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A PROSPECTIVE STUDY TO ASSESS THE DRUG USE PATTERN AND ADVERSE DRUG REACTIONS IN CHRONIC KIDNEY DISEASE PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Chronic Kidney Disease (CKD) represents a significant global health challenge, characterized by a progressive decline in renal function that necessitates complex pharmacological management. This prospective cross-sectional study, conducted over six months at a tertiary care hospital in Kerala, India, aimed to evaluate drug use patterns and the occurrence of adverse drug reactions (ADRs) among 80 hospitalized CKD patients. The study focused on clinical records and patient interviews for individuals with a creatinine clearance (CrCl) ≤ 59 ml/min. Analysis of 1,296 prescriptions revealed that cardiovascular drugs were the most frequently utilized therapeutic class (36.4%), followed by gastrointestinal agents (12.1%) and antibiotics (9.0%). Regarding safety profiles, the study identified multiple ADRs, which were predominantly gastrointestinal in nature, including symptoms such as constipation and loose stools. According to the WHO-UMC causality assessment scale, these reactions were categorized as "probable," indicating a likely relationship between the medication and the observed effect despite the underlying disease state. The study concludes that CKD patients are subject to heavy polypharmacy, particularly with cardiovascular and gastrointestinal treatments, which contributes to a notable incidence of adverse reactions. These findings emphasize the necessity for rigorous pharmacovigilance and the integration of clinical pharmacists into the care team to monitor drug therapy and minimize the risk of ADRs in this high-risk population.

KEYWORDS: Chronic kidney disease, Drug use pattern, Adverse drug reaction, Polypharmacy, Medication safety.

INTRODUCTION

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K/DOQI) definition of chronic kidney disease is the presence of kidney damage or a reduction in the glomerular filtration rate (GFR) for three months or longer.[1] Kidney plays a vital role in maintaining homeostasis, acid base balance and optimal electrolyte balance. It also plays an important role in disposition drugs and other toxic substances. Autoimmune disorder, diabetes mellitus and infections of various origin can alter normal kidney function.

Chronic Kidney Disease (CKD) presents a significant challenge in clinical pharmacology due to the progressive decline in renal function, which fundamentally alters the pharmacokinetic and pharmacodynamic profiles of numerous medications. As the kidneys are primary organs for drug elimination, patients with CKD are at a heightened risk for complications arising from complex therapeutic regimens. This study focuses on two critical components of pharmaceutical care in this population: drug utilization patterns and the incidence of adverse drug reactions (ADRs).

Drug use pattern analysis serves as a vital tool for evaluating the rationality of therapeutics in a hospital setting. In CKD patients, multimorbidity—including hypertension, diabetes, and mineral bone disorders—often necessitates polypharmacy. While these medications are essential for managing complications and slowing disease progression, the resulting complexity increases the potential for drug-drug interactions and inappropriate prescribing. Monitoring these patterns is essential to ensure that therapy aligns with established clinical guidelines and that dosages are precisely adjusted based on the patient's estimated glomerular filtration rate (eGFR) or creatinine clearance.

While medications offer essential therapeutic benefits, they can also cause Adverse Drug Reactions (ADRs) ranging from mild symptoms to severe outcomes like disability or death, necessitating medical interventions such as dosage adjustments or product withdrawal. Patients with Chronic Kidney Disease (CKD) are exceptionally vulnerable to these reactions because impaired renal filtration and secretion lead to the dangerous accumulation of drugs and metabolites in the bloodstream. Consequently, even standard therapeutic doses in CKD patients can result in heightened toxicity and systemic side effects, underscoring the critical need for precise pharmacological management in this population.

MATERIALS AND METHODS

The formula for sample size calculation,

$$N=\frac{(Z_{1-\frac{\alpha}{2}})^2\, p\, q}{E^2}$$

p is the estimated proportion of an attribute that is present in the population
q = 1-p
E is the acceptable margin of error
based on a previous study the prevalence was 44.44%.

Solution

Here p= 84/189= 0.44
q= 1-p= 1-0.44= 0.56
z= 1.96 (assuming 95% confidence level)
If we take at least 11 % precision, then E= 0.11.

$$N=\frac{z^2\, p\, q}{E^2}$$

$$N=\frac{1.96^2 \times 0.44 \times 0.56}{0.11^2}$$

= 78.22.

Anticipating loss to follow up and missing of data, the sample size is rounded to be 80.

This prospective cross-sectional study was conducted over a six-month period at a tertiary care hospital in Kerala, India, following approval from the Institutional Ethics Committee. The study included both male and female patients aged ≥18 years who were admitted as inpatients with Chronic Kidney Disease (CKD) in different departments of a tertiary care hospital. Patients with a creatinine clearance ≤59 ml/min/1.73 m² were considered eligible for inclusion. In addition, only patients who were receiving at least one medication that required dose adjustment and had available serum creatinine values during their hospital stay were included in the study.

Patients were excluded if they had End‑Stage Renal Disease (ESRD) and were on dialysis, or if they had Acute Kidney Injury (AKI) or rapidly changing renal function. Patients with incomplete medical records were also excluded from the study. Furthermore, pregnant or breastfeeding women were not included in the study population and informed written consent obtained from all participants. Data collection involved a comprehensive review of patient case records to gather socio-demographic details, clinical diagnoses, and laboratory parameters, such as serum creatinine, using a structured data collection form. To evaluate drug use patterns, all medications prescribed during the hospital stay were recorded and categorized according to their therapeutic classes. Concurrently, adverse drug reactions (ADRs) were identified through direct clinical observation, patient interviews, and medical record reviews. The identified ADRs were further evaluated for causality using the WHO-UMC causality assessment scale to determine the relationship between the suspected drugs and the observed clinical events. All gathered information regarding medication trends and adverse events was subsequently compiled and organized into descriptive tables to characterize the pharmacological profile of the study population.

RESULT AND DISCUSSION

A total of 80 patients who met with the inclusion and exclusion criteria were enrolled in the study.

SOCIO DEMOGRAPHICS AND CLINICAL DATA OF PATIENTS

GENDER DISTRIBUTION

Table 1: Distribution of CKD patients based on gender.
N=80

Sex	Number (n)	Percentage (%)
Male	42	52.5
Female	38	47.5

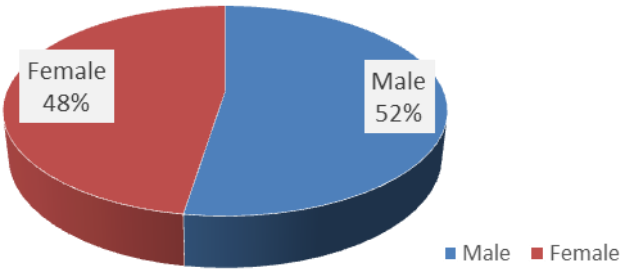

Fig 1: Distribution of CKD patients based on gender.

INFERENCE: This chart shows the distribution of CKD patients, with a higher percentage observed in males (52.5%). CKD is more prevalent in men, potentially due to both hormonal influences and lifestyle pattern. This may be due to the negative effects of testosterone on kidney function, while estrogen in females appears to have protective effect in kidney, at least until menopause. This was in accordance with the study conducted by Kiran A Kantanavar et al.,[2] where the male prevalance is more compared to female.

AGE DISTRIBUTION

Table 2: Distribution of CKD patients based on age.
N=80.

AGE IN YEARS	Number (n)	Percentage (%)
50-59	6	7.5
≥60	74	92.5

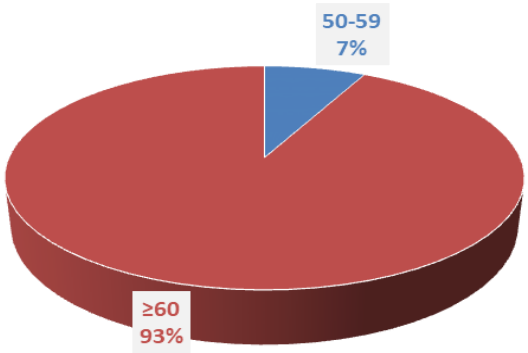

Fig 2: Distribution of CKD patients based on age.

INFERENCE: This chart shows the distribution of CKD patients across age brackets. It highlights the prevalence of CKD in older age group, ≥60 (92.5%). This is primarily due to age related structural and functional changes in the kidneys. Additionally, elderly individuals are more likely to have multiple comorbid conditions such as hypertension, diabetes and cardiovascular diseases which further contribute to the development of CKD. This finding was in accordance with the study conducted by M. Kassa Birarra et al.,[3] where a larger proportion of study participants were from ≥ 60 age group.

CKD STAGES

Table 3: Distribution of patients based on CKD stages.
N=80

CKD Stages	Number (n)	Percentage (%)
Stage 3	15	18.7
Stage 4	39	48.7
Stage 5	26	32.5

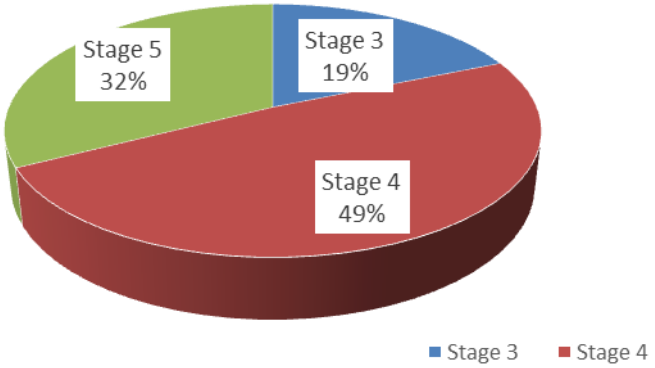

Fig 3: Distribution of patients based on CKD stages.

INFERENCE: This data shows that most patients were in stage 4 CKD, accounting for nearly half (48.7%) of the study population. This suggest that majority of the patients were in the advanced stage before end stage renal disease (ESRD). Stage 5 was also significantly represented (32.5%), indicating a high burden of severe kidney dysfunction in the study group followed by stage 3. This distribution shows that late stage CKD (stage 4 & 5) forms the majority (81.2%) of the patient population, emphazing the importance of early detection, monitoring and intervention to prevent progression. This findings coincide with previous study conducted by Zair Hassan et al.,[4] where a majority of patients were from stage 4 & 5.

COMORBIDITIES OBSERVED IN STUDY POPULATION

Table 4: Distribution of comorbidities in the CKD patients.

N=80

Comorbidities	Number (n)	Percentage (%)
Present	80	100
Absent	0	0

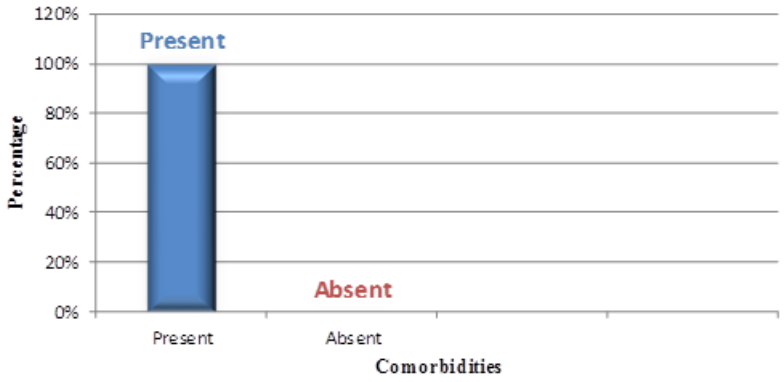

Fig. 4: Distribution based on comorbidities in the CKD patients.

INFERENCE: This data highlights that comorbidities were present in all the study subjects. This is because various comorbidities contribute to the development and progression of CKD due to their direct and indirect effects on kidney function.

Table 5: Details of Comorbidities observed in study population.

N=80

SI NO	COMORBIDITY	FREQUENCY (n)	PERCENTAGE(%)
1	Type 2 Diabetes mellitus	70	87.5
2	Hypertension	66	82.5

3	CAD	32	40
4	DLP	16	20
5	CVA	11	13.75
6	Hypothyroidism	9	11.25
7	BPH	8	10
8	Psychiatric illness	7	8.75
9	COPD	6	7.5
10	Hyperkalemia	5	6.25
11	Asthma	4	5
12	Anaemia	3	3.75
13	CLD	2	2.5
14	UTI	2	2.5
15	LRTI	2	2.5
16	Others	11	13.75

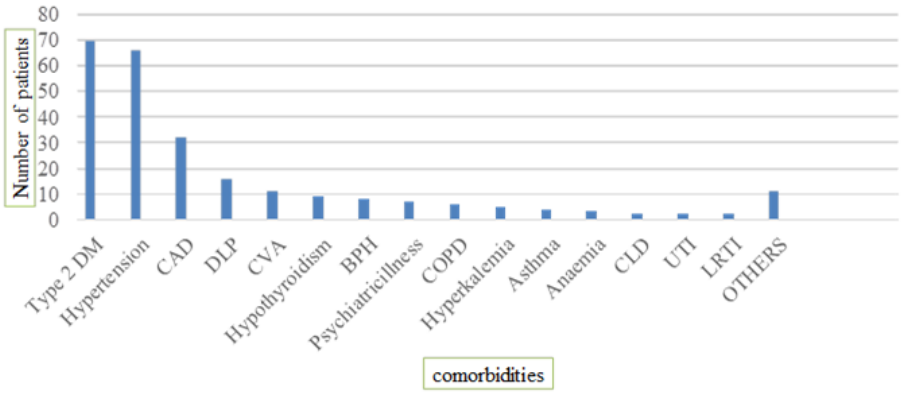

Fig 5: Different comorbidities observed in the study population.

INFERENCE: In this study, Type 2 DM affects 87.5% patients, as high blood sugar level can damage the blood vessels in the kidneys, affecting their ability to filter waste, which can lead to CKD .82.5%of patients had hypertension as a comorbidity, likely due to damaged kidneys not filtering blood effectively leading to fluid retention and increased blood pressure. CAD was experienced by 40% of patients as the presence of CAD often reflects widespread vascular damage, which also affects the kidneys blood vessels, leading to reduced kidney function. This finding was in accordance with the study conducted by Zair Hassan et al.,[4] where comorbidities were found in most of the patients with hypertension and DM at the top list.

DRUG USE PATTERN IN CKD PATIENTS

Table 6: Distribution of drugs prescribed in CKD patients.

N=80

SI NO	DRUG CLASS	FREQUENCY (n=1296)
1	CV DRUGS	472
2	GI DRUGS	157
3	ANTIBIOTICS	117

4	ANTIDIABETIC DRUGS	113
5	DRUGS FOR RESPIRATORY SYSTEM	79
6	DRUGS FOR NERVOUS SYSTEM	72
7	VITAMINS AND MINERALS	72
8	NSAIDs & ANALGESICS	70
9	CORTICOSTEROIDS	41
10	LAXATIVES	21
11	ANTIHISTAMINES	20
12	THYROID DRUGS	13
13	ANTIVIRALS	3
14	ANTIFUNGALS	2
15	OTHERS	44

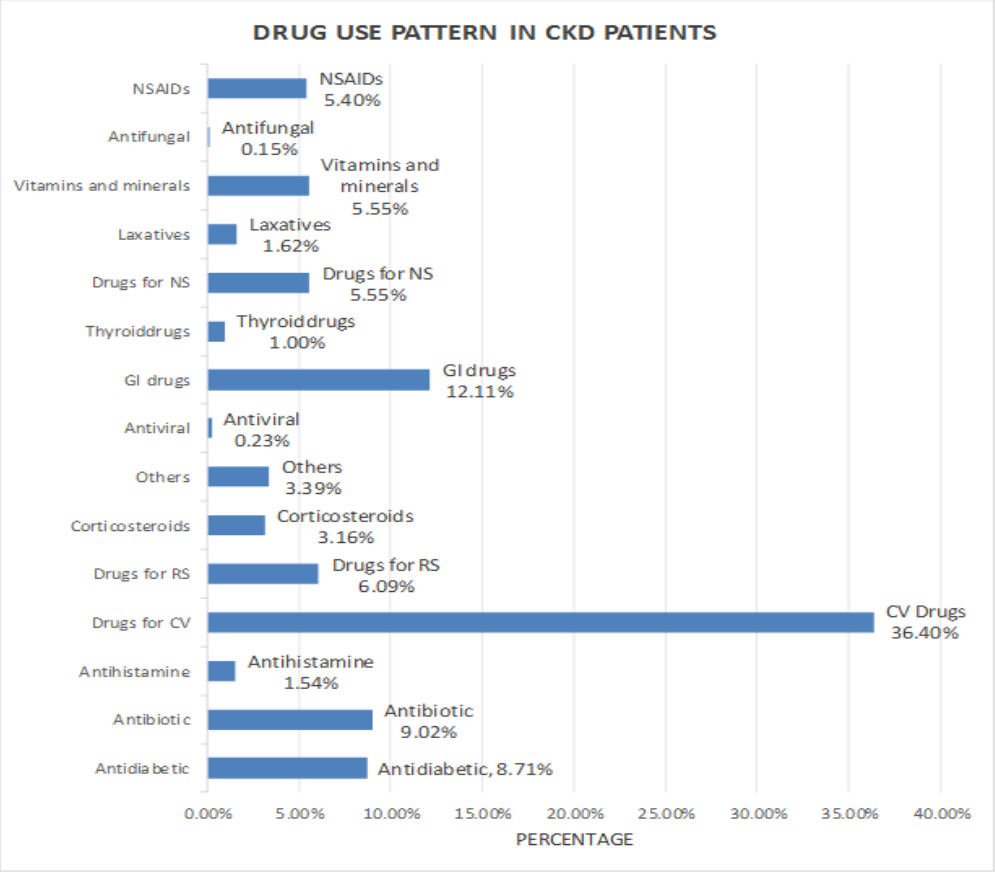

Fig 6: Drug use pattern in CKD patients.

INFERENCE: Out of different medications prescribed to the patients, CV drugs (472, 36.4%) were the most commonly prescribed class of drug followed by gastrointestinal drugs (157, 12.11%), antibiotics (117,9.02%), anti-diabetics (113,8.71%), drugs for respiratory system (79, 6.09%), drugs for nervous system (72, 5.55%). This is because CKD patients are highly prone to cardiovascular complications such as hypertension, heart failure and fluid overload necessitating CV drug use. This result was similar to the study conducted by C.S. Shastri et al.,[5] where CV drugs were the most commonly prescribed class of drug.

Table 7: Distribution of CV drugs prescribed in CKD patients.
N=80

Cardiovascular Drugs (n=472, 36.4%)	
Drug	**Frequency**
Atorvastatin	48
Cilnidipine	48
Aspirin	45
Clopidogrel	32
Furosemide	30
Torsemide	27
Clonidine	21
Tolvaptan	19
Prazosin	17
Tranexamic acid	17
Rosuvastatin	16
Metoprolol	15
Nifedipine	14
Telmisartan	11
Heparin	11
Nebivolol	10
Moxonidine	9
Carvedilol	8
Dihydralazine	8
Isosorbide dinitrate	8
Lignocaine	8
Nicorandil	5
Amiodarone	4
Enoxaparin	4
Mannitol	4
Metolazone	4
Others	27

Table 8: Distribution of GI drugs prescribed in CKD patients.
N=80

Gastrointestinal Drugs (n=157, 12.11%)	
Drug	**Frequency**
Sodium bicarbonate	46
Pantoprazole	41

Esomeprazole	38
Ondansetron	20
Rabeprazole	3
Ranitidine	3
Domperidone	2
Others	3

Table 9: Distribution of Antibiotics prescribed in CKD patients.
N=80

Antibiotics (n=117, 9.02%)	
Drug	**Frequency**
Cefoperazone + sulbactam	38
Piperacillin + tazobactam	24
Meropenam	18
Linezolid	7
Ceftriaxone	6
Clindamycin	4
Metronidazole	3
Clarithromycin	3
Rifaximin	3
Levofloxacin	2
Imipenem	2
Others	7

Table 10: Distribution of Antidiabetic drugs prescribed in CKD patients.
N=80

Antidiabetic Drugs (n=113, 8.71%)	
Drug	**Frequency**
Insulin	33
Glimepiride	21
Metformin	13
Linagliptin	12
Teneligliptin	9
Gliclazide	7
Rapaglinide	6
Vildagliptin	6
Others	6

Table 11: Distribution of drugs used for Respiratory system in CKD patients.
N=80

Drugs For Respiratory System (n= 79,6.09%)	
Drug	**Frequency**
Salbutamol	28
Ipratropium bromide	21
Acebrophylline	11
Acetylcysteine	10
Levodropropizine	6
Xylometazoline	2
Orciprenaline	1

Table 12: Distribution of drugs for Nervous system in CKD patients.
N=80

Drugs For Nervous System (n=72, 5.55%)	
Drug	**Frequency**
Levetiracetam	8
Gabapentin	6
Pregabalin	6
Citicoline	4
Donepezil	4
Midazolam	4
Quetiapine	5
Amitriptyline	3
Nortriptyline	3
Clonazepam	3
Lacosamide	3
Others	23

Table 13: Distribution of Vitamins and Minerals in CKD patients.
N=80

Vitamins And Minerals (n=72 ,5.55%)	
Drug	**Frequency**
Calcium supplement	16
Ferrous ascorbate + Folic acid	16
Vitamin D3	12
Zincovit	9
Thiamine	5
Methyl cobalamin	5
Trypsin + Chymotrypsin	4
Vitamin E + Levocarnitine	3
Vitamin K	2

Table 14: Distribution of NSAIDs and Analgesics in CKD patients.
N=80

NSAIDs And Analgesics (n=70, 5.40%)	
Drug	**Frequency**
Paracetamol	47
Tramadol	18
Others	5

Table 15: Distribution of Corticosteroids in CKD patients.
N=80

Corticosteroids (n=41, 3.16%)	
Drug	**Frequency**
Methylprednisolone	12
Budesonide	12
Hydrocortisone	11
Dexamethasone	3
Fluticasone	2
Deflazacort	1

Table 16: Distribution of laxatives in CKD patients
N=80

Laxatives (n=21 ,1.62 %)	
Drug	**Frequency**
Bisacodyl	8
Lactulose	6
Lactitol monohydrate	3
Liquid paraffin + milk of magnesia	3
Sodium picosulfate	1

Table 17: Distribution of Antihistamines prescribed in CKD patients
N=80

Antihistamine (n=20 , 1.54%)	
Drug	**Frequency**
Chlorpheniramine maleate	7
Bilastine	4
Levocetirizine	3
Montelukast	3
Cinnarizine	2
Dimenhydrinate	1

Table 18: Distribution of Thyroid drugs prescribed in CKD patients.
N=80

Thyroid medication (n=13, 1.0%)	
Drug	**Frequency**
Thyroxine sodium	13

Table 19: Distribution of Antiviral drugs prescribed in CKD patients.
N=80

Antiviral Drugs (n=3, 0.23%)	
Drug	**Frequency**
Oseltamivir	2
Valacyclovir	1

Table 20: Distribution of Antifungal drugs prescribed in CKD patients.
N=80

Anti Fungal Drugs (n=2, 0.15%)	
Drug	**Frequency**
Fluconazole	1
Itraconazole	1
Others (n=44 ,3.39 %)	
Others	44

INFERNECE: These data represents the distribution and frequency of various drug classes prescribed to CKD patients, revealing significant polypharmacy. Out of CV drugs (36.4%) the most commonly prescribed were Atorvastatin and Cilnidipine followed by Sodium bicarbonate among GI drugs (12.11%), Insulin and Glimepiride among antidiabetic drugs (8.71%).

ADR ASSOCIATED WITH DRUG USE

Table 21: Distribution of ADR associated with drug use in CKD patients.
N=80

Sl No	Suspected Drug	Total No Of Drugs Prescribed	No Of Drugs Ca used Adr	Reaction	Causality
1	Ferrous ascorbat e + Folic acid	16	5	Abdominal discomfort & Constipation	5 (Probable)
2	Cefoperazone + Sulbactam	38	2	Constipation	5(Probable)
3	Cefuroxime + Sulbactam	1	1	Constipation	5(Probable)
4	Pantoprazole	41	1	Loose stools	5(Probable)
5	Tolvaptan	19	1	Constipation	5(Probable)
6	Insulin	33	5	Hypoglycemia	7(Probable)
7	Tramadol	18	3	Constipation	6(Probable)

INFERENCE: This table lists 7 drugs or combinations that caused ADR in the CKD patients. Causality of ADRs were evaluated using WHO-UMC criteria. Constipation was the most frequent ADR reported, associated with multiple drugs. Other ADRs include abdominal discomfort, loose stools and hypoglycemia.

All ADRs were assessed as probable. The presence of ADR in commonly prescribed medication emphasizes the need for careful monitoring in CKD patients, who may be more vulnerable due to impaired drug excretion. Constipation being recurrent suggest that GI effects are particularly relevant in this population and should be managed proactively.

CONCLUSION

This prospective study explores the complexities of managing pharmacotherapy in Chronic Kidney Disease (CKD) patients, whose impaired renal function necessitates precise medication management to avoid toxicity. By examining prescribing patterns and the incidence of adverse drug reactions in a hospital setting, the research aims to identify critical areas for improving patient safety and clinical outcomes.

The research concludes that cardiovascular drugs are the most frequently prescribed class in Chronic Kidney Disease (CKD) patients (36.4%), followed by gastrointestinal agents (12.11%), antibiotics (9.02%), and antidiabetic drugs (8.71%). Adverse drug reactions (ADRs) were identified, with constipation being the most frequent, alongside abdominal discomfort, loose stools, and hypoglycemia; notably, all ADRs were evaluated as "probable" based on WHO-UMC causality criteria. The study underscores the necessity for systematic renal function evaluation during hospitalization and advocates for the active involvement of clinical pharmacists and the use of electronic decision-support systems to reduce medication-related risks in this vulnerable, often poly-medicated demographic.

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