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Drug Utilization Pattern in Chronic Kidney Disease Patients at a Tertiary Care Public Teaching Hospital: Evidence from a Cross- Sectional Study

Rajiv Ahlawat[1], Sanjay D'cruz[2] and Pramil Tiwari[3*]

[1]Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), Punjab, India
[2]Department of General Medicine, Government Medical College and Hospital, Chandigarh, India
[3]Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), Punjab, India

Abstract

Introduction: Patients with chronic kidney disease usually have multiple co-morbidities and, therefore, require multiple pills.

Objective: To evaluate the prescribing pattern in patients of chronic kidney disease.

Method: This study was carried out at a renal clinic of medicine OPD of a tertiary care public teaching hospital for a period of one year. Patients diagnosed with CKD according to KDIGO guideline were included in the study. Medications were classified into different groups on the basis of Anatomic Therapeutic Chemical (ATC) classification

Results: A total of 408 patients diagnosed with CKD were included in study. The average age of the patients was 53.8 (6.4). Of all, 18% of the patients were on dialysis. It was found that 42% of the patients belonged to end stage of renal disease. The mean (SD) of drugs was found to be 6.57 (2.3). Only 19% of the drugs prescribed out of Indian National List of Essential Medicine (NLEM). No drug was found to be prescribed by generic name. Out of total 2,681 drugs prescribed, most commonly prescribed were cardiovascular drugs (33.9%). Further, it was also found that 14.7% of the patients were prescribed with antimicrobials. Among all, 22.3% of the patients were vaccinated with hepatitis B vaccine. Five most commonly prescribed drugs were calcium carbonate, vitamin D, iron, torsemide and amlodipine (13.9%, 12.2%, 11.5%, 8.1% and 6.1%, respectively). Ninety-five percent of the patients were prescribed phosphate binder (PB). Calcium carbonate was the most commonly used PB prescribed to 91.1% of the patients. Sevelamer was prescribed to only 18 patients.

Conclusion: The calcium based phosphate binders were found to be the most commonly prescribed drug. Maximum number of drugs was prescribed from cardiovascular drugs. Prescribing was found consistent with NLEM.

Keywords: Chronic kidney disease; Prescribing pattern; Drug utilization; Pharmacoepidemiology; India

Introduction

Chronic kidney disease (CKD) is widely prevalent non-communicable disease that is responsible for increasing morbidity in India [1]. Diabetes and hypertension have been reported to be the most common risk factors for CKD [2]. In view of this, it is fair to anticipate a parallelism between the number of diabetics and hypertensive and the number of CKD patients.

CKD patients present with several other co-morbidities such as hypertension, diabetes mellitus, coronary artery disease and infection [2,3]. The presence of these comorbidities has a twofold impact – first, it increases the cost of treatment and secondly, it poses a challenge for the treatment of CKD patients. Because of the multiple medications, CKD patients are at higher risk of developing drug-related problems. They need complex therapeutic regimen requiring frequent monitoring. Inappropriate use of drugs in these patients can lead to adverse drug reaction, increased hospital stay and increased cost of treatment.

Drug utilization changes with time period, physician, disease conditions and population, which makes it is important to study the drug utilization continuously over a period of time [4]. Drug utilization studies in CKD patients help to understand and build evidence for the drug use. CKD patients need to take medicines lifelong, which makes it is very important to study the prescribing trend on a regular basis.

There is very limited evidence from India on the prescribing trends in CKD patients [5,6]. This study offers such evidence from a public teaching Indian hospital.

Method

Study design, setting and patient population

This cross-sectional study was carried out at the renal clinic of medicine OPD at Government Medical College and Hospital, Chandigarh.

Patients of either sex, age 18 years or more, diagnosed by the clinician to have chronic kidney disease and currently on drug treatment were included in study. Patients with cognitive impairment and those unable to complete the interview were excluded. The patients were included in this study after obtaining a written informed consent for participation. The patients with age 60 years or more were considered as elderly [7].

***Corresponding author:** Pramil Tiwari, Department of Pharmacy Practice, National Institute of Pharmaceutical Education and Research (NIPER), Sector 67, S.A.S. Nagar, Punjab-160062, India, Tel: +91-172-2292135; E-mail: ptiwari@niper.ac.in

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Data collection and interpretation

A predesigned case record form was used for data collection. The case record form did not contain the name of the patient, in order to protect the patient's identity at all points of time. Patient information regarding demographics, socioeconomic, lifestyle (smoking, alcohol consumption) and medication was collected from patients OPD card and through patient interview. Biochemical parameters were captured from the latest laboratory investigation reports documented in the clinical records. Socioeconomic status was assessed by using the modified Kuppuswamy's scale [8], which takes into account the educational qualification, occupation of the family head and monthly family income of the participant.

Anthropometric measurements including weight and height were taken from the patient OPD card. Serum creatinine, urea, calcium, potassium and phosphate levels were recorded from biochemical tests performed. Hemoglobin level was collected from the hemogram. Clinical systolic blood pressure (SBP) and diastolic blood pressure (DBP) levels, serum lipids, blood glucose and glycated hemoglobin (HbA_{1c}) was also recorded.

Data collected in the case record form was utilized to study the prescribing trends in patients of CKD. Drugs were classified into different groups based on Anatomic Therapeutic Chemical (ATC) classification. Data on utilization of different classes as well as individual drugs were subjected to descriptive analysis.

Sample size

According to the sample size calculation (with estimation error of 5% and a 95% confidence level), 384 patients were required.

Ethical consideration

This study was approved by the Research and Human Ethics Committee of Government Medical College and Hospital, sector 32, Chandigarh. Further, the study was conducted in accordance with ICMR rules and guidelines applicable for such studies [9].

Statistical analysis

Mean with standard deviation or median with interquartile range (IQR) were used to represent the continuous data. Percentage was used for representing the discrete variables. Student's t-test (unpaired) was used to evaluate the difference between mean of Independent categorical variable and dependent continuous variable. A p-value of 0.05 was considered statistically significant. All analyses were done with IBM SPSS Statistics package ver 20.0 (SPSS Inc., Chicago, IL, USA).

Definitions of outcome parameters used in the study

CKD is defined as abnormalities of kidney structure or function (Albuminuria, urine sediment abnormalities, electrolyte and other abnormalities due to tubular disorders, abnormalities detected by histology, structural abnormalities detected by imaging, history of kidney transplantation, GFR<60 ml/min/1.73m^2), present for over 3 months, with implications for health and CKD is classified based on cause, GFR category, and albuminuria category (CGA). The patients were classified into five stages on basis of GFR categories [10].

Further, the patients were classified on the basis of BMI as 'underweight' (<18.50kg/m^2), 'normal' (<18.50-24.99 kg/m^2), 'overweight' (≥ 25.00 kg/m^2), 'pre-obese' (25.00-29.99 kg/m^2) and 'obese' (≥ 30 kg/m^2) [11]. Haemoglobin concentration less than 13 g/dl in males and less than 12 g/dl in females were considered as anemic in age group more than 15 years [12]. Coronary artery disease was identified through the patient's medical record for angina or myocardial infarction. Patients with fasting blood glucose ≥ 7.0 mmol/l (126 mg/dl) or post-prandial over ≥ 11.1 mmol/l (200 mg/dl) or patients with HbA_{1c} ≥ 6.5%/48 mmol/mol or random plasma glucose ≥ 11.1 mmol/l (200 mg/dl) were considered as diabetic [13,14]. The participants were considered to be hypertensive if the patient was on antihypertensive medication (as documented in clinic records) or SBP ≥ 140 mmHg or DBP ≥ 90 mmHg [15]. Patients on hypolipidemic drug or patients with defined dyslipidaemia according to American association of clinical endocrinologist guideline for management of dyslipidemia and prevention of atherosclerosis were considered as dyslipidemic [16]. Cockcroft Gault equation (with SI units) was used for calculating the glomerular filtration rate (GFR) [17].

Results

These results were based on the data from 408 patients included for study purpose. Of all, 217 were male (84 were elderly) and 191 were female (67 were elderly).The mean age of the patients was 53.8(6.4) years. The mean age of the female patients was found higher than the male patients; however, the difference was statistically insignificant (Unpaired Student's t-test; p=0.54). Mean hemoglobin, HbA_{1c} and serum creatinine was 9.5 (1.5), 7.7 (1.5) and 4.3 (0.9).

Of all, 37% were found to be elderly. On the basis of Kuppuswamy scale of socioeconomic status, the largest number of the patients belonged to lower middle class (40%).

This was followed by upper lower (27%), upper middle (22%), upper (6%) and lower socioeconomic categories (4%). Eighty-one percent of the patients paid out of pocket for treatment.

Of all the patients, 42% belonged to CKD stage 5 followed by stage 3, 4, 1 and 2 (22, 21, 8 and 7%, respectively). Over half of the patients (55%) were found to have hypertension as a comorbidity followed by anemia (46%), diabetes (40%), hyperlipidemia (36%), coronary artery disease (10%) and hypothyroidism (7%). Only 18% of the patients were found to be on hemodialysis.

Patients were classified on the basis of BMI. The median (IQR) BMI was 22.7 (19.8-25.7) Kg/m^2. Of all, 47% of the patients belonged to normal weight category followed by patients in overweight and underweight category (17% and 36%, respectively). Further, in overweight category, the pre-obese and obese patients were to the tune of 27% and 9%, respectively (Table 1).

On the basis of this ATC classification, cardiovascular system (33.9%) class of drugs was the most commonly prescribed followed by drugs for alimentary tract and metabolism (15.8%) and drugs for treatment of musculoskeletal system (14.5%), blood and blood forming agents (14.1%) (Table 2).

A total of 2,681 drugs were prescribed in 408 prescriptions. The mean number of drugs was found to be 6.57 (2.3). Mean number of diagnosis was 3.6 (0.3). Median (IQR) duration of diabetes, CKD and hypertension was 12 (5-16), 3 (1-6), and 6 (2-9) years, respectively. All the drugs were prescribed with brand name only. Of total number of drugs prescribed, Eighty-one percent were prescribed from within the NLEM-2011. Only 11% of the medicines were prescribed as injections (Table 3).

Antihypertensive agents were the most commonly prescribed class of drugs constituting 28.8% of the total number of drugs prescribed; this was followed by hematopoietic drugs (15.2%), phosphate binders

Characteristics	No. (%) (N=408)
Socio-economic status	
Upper	25 (6)
Upper middle	91 (22)
Lower middle	165 (40)
Upper Lower	110 (27)
Lower	17 (4)
Treatment Funding	
Out of pocket	330 (81)
Employer	78 (19)
Comorbidities	
Hypertension	225 (55)
Diabetes	164 (40)
Anemia	186 (46)
Coronary artery disease	41 (10)
Hyperlipidemic disease	146 (36)
Hypothyroid	30 (7)
No-comorbidity	84 (21)
Stages of CKD	
CKD I	32 (8)
CKD II	29 (7)
CKD III	90 (22)
CKD IV	86 (21)
CKD V	171 (42)
Hemodialysis	72(18)

CKD: Chronic Kidney Disease; HbA_{1c}: Glycosylated Hemoglobin; IQR: Interquartile Range; SD: Standard Deviation

Table 1: Baseline characteristics of CKD patients.

#	Class of medicine	No. (N=2681)	%
A	Alimentary tract and metabolism	424	15.8
B	Blood and blood forming organs	378	14.1
C	Cardiovascular system	909	33.9
D	Dermatology system	4	0.1
G	Genito-urinary system and sex hormones	112	4.2
H	Systemic hormonal preparations	163	6.1
J	Antiinfectives for systemic use	154	5.7
L	Antineoplastic and immunomodulating agents	40	1.5
M	Musculo-skeletal system	390	14.5
N	Nervous system	98	3.7
P	Antiparasitic products, insecticides and repellents	0	0.0
R	Respiratory system	0	0.0
S	Sensory organs	0	0.0
V	Various	9	0.3

Table 2: Drug classification according to ATC classification system.

Prescription details	No. (%)	Mean (SD)
Total number of drugs prescribed	2681	
Number of drugs per prescription		6.57 (2.3)
Number of antihypertensive drugs per prescription		2.2 (0.8)
Drugs prescribed by generic name	0	
Drug prescribed from NLEM	2172 (81)	
Drugs prescribed as injections	295 (11)	
Patients prescribed with antimicrobials	60 (14.7)	
Patients prescribed with calcium based phosphate binders	371 (91)	
Patients prescribed with non-calcium based phosphate binders	163 (4)	
Patients prescribed with a diuretic	220 (54)	
Patients prescribed with oral iron	309 (76)	
Patients prescribed with erythropoietin	29 (7)	
Patients prescribed with Vitamin D	327 (80)	
Patients prescribed with Vitamin B12	29 (7)	
Hepatitis B vaccination	91 (22.3)	

Table 3: Prescriptions analysis in CKD patients.

(14.5%) and vitamins and minerals (13.3%) in that rank order. Among the antihypertensive agents, the prescribing of the diuretics was followed by the calcium channel blockers, beta blockers, alpha blockers, ACE inhibitors and ARB (Table 4).

Five most commonly prescribed drugs were calcium carbonate, vitamin D, iron, torsemide and amlodipine. Out of total, 176 patients were prescribed with more than six medications. The percentage of medication prescribed was found higher when the treatment was funded by the employer on compare to patients paying out of pocket (23% vs. 16%; Table 5).

Discussion

This discussion is based on the data from 408 patients included in the study. The mean age of the patients in present study was 53.8 (6.4) years. The mean age was found similar to the results of Devi et al. and Al-Ramahi et al. (55.1 years and 55.6 years, respectively) [5,18]. This is higher than reported by Bajait et. al. (51 years) [19]. The mean age is on slightly higher side as in most of the cases CKD is caused by chronic illness like hypertension and diabetes.

The number of male patients was higher than the number of female patients in the study. This finding is in concurrence with the results of Bajait et. al. and Devi et al.[5].

In this study, maximum number of the patients (42%) had the end stage renal disease. These findings were similar to that of the results of Bajait et al. (42%) [19]. However, in the results of Devi et al. and Al-Ramahi et al. the ESRD patients were as high as 90% of the patients [5,18]. The reason for this difference lies in the inclusion and exclusion criteria of the study. In these studies only the patients of CKD stages III-V were recruited; however, in our study, the patients from all stage of CKD were included.

In the present study, hypertension was found to be the most commonly occurring co-morbidity (55% of the cases) followed by diabetes, anemia, coronary artery disease and hyperlipidemia. These findings were found similar to that of study by Bajait et al. where hypertension was found to be the most commonly occurring comorbidity reported in 55% of the patients followed by the occurrence of diabetes, anemia and coronary artery disease. However, in the study carried out by Al-Ramahi et al. hypertension was found to affect 84% of the CKD patients followed by anemia in 80% of the patients [18,19]. The

Drug Class	ATC code	No	%
Antihypertensive		772	28.8
Diuretics	C03CA	220	8.2
Calcium channel blockers	C08CA	168	6.3
CCB+BB		24	0.9
Beta blockers	C07AB	44	1.6
Alpha blockers	C02CA	47	1.8
ACE inhibitors	C09AA	54	2.0
ARBs	C09CA	75	2.8
ARB+DU		44	1.6
Others (Nitrates, ARB+CCB, ACE inhi.+DU, CAA)		96	3.6
Hypolipidemic drugs		137	5.1
Statins	C10AA	74	2.7
Fibrates		15	0.5
Statins+Aspirin		48	1.8
Antidiabetic		189	7.0
Insulin	A10A	121	4.5
DPP-4 inhibitors	A10B	38	1.4
Sulphonylureas	A10B	30	1.1
Vitamins and Minerals			13.3
Vitamin D	A11HA	327	12.2
Vitamin B12	A11EA	29	1.1
Phosphate binders		390	14.5
Calcium	A02AA04	372	13.9
Sevelamer	V03AE02	18	0.7
Hematopoietic agents		407	15.2
Iron (oral)	B03A	309	11.5
Iron (inj)		35	1.3
Folic acid	B03B	34	1.3
Erythropoietin	B03XA01	29	1.1
Antimicrobials	J01	60	2.2
Others#		279	13.8

CCB: Calcium Channel Blocker, BB: Beta Blocker, DU: Diuretic, ARB: Angiotensin II Receptor Blockers (ARBs), ACE: Angiotensin-Converting Enzyme, DPP: Dipeptidyl Peptidase, CAA: Centrally Acting Antihypertensive Agents
#- Cyclophosphamide, Prednisolone, pantoprazole, pyridoxine, febuxostat, carbidopa+levodopa, Finasteride

Table 4: Therapeutic class wise distribution of drug use.

	No. of medications (%)	
	≤ 6 (N=232)	**>6 (N=176)**
Treatment Funding		
Out of pocket	192 (83)	138 (78)
Employer	38 (16)	40 (23)
Comorbidities		
Hypertension	92 (40)	133 (57)
Diabetes	40 (17)	124 (53)
Anemia	92 (40)	94 (41)
Coronary artery disease	19 (8)	22 (10)
Hyperlipidemic disease	25 (11)	121 (52)
Hypothyroid	8 (3)	22 (9.4)
No-comorbidity	66 (28)	18 (8)
Stages of CKD		
CKD I	14 (6)	18 (8)
CKD II	17 (7)	12 (5)
CKD III	46 (20)	44 (19)
CKD IV	53 (23)	33 (14)
CKD V	58 (25)	113 (49)
Hemodialysis	25 (11)	47 (20)

Table 5: Pattern of poly-pharmacy among CKD patients.

most likely reason for the hypertension as most commonly occurring comorbidity is well explained by the fact that renin angiotensin system is affected in the patients of CKD which helps in controlling blood pressure.

Only 18% of the patients were found to be on hemodialysis. The main reason for this might be that patients in this study belonged to lower socioeconomic class and they could not afford the cost of hemodialysis. Only 25% of the patients were found to be on hemodialysis in study carried out by Bajait et al. However the study by Al-Ramahi et al. reported over 50% of the patients on hemodialysis [18,19].

Most of the patients in the present study belonged to lower middle socioeconomic class of status (40%). However, Tanvir et al. have reported maximum number of patients in lower socioeconomic class [20].

Body mass index is known to affect the outcomes in the patient of CKD. Overweight is a major problem in the patients of diabetic nephropathy. However underweight was found to associated with more mortality and morbidity in certain studies [21,22]. In present study 36% of the patients were found underweight.

According to ATC classification system drugs from the cardiovascular class was the most commonly utilized class of drugs (33.9%). This was found higher than the study carried out by Devi et al. and Bajait et al. which reported it to be 28% and 22%, respectively [5,19].

Alimentary tract and metabolism class of drugs, and blood forming agents was prescribed to a tune of 15.8% and 14.1%, respectively. However, according to the study by Bajait et al. the drugs from blood forming agents and alimentary tract and metabolism class of drugs were contribute 21% and 45% of the prescribed drugs, respectively.

The average number of drugs prescribed in the present study was 6.57, which is smaller than that reported by Devi et al., Bajait et al., and Al-Ramahi et al. (7.4, 9.4 and 9.3, respectively). This difference in average number of medicines can be due to different study population, comorbidities and difference in physician prescribing behaviour [5,18,19]. All the drugs in the present study were found to prescribed by brand name only like that of study carried out by Devi et al.[5]. Bajait et al., reported 12% of drugs prescribed by generic name [19]. Physician trust in the quality of branded medicine might be one of the reasons for this high number of drug prescribing by brand name in present study. The drug prescribing from the national list of essential medicine in present study was found much higher than the reported by the other studies carried out by Devi et al. and Bajait et al. in similar settings (81%, 53% and 42%) [5,19].

The cost and pain associated with parenteral drugs is likely to reduce adherence. However, there are certain medicines like insulin and erythropoietin that are available only as parenteral form. The number of drugs prescribed as parenteral was found 11% of the total number of medicines. The study carried out by Devi et al. reported the use of injections for 32% [5,19]. This difference might be due to smaller number of diabetic patients on insulin therapy in the present study.

Diuretics were the most commonly used cardiovascular agents in the present study followed by calcium channel blockers and Angiotensin II Receptor Blockers (ARB) (8.2%, 6.3% and 2.8%, respectively). Bajait et al. reported that diuretics, calcium channel blockers and beta blockers contribute to 10%, 6% and 1%, respectively of total drugs prescribed [5,19]. Sonawane et al. and Jessani et al., however, had shown beta blockers as the most commonly used antihypertensives [23,24]. In

present study, 54% of the patients were prescribed with diuretics. The other studies by Yazdanshenas et al., St. Peter et al. and Devi et al. reported that 60% 59% and 50% of the patients, respectively were prescribed with diuretics [25,26]. The use of hypolipidemic agents in present study was found lower than that of the other study carried out by Al-Ramahi et al. (34% and 47%, respectively).

Phosphate binders are one of the most commonly prescribed medicines in CKD. In present study, 91% of the patients were prescribed with calcium based phosphate binders followed by non-calcium based phosphate binders (4%). While the study by Navaneethan et al. reported the use of calcium based phosphate binders and non-calcium based phosphate binders to a tune of 75% and 25% respectively [27]. Hematopoietic agents are required to correct the deficiency of blood in CKD patients. Iron was found to be the most commonly utilized agents. 13% of all drugs were given as iron; 15% of drugs were given as hematopoietic agent in the study carried out by Bajait et al. [19]. The use of vitamin D in present study was found to be higher than of the study by Bajait et al. (15% and11%, respectively).

Conclusion

Drugs from cardiovascular system were the most commonly utilized according to the ATC system of classification. All of the drugs were prescribed by brand name. A fair proportion of drugs were prescribed from the NLEM. Iron, calcium, vitamin D and torsemide were found to be most commonly utilized drugs in the present study.

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