January 2017 to June 2018. This study was conducted in compliance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (ICMR) and Indian GCP guidelines.¹⁰⁻¹² Patients aged 18-65 years of either sex with confirmed diagnosis of CKD attending Nephrology OPD were included in the study. Admitted patients and those planning renal transplant were excluded. Adult caregivers of either sex taking care of the patient >1 year were included. Both patients and caregivers after providing written informed consent were enrolled in the study. The demographic details of patients and caregivers such as age, sex, socioeconomic status, literacy level was recorded. Information regarding patient's disease i.e., CKD stage, presence of co-morbid conditions and in dialysis patients-type of dialysis and number of dialysis sessions / per week were also noted. Subsequently to assess awareness of the patient and their caregivers with regards to drug treatment a pre-validated (9 experts, CVR=0.76) drug awareness questionnaire (8 items) was administered. Each item had

dichotomous response as yes (scored as 1) or No (scored as 0).¹³ Certain items like specifying names of medicines, reasons for medication intake, frequency, action plan for missed doses, adverse drug reactions (ADR) and naming the comorbid conditions were further probed and if patient/caregiver gave correct response was scored as 2, no response as 0 and incomplete response as -1. Thus, the total awareness score range was calculated as +20 to -6 (Table1).

Statistical analysis

The data obtained were computerized and analyzed using descriptive statistics. The data from patients and caregivers had been stratified as dialysis and non-dialysis and comparison was done between the two subsets. The number of respondents stating 'yes' in the drug treatment awareness in dialysis and non-dialysis group was compared using chi-square test and $p < 0.05$ was considered statistically significant. Total drug awareness scores were calculated for each patient and mean scores between dialysis and non-dialysis group were compared using Mann-Whitney test. Correlation was done using spearman's correlation test between the patient's/caregiver's demographic factors such as age, gender, socio economic status and literacy and their treatment awareness score.

RESULTS

Patient and caregiver awareness regarding drug treatment was evaluated in this study. Out of the total 300 patients; there were more males (164, 55 %) as compared to females (136, 45%). The mean age of patients was 48±11 years while mean age of dialysis patients and non-dialysis patients was 49.19±9.89 and 46.77±11.08 years respectively. Majority of the patients (264, 88% patients) belonged to upper lower class while 36 (12%) patients belonged to lower middle class. Literacy level was low, as evident with 96 (32%) patients being illiterate followed by primary education 84 (28%) and secondary education 88 (29%) while only 32 (11%) patients were graduates. Maximum number of patients belonged to Stage 5 (95, 32% patients), followed by Stage 4 (75, 25% patients) and Stage 3 CKD (48, 16% patients). All dialysis patients belonged to stage 4 (40%) and stage 5(60%) who underwent hemodialysis with average number of cycles/week/patients as 4.5. Maximum patients (33%) had disease duration >10 years followed by 30% patients with disease duration between 5-10 years. Hypertension was found to be the most common co-morbidity (186, 62% patients), followed by diabetes (168, 56% patients) and anemia (60, 20% patients).

Similarly, out of total 100 caregivers, there were a greater number of males (61%) compared to females (39%). Mean age of caregivers was 50±12.8 years, while mean age of caregivers of dialysis and non-dialysis patients were 46±10.1 years and 49±11.2 years respectively.

Table 1: Positive responses of the patients and caregivers to drug therapy awareness questionnaire.

Questionnaire item	Total patients (N=300)	Dialysis (N=150)	Non-Dialysis (N=150)	P value	Total Caregiver (N=100)	Dialysis Caregiver (N=50)	Dialysis Caregiver (N=50)	P value
	Yes	Yes	Yes		Yes	Yes	Yes	
Can you specify the number of medicines you have been given in today's prescription form?	212 (71)	115* (77)	97 (65)	0.0311	93 (93)	48 (96)	45 (90)	0.4331
Do you know the reason for which you have been given these medicines?	92 (31)	61* (41)	31 (21)	0.0003	44 (44)	29* (58)	15 (30)	0.0088
Do you know about how many times a day the medicines are to be taken?	215 (72)	108 (72)	107 (71)	0.8981	88 (88)	45 (90)	43 (86)	0.7583
Do you take your medicines regularly?	229 (76)	118 (79)	111 (74)	0.4151	94 (94)	48 (96)	46 (92)	0.6737
Do you know what to do if you miss multiple doses?	66 (22)	35 (23)	31 (21)	0.6759	15 (15)	9	6	0.5754
Have you ever skipped medications?	81 (27)	41 (27)	40 (27)	0.8965	11(11)	6 (12)	5 (10)	0.7493
Can you tell the side-effects of medicines given to you ?	52 (17)	26 (17)	26 (17)	1.0000	5 (5)	3 (6)	2 (4)	0.6464
Do you have any other diseases or health problems for which you are taking treatment?	122 (41)	64 (43)	58 (39)	0.5567	45 (45)	26 (52)	19 (38)	0.2278

Numbers in parentheses indicate % p < 0.05 when responses of dialysis group compared with non-dialysis group using chi square test

Majority of caregivers (85) belonged to upper lower class while rest (15) caregivers belonged to lower middle class. Regarding literacy level, 22 caregivers were illiterate, 20 had primary education, 43 had secondary education and 15 caregivers were graduates. In the drug treatment awareness questionnaire the responses for the following items - specifying number of medicines (71% patients, 93% caregivers), medication frequency (72% patients and 88% caregivers) and regular intake of drugs (76% patients and 94% caregivers) was better in patients as well as care givers but alarming fact is that awareness regarding action

plan for skipped (27% patients, 11% caregivers) or missed doses (22% patients, 15% caregivers) and adverse effects (17% patients, 5% caregivers) was present in very few patients and caregivers. The number of responders on items specifying names of medicines (p=0.0311) and reasons for drug therapy (p=0.0003) was statistically higher in dialysis group compared to non-dialysis group in patients. The patient/caregiver responses for frequency of medicines, regularity of medicines, information on action plan for missed/skipped doses, information on side effects of medicines and associated co-morbidities, was comparable between dialysis and non-dialysis group.

Table 2: Number of accurate responses given by CKD patients who responded as 'yes' in drug awareness questionnaire.

Questions	Total Patients			Dialysis			Non-Dialysis		
	C	I	N	C	I	N	C	I	N
Names of medicines prescribed (T=212, D= 115, ND=97)	3 (1.4)	200 (94)	9 (4.2)	3 (2.6)	102 (89)	10 (8.7)	0 (0)	93 (96)	4 (4.1)
Indications of medicines prescribed (T=92, D= 61, ND=31)	3 (3.2)	78 (85)	11 (12)	3 (4.9)	51 (84)	7 (11)	0 (0)	26 (84)	5 (16)
Frequency of medicines to be taken (T=215, D= 108, ND=107)	150 (70)	62 (29)	3 (1.4)	77 (71.2)	28 (26)	3 (2.7)	73 (68)	29 (27)	5 (5)
Action plan about missed drug dose (T=66, D= 35, ND=31)	10 (15)	25 (38)	31 (50)	6 (17.1)	16 (46)	13 (37)	4 (13)	15 (48)	12 (39)
Information on side effects of medicines prescribed (T=52, D=26, ND=26)	1 (1.9)	13 (25)	38 (73)	1 (3.8)	17 (65)	8 (31)	0 (0)	12 (46)	14 (54)
Information on associated co-morbidities (T=122, D=64, ND=64)	26 (21)	63 (52)	33 (27)	14 (22)	36 (56)	14 (22)	12 (21)	39 (67)	7 (12)

Numbers in parentheses indicate %, C= Complete information; I= Incomplete information; N= No information; T= Total patients; D= Dialysis patients; ND= Non-dialysis patients.

Table 3: Number of accurate responses given by caregivers of CKD patients who responded as 'yes' in drug awareness questionnaire.

Question	Total Caregiver			Dialysis Caregiver			Non-Dialysis Caregiver		
	C	I	N	C	I	N	C	I	N
Information about medicines prescribed to patient (T=93, D= 48, ND=45)	7 (8)	81 (87)	5 (5)	4 (8)	44 (92)	0	3 (7)	37 (82)	5 (11)
Indications of medicines prescribed (T=44, D= 29, ND=15)	10 (23)	34 (77)	0	7 (24)	22 (76)	0	3 (20)	12 (80)	0
Frequency of medicines to be taken (T=88, D= 45, ND=43)	74 (84)	12 (14)	2 (2)	43 (96)	2 (4)	0	31 (72)	10 (23)	2 (5)
Information about missed drug dose (T=15, D=9, ND=6)	3 (20)	4 (27)	8 (53)	2 (22)	4 (45)	3 (33)	1 (17)	0	5 (83)
Information on side effects of medicines prescribed (T=5, D= 3, ND=2)	2 (40)	1 (20)	2 (40)	2 (67)	1 (33)	0	0	0	2 (100)
Information on associated co-morbidities (T=45, D= 26, ND=19)	41 (91)	4 (9)	0	24 (92)	2 (8)	0	17 (89)	2 (11)	0

The item-wise responses of the on the drug treatment awareness questionnaire of both patients and caregivers is represented in (Table 1). Positive patient respondents were further probed to specify names of medicines, indications,

dosage regimen, action plan for missed doses, adverse effects and the number of accurate respondents is represented in (Table 2). Thus, it is evident that only 3 /300 patients knew the names of the drugs and purpose for taking the drugs.

Table 4: Drug treatment awareness scores of patients /caregivers for drug therapy awareness questionnaire.

Mean score	Total patients (n = 300)	Dialysis (n = 150)	Non-dialysis (n = 150)	p value	Total caregiver (n = 100)	Dialysis caregiver (n=50)	Dialysis caregiver (n = 50)	p value
Mean score: According to the gender	8.16±3.41	9.31±2.66*	8.22±1.89	p<.0001	8.3±1.6	7.19±1.46	6.96±2.04	0.5185
Female	8.63±1.09	8.11±2.11	9.05±2.10*	P = 0.0001	7.1±1.78#	7.41±1.25*	6.43±2.44	0.0136
Male	9.03±2.13#	10.03±3.63	9.55±3.0 3	P = 0.2147	6.3±1.64	7.25±0.62*	7.9±0.26	< 0.0001
According to the duration of disease						6.3±1.86*	7.11±0.56	0.0046
Less than 1 year	7.10±2.03	8.33±1.09*	7.43±1.23	P< 0.0001	6.81±1.6& 6.93±1.9	6.8±1.36*	6.14±1.2	0.0116
1-5 years	8.46±2.67	11±2.37*	8.20±2.06	P< 0.0001	7.12±1.13	7.64±0.93*	6.96±1.53	0.0088
5-10 years	10. 53±1.30	12.7±2.43*	11.07±1.73	P< 0.0001	7.54±1.36	7.99±1.13*	6.86±2.14	0.0015
More than 10 years	10.06±1.86@	12.06±2.70	11.86±1.90	p = 0.4587	7.91±1.89	6.83±1.41	6.16±2.1	0.0645
iii) According to the literacy level								
Illiterate	5.12±1.17&	6.33±3.11*	5.33±2.10	P = 0.0012	7.11±2.13	8.14±1.28	7.81±0.12	0.7678
Primary education	6.88±0.19	7.0±1.05*	6.33±1.07	P< 0.0001	7.21±2.46	7.86±1.17*	7.12±0.69	0.0002
Secondary education	7.69±1.01	7.33±2.93	8.33±2.55*	P = 0.0018				
Higher secondary education	8.53±1.76	9.24±3.63	10.04±2.03*	P = 0.0191				
Graduate	10.06±1.23	12.0±2.96	11.50±3.06	p = 0.1514	8.3±1.6	7.19±1.46	6.96±2.04	0.5185
According to the socio-economic status								
Upper lower class	7.18±1.09	11.23±3.13*	8.23±3.13	P< 0.0001	7.1±1.78#	7.41±1.25*	6.43±2.44	0.0136
Lower middle class	8.36±0.73\$	9.33±1.5*	8.39±1.55	P< 0.0001	6.3±1.64	7.25±0.62*	7.9±0.26	<0.0001

Only 1 patient could accurately state 1-2 common adverse effects of the drugs that were prescribed. Hence inspite of stating 'yes' for drug indications, and adverse effects the actual awareness is lacking. In a similar manner, positive caregiver respondents were further probed to specify names of medicines, indications, dosage regimen, action plan and their accurate responses is represented in (Table 3). Only 7/93 caregivers gave accurate information regarding names of the medicines and 10/44 caregivers specified the indications of medicines correctly. Further only 3 /100 caregivers and 5/100 caregivers provided accurate information on action plan for missed doses and side effects of the drugs.

The mean awareness score of patients was 8.16±3. 41, while awareness score in dialysis patients and non-dialysis patients was 9.31±2.66 and 8.22±1.89 respectively. The mean score in females was 8.63±1.09, which was significantly higher score in non-dialysis compared to dialysis group (p=0.0001). The mean drug awareness score was significantly higher in dialysis compared to non-dialysis group, in patients stratified based on disease duration (p<0.0001). The mean drug awareness score in illiterate patients (p=0.0012) and patients who received primary education (p<0.0001), was significantly higher in dialysis compared to non-dialysis group. On the contrary, in patients with secondary (p=0.0018) and higher secondary education (p=0.0191), the mean drug awareness

score was significantly higher in non-dialysis compared to dialysis group. The mean drug awareness score of caregivers was 8.3 ± 1.6 , score of caregivers of dialysis patients and non-dialysis patients was 7.19 ± 1.46 and 6.96 ± 2.04 respectively. The mean score in female caregivers was 7.1 ± 1.78 , which was significantly higher ($p=0.0136$) in dialysis group. The mean awareness score in male caregiver was 6.3 ± 1 which was significantly higher in dialysis group ($p<0.0001$). The mean caregiver awareness score in caregivers based on literacy level was significantly higher in dialysis group. Similarly, mean awareness score for caregivers who belonged to lower middle class, was significantly higher in dialysis compared to non-dialysis group ($p=0.0002$). The mean drug awareness scores for patients and caregivers is represented in (Table 4). The patients' treatment awareness score correlated significantly with patient's socioeconomic status (Correlation co-efficient (r)= 0.9 , $p<0.00001$) and duration of disease ($r=0.8$, $p<0.00001$) whereas the awareness scores had no correlation with patient's age ($r=0.09$, $p=0.1198$) and gender ($r=0.18$, $p=0.17$). The caregiver's awareness score showed strong positive correlation with socioeconomic status ($r=0.63$, $p<0.00001$) while no correlation with age ($r=0.11$, $p=0.2759$) and gender ($r=0.08$, $p=0.4288$).

DISCUSSION

The lack of awareness about the treatment in CKD patients as well as their caregivers has posed an obstacle in treatment adherence and subsequently controlling the disease successfully. There are published studies globally and India regarding disease awareness in CKD patients but no published studies of treatment awareness in CKD patients/ caregivers exist, hence this study was executed.

In our study, out of 300 patients, 164 (55%) patients were males and 136 (45%) patients were females. This finding is similar to the results of Kantanvar et al in which there were 53.7% males and 46.3% females.¹⁴ The mean age of patients was 48 ± 11 years which was similar to the report of Indian CKD registry where in mean age documented was 45.22 ± 15.2 years.¹⁵ The mean age of the patients in Ahlawat et al study was 53.8 years and similar to the results of Devi et al. and Al-Ramahi et al. wherein age was 55.1 years and 55.6 years, respectively.¹⁶⁻¹⁸ The reason for lower mean age in current study could be due to inclusion of both non-dialysis and dialysis patients. In present study, hypertension (62%) followed by diabetes (56%) were the most common co-morbidities similar to Ahlawat et al study where hypertension (55%) and diabetes (40%) were the reported co morbidities in CKD patients.¹⁶ Several studies have proven that diabetes mellitus (DM) is a risk factor for CKD and end stage renal disease.¹⁹ In current study, average number of dialysis cycles/week/patient was 4.5 which was exactly same as in study conducted by Chakraborty et al.²⁰ The total treatment awareness score was 20 while the mean score was found to be less than 10 in CKD patients and their caregivers indicating they were not aware of half of the items in the questionnaire. The

awareness on items such as number of medicines, medication frequency and regular intake of medicines was present in majority of the patients and caregivers which is a positive finding. This could be due to the fact that number/ frequency of medicines is reiterated by the hospital pharmacists. This implies that reinforcement of the information by various health care professional such as pharmacists, nurses could also aid in improving retention of information by the patients. Thus, the sole responsibility of disseminating treatment information may not rest with the treating physician but can be a shared responsibility of clinical team including doctors, clinical pharmacists and nurses. But equally disappointing fact is that patients and their caregivers have poor/no awareness towards the names and doses of medicines, their indications, action plan for missed doses, side effects and co-morbidities. Since CKD patients are associated with co-morbidities such as hypertension, diabetes and anemia, drug therapy awareness for each of the co-morbidity is essential. Lack of knowledge of concomitant medication in CKD patients could affect their treatment and compliance. According to WHO Good Prescribing Practices, in doctor –patient medication communication, patients have to be counseled regarding names of medicines, drug regimen, purpose for prescribing the drug, common adverse effects, action plan on how to tackle missed/ skipped doses in simple non-technical and non-medical language. If patients and their caregivers are informed and they imbibe this information they themselves realize the need of medication and its due compliance. The study site being a government tertiary care hospital and high patient load, the treating nephrologists may have time constraints to ensure that patient has understood all this vital information which he has provided.

The awareness score of dialysis patients and their caregivers was comparatively higher than non-dialysis patients. The significant higher level of awareness in dialysis patients could be due to their regular OPD follow up that is, twice a month compared to non-dialysis patients with a follow up of once per 1 month or 3 months. Majority of dialysis patients (94%) knew about the medicines prescribed to them, only a very meagre proportion (<2%) of patients are fully aware about the drug therapy given to them. In non-dialysis group, none from the 65% patients who said yes, could give the complete information. Similarly, caregivers were found to be comparatively more aware than the patients as they provide important support to patients and accompany the patients during OPD visits. Male patient/caregiver awareness scores were more, this could be because of possible reasons: male predominance in overall study, more general awareness amongst males due to higher literacy or outdoor exposure. The extreme low level of awareness in patients regarding the side-effects of medicines is disappointing. Counselling about adverse effects and remedial measures taken by treating physician to minimize them is essential to lessen the stress in CKD patients. In addition, explaining side effects of drug is very crucial in elderly CKD population where occurrence of ADR is more than in normal population.

Elderly are at higher risk of side effects even for a single drug for pharmacokinetic reasons. The most common causes of ADR in elderly patients are the unwanted interactions among the multiple drugs taken, due to comorbidities, for example, hyperkalemia due to interaction between ACE inhibitors or angiotensin-receptor blockers and potassium-sparing diuretics, hypotension and shock with calcium-channel blockers plus macrolide antibiotics.²¹ Patient education programs with focused content on drug regimens, common adverse effects and due emphasis on drug adherence need to be implemented, these programs could be designed as continuous reinforcing modules as audio/ video clips or as pamphlets to be displayed in the OPDs. Repeated display information will not only achieve retention of knowledge but also save nephrologists time to reiterate this vital information

It was noted that as the duration of disease increased, the mean awareness score increased significantly. This indicates that the longer disease duration and so longer treatment duration increased the patients' awareness towards the drug therapy. However, the awareness score was comparable between dialysis and non-dialysis patients with disease duration more than 10 years. This may be because after 10 years of disease duration, the awareness in both subsets of patient may be coming at par. Similarly, as the literacy level of patients/caregiver increased, the mean awareness score increased significantly. However, for both dialysis and non-dialysis patients who were graduate or post graduate, the awareness score was comparable. This implies that in case of literate and qualified patients, the number of doctor patient encounters may not contribute essentially to awareness as even 1-2 doctor patient encounters may be sufficient for literate and qualified patients to be aware about the prescribed information. In previous studies, it is shown that low health literacy is a significant problem impacting 23%-28% of patients with CKD.²² Low health literacy may contribute to inferior CKD knowledge and poor dialysis patient self-management.^{18,23} The mean awareness score was significantly higher in lower middle-class patients compared to upper lower-class patients. Zeng et al study showed that there was a significant association between lower levels of income, occupation ($p=0.012$), combined socio-economic status ($p=0.009$) and progression to end-stage renal disease.²⁴

Limitations

The limitation of the study was that this was a cross-sectional study and the authors did not follow up the patients to assess their improved awareness.

CONCLUSION

The overall awareness regarding drug treatment is less than 50% in patient and caregivers with strikingly low awareness about dose regimen, adverse effects, action plan for missed doses and co morbidities. Patient education

programs to reinforce and retain this knowledge need to be implemented in CKD patients.

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