

A STUDY ON DRUG RELATED PROBLEMS IN CHRONIC KIDNEY DISEASE PATIENTS OF A TERTIARY CARE TEACHING HOSPITAL IN SOUTH INDIA

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ABSTRACT

Background: Chronic Kidney Disease (CKD) is a progressive condition with an increase in drug usage, resulting in increased prevalence of actual and potential drug related problems (DRPs) in these patients, posing significant challenge to health care providers.

Objective: The aim of the study was to identify drug related problems in patients with chronic kidney disease (stages I to V), to resolve them by providing interventions to the health care providers and to educate the patients regarding the drug therapy. **Methodology:** A study was conducted in 226 patients (159 (70.4 %) males and 67 (30%) females), aged 18 years or older, diagnosed with all stages of Chronic Kidney Disease and hospitalized, including patients on maintenance

hemodialysis and post renal transplantation. Patients data were collected by direct history interview and from the patient medical records, the prescriptions were analyzed and the DRPs were identified and classified and pharmacist intervention was done as per the simplified Iaser methodology. Descriptive analysis was done for age, drugs and DRPs and Kendall's tau non-parametric test was used to assess the correlation between drugs prescribed and DRPs. All statistical tests were two tailed and $P < 0.05$ was used to indicate statistical significance. **Results:** The average number of drugs per prescription was found to be $8.93 \pm$

3.26. A total of 184 (81%) of DRPs were identified in 226 patients with an average of 0.81 ± 0.896 DRPs per prescription. The number of DRPs was found to be increasing with an increase in number of drugs per prescription. The common drug related problems found in the study were drug-drug interactions in 40.2% patients which included 11(4.8%) severe, 79 (34.9%) moderate and 2 (0.88 %) minor interactions; non-compliance in 38.2 % patients and treatment duplicity in 5 patients (2.2%). The main reasons for non-compliance were found to be lack of adherence to recommendation (11.1%), lack of understanding to therapy (14.66%), difficulties for administration (5.33%) and economic reasons (7.11%). Interventions were made at the prescriber level for drug interactions and treatment duplicity and at the patient level to resolve non-compliance by educating them on their drug therapy. **Conclusion:** Continual identification, intervention and resolution of drug related problems in CKD could play a vital role in achieving better clinical outcomes.

KEY WORDS: Drug related problems, hemodialysis, adherence, chronic kidney disease.

INTRODUCTION

Chronic Kidney Disease (CKD) is highly prevalent and is increasing in public health concern as the number of people affected by it is increasing each year¹. As CKD progresses, the drugs that are given for these patients also increases and the prevalence of drug related problems also increases². Patients with CKD and on maintenance hemodialysis are prescribed with an average of 12 medications per patient and are at a higher risk of developing drug related problems thus leading to untoward effects³.

Patients with CKD do not have symptoms until the kidney function is severely impaired and as the disease advances, symptoms like loss of appetite, somnolence, uremia, nausea, vomiting, and confusion may develop. Patients also develop hypertension, electrolyte abnormalities like hyperkalemia, hypocalcemia, hyperphosphatemia, anemia and renal osteodystrophy. The first step in the treatment of chronic kidney disease is to determine the underlying cause, treating it and initiation of dialysis in advanced CKD along with the management of clinical manifestations of CKD. Hypertension is present in 80 to 85 percent of people with chronic kidney disease and it is managed by giving angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB) which not only reduces blood pressure and levels of protein in the urine, but is also thought to slow the progression of chronic kidney disease to a greater extent. Sometimes, a diuretic is also added.⁴

Anemia is the next major complication of CKD and patients are treated with erythropoietin or iron supplements. Other drugs given for CKD patients includes diuretics and potassium binding resin for hyperkalemia, drugs like Lanthanum Hydrochloride, Sevelamer and Calcium salts to treat hyperphosphatemia, sodium bicarbonate to manage metabolic acidosis, calcium and vitamin D supplementation for renal osteodystrophy and drugs for other co-morbidities.

A Drug Related problem (DRP) or Medication related problem (MRP) is an event occurring as a result of the drug therapy that actually or potentially interferes with desired health outcomes. DRP is considered as actual if the event has already occurred in a patient, whereas it is considered as potential if it is likely to develop if no appropriate intervention is made.⁵ DRPs pose a major challenge to the prescribers by causing significant morbidity and also negatively influencing the quality of life of the patients. A thorough knowledge of DRPs may help in identifying DRPs, resolving actual DRPs and preventing potential DRPs for the provision of better patient care.

Categories of DRPs

DRPs are broadly classified into eight categories as follows.⁶

Indication without Drug (IWD)

An indication without drug is referred to as not giving drug therapy for a previously untreated indication or failure to deliver prophylactic or preventive drug therapy.

Drug without Indication (DWI)

A patient given an unnecessary drug therapy without any clinical indication at that time is referred to as drug without indication.

Improper Drug Selection (IDS)

Improper selection of a drug or prescribing the wrong or ineffective drug for the patient.

Inappropriate Dosage Adjustments

Drug dosing for patients on dialysis is often challenging for health care providers due to the progressive increase in co-morbidities and laboratory abnormalities, alterations in the pharmacokinetic and pharmacodynamic parameters during dialysis. Inappropriate dosage adjustment can be due to under dosing (UD) and over dosing (OD) of the drugs.

- Incorrect dosing frequency and dosing interval, shorter duration of therapy, inappropriate drug administration are termed as under dosing.
- A dose-dependent or concentration-dependent toxic effect due to a high dose of a drug occurs due to overdosing.

Adverse Drug Reactions (ADRs): “ADRs can be defined as unpredictable, undesirable, untoward effects caused by the medication.” World Health Organization defines ADR as “A response to a drug which is noxious and unintended, and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function”.

Drug Interactions (DIs)

Interactions between drug-drug, drug-food and drug-laboratory tests. An interaction between calcium and iron is the most common DI seen in CKD patients.

Inappropriate Laboratory Monitoring: Biochemical abnormalities that may occur due to drug therapy should be monitored by appropriate laboratory investigations and failing to do so may be considered as a DRP.

Patient Non-adherence

A patient's inability or unwillingness to follow a prescribed drug regimen which is judged to be clinically appropriate, effective and able to produce the desired outcome without harmful effects is termed as non-adherence. It may occur due to various reasons, some of which includes the socio economic status of the patients, failures in the drug distribution or administration, lack of health literacy and disability.⁶

Identifying a DRP is a major task which could be taken care of by a clinical pharmacist in coordination with other health care providers through medication reconciliation - a three step process of verifying medication use, identifying variances and rectifying medication errors at interfaces of care, comparing a patient's medication orders to all of the medications that the patient has been taking.⁷ On the other hand, educational intervention at discharge and follow up of patients by the clinical pharmacists may also prevent adverse events and other medication-related problems. Continuous education can improve a patient's awareness of their drug therapy which in turn would improve their adherence to drug therapy.⁸⁻¹⁰ A study was conducted with the objective of identifying drug related problems in patients with

chronic kidney disease (stages I to V), and resolve them by providing interventions to the health care providers and to promote adherence to drug therapy by patient education.

METHODOLOGY

A prospective observational study was conducted in 226 patients (159 (70.4 %) males and 67 (30%) females), aged 18 years or older, diagnosed with all stages of Chronic Kidney Disease and hospitalized, including patients on maintenance hemodialysis and post renal transplantation patients in the nephrology wards and the dialysis unit of a South Indian Tertiary care teaching hospital. The study was conducted with the approval of the Institutional ethics committee and the consent of the study participants.

Patients' data collection was carried out during hospital stay and at the discharge by direct history interview and from the patient medical records. Data collected included patient demographics (age, sex, weight, height), past medical history, personal history (sleep and dietary pattern, smoking, alcohol, substance abuse), physical and general examination, clinical information, current treatment and other relevant information such as allergies, compliance and life style, laboratory investigations (Complete blood count, Liver function and renal function tests, Blood glucose levels, lipid levels and other tests), drug chart and discharge medications were collected and entered in the data collection forms specially designed for the study. The DRPs were identified and classified and pharmacist intervention was done as per the following IASER methodology¹¹ after obtaining the consent of the authors.

IASER methodology is a Spanish pharmaceutical care method that involves the following steps: Identification of patients who need improvement in their pharmacotherapy, pharmacist intervention, follow-up, assessment and results (Table 1).

Table 1: Drug related problems and pharmaceutical intervention classification according to simplified IASER Methodology

DRP TYPES	
INDICATION 1.Need Of Additional Treatment Untreated indication. Discontinuation of a needed treatment. Need of a combined treatment. Need of prophylaxis or premedication.	SECURITY 5.Adverse Reaction Allergy Side effect Contraindicated due to risk factors Interactions with drugs or food Inappropriate administration method
2.Unnecessary Treatment	

Not indicated Alternative more cost-effective. Inappropriate treatment duration. Alternative administration route. Non-pharmacological route. Treatment duplicity. Treatment for a preventable adverse effect EFFECTIVITY 3.Inappropriate Treatment Not indicated. Non-effective/resistance Inappropriate Dosage Other medication more effective 4.Underdosage a)Dose too low Inappropriate treatment duration Inappropriate administration Interactions with drugs or food	6.Overdosage Dose too high Inappropriate treatment duration Inappropriate administration Interactions with drugs or food ADHERENCE 7.Non-Compliance Lack of adherence to recommendations. Difficulties for administration. Economic reasons Lack of understanding of therapy Other
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Pharmacist Intervention

Pharmacotherapeutic Recommendation	Preventive Pharmaceutical care	Educational Pharmaceutical care
Drug discontinuation Alternative treatment Drug addition Individualized dosage regimen Individualized treatment Therapeutic drug monitoring Change to more efficient treatment No Recommendation	Prevent allergy reaction Prevent adverse effect Prevent treatment failure Clarify prescription	Provide information to the physician Provide information to the patient or caregiver

Statistical analysis

Statistical Package for social sciences (SPSS) version 15.0 was used to analyze the data obtained. Descriptive analysis was done for age, drugs prescribed and DRPs. The continuous variables were summarized as mean \pm SD; categorical variables were summarized as frequency counts and percentages. The Kendall's taub non-parametric test was used to assess the correlation between drug and DRPs. All statistical tests were two tailed and $P < 0.05$ was used to indicate statistical significance.

RESULTS

A prospective study was conducted in 226 patients (159 (70.4 %) males and 67 (30%) females) diagnosed with Chronic kidney disease (Stages I to V of CKD), admitted in the

wards of nephrology department including patients on maintenance hemodialysis and renal transplant patients.

The age range of the study population was found to be 9-80 years, with a mean age of 52.18 ± 13.83 years. The age distribution of the patients were as follows: 1 male (0.44 %), 3 females (1.33 %) were in less than 20 years age range; 28(12.44 %) males and 6 (2.66%) females in the range of 21-40 years, 90(40%) males and 37 (16.44%) females in the range of 41-60 years, 40 (17.77 %) males and 19 (8.44%) females in the range of 61-80 years, and one male (0.44 %) was above 80 years of age. Majority of the patients were in the age range of 41-60 years which included 90 (40%) in males and 37 (17 %) in females (Table 2).

The prevalence of Chronic kidney disease in the study population according to the stages of CKD as per National Kidney Disease Foundation classification was as follows: 26 (11.5 %) patients were in CKD-I stage , 6(2.6 %) were in CKD-II, 5(2.22%) were in CKD-III, 6 (2.6%) were in CKD-IV and 182 (81%) were in CKD-V stage.

Table 3 shows the prevalence of chronic co-morbid conditions among the study population. 158(45.2%) patients had Hypertension , 103(29.5%) had Diabetes Mellitus, 34 (9.7%) had Coronary artery disease , 7 (2%) patients each had pulmonary edema, tuberculosis ,HCV positive, 5 (1.4%) patients each had Seizure , hypothyroidism , respiratory tract infections , 4 (1.1 %) had acute pyelonephritis , 3 (0.8%) patient each had uremic gastritis , nephritic syndrome, 2 (0.57 %) patients each had hyperthyroidism ,metabolic encephalopathy, HBsAG, 1 (0.2 %) patients each had HIV and HBV.

Table 4 depicts the usage of anti-hypertensives among the study population, which included Calcium channel blockers for 115 (42 %) patients, Diuretics for 69 (25 %), Beta blockers for 33(11.7%), Angiotensin receptor blockers for 8 (2.9 %) and Centrally acting anti-adrenergic agents for 49(17.8 %) patients. The usage of anti-diabetic medications in the study population were as follows: Sulfonylureas such as glimepiride and glipizide were given for 3 (5.2 %) patients and 1(1.7%) patient respectively, biguanides for 1(1.7 %), alpha glucosidase inhibitors for 2 (3.5%) and Insulin for 50 (87.7 %) patients (Table 5).

Table 6 shows the usage of Phosphate binders which included Phostat for 18 (8.1 %) , Sevelamer for 6 (2.7 %) patients and Iron supplements which included livogen for 53 (24 %), Erythropeotin for 75 (33.7%), Vintor for 18 (8.1%) , autrin for 2(0.9 %) and folvite for

50 (22.5 %) patients. Table 7 shows the usage of Calcium and vitamin –D supplements which included shelcal for 95 (80%), Rocaltrol for 17 (14.3%) and Alpha D3 for 7(5.8 %) patients.

Table 8 shows the usage of antibiotics for 79 (35 %) patients, of which Piperacillin+tazobactam (Tazine) was given to majority of patients and other drugs were given as depicted in the table. Other drugs given included: statins for 30 (34.8 %) , immunosuppressants for 15 (17.4 %), Corticosteroids for 10 (12%) ,anti-epileptics for 8 (9.3 %) , Anti-tubercular drugs , Thyroid drugs for 7 (8.1 %) patients each ,anti-viral drugs and digoxin for 4 (4.6%) patients each and anti-fungals 1(1.1%) as depicted in table 9. A total of 183 cases were found to have Drug related problems with an average of 0.81+ 0.896 DRPs per prescription. The most frequent Drug related problems were identified during their hospital stay, of which 91 cases were with interactions with drug and food (40.7%), lack of understanding was found in 33 cases(14.66%), lack of adherence to recommendation was found in 25 cases (11.1%), difficulty in administration was found in 12 cases (5.33%), economic reasons in 16 cases (7.11%), and treatment duplicity was identified in 5 cases (2.2%) as per Iaser methodology (Table 10).

There was an average of 8.93 ± 3.26 drugs per prescription with an average of $0.81 + 0.896$ DRPs per prescription. There was an increase in the number of drug related problems with an increase in the number of drugs per prescription but the association was not statistically significant ($P > 0.075$) (Table 11).

Table 12 depicts the number of drug-drug interactions identified, which included 11 (4.8 %) Severe, 79 (34.9%) moderate, 2 (0.88 %) minor interactions.

Table 2: Age Vs Sex Of The Study Population

Age In Years Range	No Of Patients (N=226)			
	Males		Females	
	n	%	n	%
< 20	1	0.44	3	1.33
21-40	28	12.44	6	2.66
41-60	90	40	37	16.44
61-80	40	17.77	19	8.44
>80	1	0.44	-	-

Table 3: Co-Morbid Conditions In The Study Population

Co-Morbidities	No Of Patients (N=226)	Percentage
Hypertension	158	45.2%
Diabetes Mellitus	103	29.5 %
Coronary Artery Disease	34	9.7%
Pulmonary edema	7	2 %
Tuberculosis	7	2%
HCV Positive	7	2%
Seizure	5	1.4%
Hypothyroidism	5	1.4%
Lower respiratory tract infection	5	1.4%
Acute pyelonephritis	4	1.1%
Uremic gastritis	3	0.8%
Nephrotic syndrome	3	0.8%
Hyperthyroidism	2	0.57%
Metabolic encephalopathy	2	0.57%
HBSAG	2	0.57%
HIV	1	0.2%
HBV	1	0.2%

Table 4: Anti-Hypertensives Prescribed For Study Population

Category	No Of Patients (N=226)	Percentage
Calcium channel blockers		
Amlong(Amlodipine)	25	9%
Depin (Nifedipine)	90	33%
Diuretics		
Furosemide(Lasix)	64	23.3%
Dytor(Torseamide)	4	1.4%
Aldactone (Spiranolactone)	1	0.3 %
Beta blockers		
Revelol(Metoprolol)	15	5.4 %
Carvedilol	9	3.2%
Atenolol	6	2.1%
Concor (Bisoprolol)	3	1.0%
Angiotensin receptor blockers		
Losartan	8	2.9%
Centrally acting antiadrenergic agents		
Arkamine(Clomidine)	32	11.6 %
Minipress XL(Prazosin)	17	6.2%

Table 5: Anti-Diabetics Prescribed For Study Popualtion

Category	No Of Patients (N=226)	Percentage
Biguanides		
Metformin	1	1.7%
Sulfonylureas		
Glimepiride	3	5.2%
Glipizide	1	1.7%
AlphaGlucosidase Inhibitors		
Acarbose	2	3.5%
Insulin	50	87.7%

Table 6: Phosphate Binders And Iron Supplements Prescribed For Study Population

Category	No Of Patients (N=226)	Percentage
Phosphate binders		
Phostat(Calcium acetate)	18	8.1 %
Sevelamer	6	2.7 %
Iron supplements		
Livogen	53	24 %
Erythropeotin	75	33.7
Vintor	18	8.1%
Autrin	2	0.9%
Folvite	50	22.5%

Table 7: Calcium And Vitamin-D Supplements Prescribed For Study Population

Category	No Of Patients (N=226)	Percentage
Shelcal (Calcium carbonate+Vitamin-D)	95	80%
Rocaltrol(Calcitriol)	17	14.2%
Alpha D3(Alfacalcidol)	7	5.8 %

Table 8: Antibiotics Prescribed For Study Population

Antibiotics	No Of Patients (N=226)	Percentage
Tazine (Piperacillin+Tazobactum)	48	60.7%
Meromer (Meropenem)	8	10.1%
Imipenem	7	8.8%
Linezolid	1	1.2%
Ciprofloxacin	2	2.5%
Levofloxacin	2	2.5%
Moxifloxacin	2	2.5%
Cefixime	2	2.5%

Novamax (Amoxicillin)	5	6.3%
Cephalexin	2	2.5%

Table 9: Other Drugs Prescribed For Study Population

Category	No Of Patients (N=226)	Percentage
Statins		
Atorvastatin	18	20.9%
Rosuvastatin	10	11.6%
Telimisartan	2	2.3 %
Immunosuppressants		
Azathioprine	5	5.8%
Tacrolimus	4	4.6%
Everolimus	1	1.2%
Mycophenolate Mofetil	4	4.6%
Cyclosporine	1	1.2%
Corticosteroids		
Prednisolone	10	12%
Anti-Epileptics	8	9.3 %
Thyroid Drugs	7	8.1%
Anti-Tubercular Drugs	7	8.1%
Anti-Viral Drugs	4	4.6 %
Digoxin	4	4.6 %
Antifungals	1	1.1 %

Table 10: Drps Among The Study Population

INDICATION			SECURITY		
Need of additional treatment NIL UNNECESSARY TREATMENT			Adverse reaction	Total(N=226)	Percentage
Unnecessary treatment	No/ patients (n=226)	%		6)	
Treatment duplicity	5	2.2 %	Allergy	-	-
			Inappropriate Administration Method	-	-
			Side effects	-	-
			Contraindicated due to risk factors	-	-
			Interactions with drugs or food	91	40.2 %

	ADHERENCE		
	Non compliance	Total (N=226)	Percentage
Effectivity : Nil	Lack of adherence to recommendation	25	11.1 %
	Difficulties for administration	12	5.33 %
	Economic reasons	16	7.11 %
	Lack of understanding	33	14.66 %

Table 11 : Drugs Vs Drug Related Problems

	Mean \pm SD	P-Value
DRUGS	8.93+3.26	0.075 (NS)
DRPs	0.81+0.896	

P < 0.05 was considered significant

TABLE 12: Drug-drug interactions

Severity	No Of Patients (N=226)	Percentage
Severe	10	4.8 %
Moderate	79	34.9 %
Minor	2	0.88 %

DISCUSSION

In this study, patients diagnosed with Chronic kidney disease of all stages including renal transplant patients admitted in nephrology wards and patients on maintenance hemodialysis at dialysis unit of a tertiary care teaching hospital in South India, were included to assess the Drug related problems and to provide necessary interventions. Majority of patients in the study population belonged to the age range 41-60 years, which included 37 % females and 40 % males. A study conducted by Lesley A. Stevens et al.,¹² have also reported that chronic kidney disease was a substantial concern in the elderly population with an increasing incidence of treated kidney failure resulting in dialysis.

In this study, several co-morbidities were found among the study population, and the major co-morbid conditions included hypertension (45.2%), Diabetes mellitus (29.5 %) and Coronary artery disease (9.7%). This is concordant to the findings of the studies conducted by Lesley A. Stevens et al.,¹² and Dena E. Rifkin et al.,¹³ in which they have reported that the

high prevalence of CKD increased with rise in the risk of obesity, diabetes mellitus, cardiovascular disease and hypertension.

In the present study, the average number of drugs per prescription was found to be 8.93 ± 3.26 . This study also assessed the Drug related problems in each prescription using IASER methodology. A total number of 183 cases were found to have Drug related problems with an average of $0.81+0.896$ DRPs per prescription and the number of DRPs were found to be increasing with an increase in number of drugs per prescription. This is in accordance with the reports of the study conducted by Katie E. Cardone et al.,¹⁴ which stated that dialysis patients were prescribed an average of 12 medications and were at higher risk for Drug related problems. Another study conducted by Wendy L.St.Peter.,¹⁵ also reported that patients with chronic kidney disease on dialysis were prescribed an average of 10 -12 medications and their drug related problems continued to be in present in large numbers as the number of drugs prescribed increased.

The most frequent DRPs that were observed in this present study as per IASER methodology were Interactions with drugs or food under the classification of "Security" in 40.2% of patients, 38.2 % of noncompliance classified under "Adherence", 2.2% of unnecessary treatment which included treatment duplicity classified under "Indication". The non-compliance to therapy was due to lack of adherence to recommendation in 11.1% of patients and the main reason was found to be complex medication regimen, difficulties for administration was seen with erythropoietin in 5.33 %, economic reasons in 7.11% and lack of understanding to drug therapy in 14.66% was because of poor understanding about the need of drugs prescribed for them.

A study was conducted by Angeles Pardo Lopez et al.,¹⁶ using IASER methodology, to identify the DRPs in prescriptions of patients admitted in medical and surgical departments. In their study, they have identified a total of 2110 DRPs in 7711 patients with a mean DRP of 1.2 ± 0.5 . The DRPs identified by them were as follows: 34.5% had a DRP of the need for additional treatment in medical departments and 21.5% in surgical departments, 30.2% in medical and 14.3% in surgical departments had a DRP of unnecessary treatment under the classification of "Indication". In conclusion, 25.3% in medical and 4.8% in surgical departments had adverse reactions as DRPs classified under "Security" during their hospital stay and 0.9% in surgical and 0.6% in medical departments had non-compliance which was classified under "Adherence" after discharge and during follow up. The DRPs identified were

brought to the notice of physicians and the patients were educated on compliance to therapy to achieve better therapeutic outcomes.

The current study was the first to apply IASER methodology for identifying drug related problems in patients with chronic kidney disease and patients on hemodialysis, and it was found to be more effective and could be routinely used for the identification of DRPs in clinical practice. Monitoring the drug therapy for the occurrence of DRPs is a valuable way of preventing DRPs. This could be achieved by helping physicians and other health care providers to act and adjust drug regimens before adverse events arise and treatment failure occurs. A clinical pharmacist could be a part of the multidisciplinary health care team in screening for the incidence of DRPs and preventing their occurrence in patients with CKD who are subjects of polypharmacy, thus providing them better patient care.

CONCLUSION

The present study identified 81 % of DRPs using IASER methodology with an average of 0.81 ± 0.896 DRPs per prescription and the number of DRPs were found to be increasing with an increase in number of drugs per prescription. The common DRPs found in the study were Drug interactions (40.2 %) under the classification of security and Non-compliance under the classification of adherence (38.2 %) as per IASER methodology. The main reasons for non-compliance were found to be due to lack of adherence to recommendation, difficulties for administration, economic reasons and lack of understanding of therapy. Continual identification and resolution of drug related problems by using simple tools like IASER methodology can help to improve the health status and quality of life of these patients and a clinical pharmacist's participation in multidisciplinary health care team could play a vital role in achieving the better clinical outcomes.

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