International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 9, September 2024 **ijppr.humanjournals.com** ISSN: 2349-7203

The Impact of Pharmaceutical Care Intervention in Preventing Drug Related Problems in Renal Disorder Patients - A Randomized Controlled Trial

Kannan Subramaniam*, Agnes Kanimozhi A[1], Aishvariya D.A[2], Dhananjayan M[3], Anandhasayanam A[4], Sangameswaran B[5]

*Professor & HOD Department of Pharmacy Practice, SSM College of Pharmacy,

[1,2,3]PharmD Research Scholars, SSM College of Pharmacy,

[4]Professor, Department of Pharmacy Practice, SSM College of Pharmacy,

[5]Principal, SSM College of Pharmacy,

The Dr. M.G.R Medical University, India.

Received: 2024-09-03 Revised: 2024-09-11 Accepted: 2024-09-15

ABSTRACT

Objectives: The inappropriate use of medications is harmful and is a common issue in hospitalized patients. Patients hospitalized in urology and nephrology department are usually at high risk for drug- related problems (DRPs). This randomized controlled trial aimed to explore the value of a pharmaceutical care service conducted in renal disorder patients in the identification and reduction of DRPs in comparison with standard medical care. **Methods:** The Randomized Control Trial was conducted in Nephrology and Urology department of Sudha Hospital Erode, A specialized data collection form was designed for collecting the patient details. The patients were randomly categorized into intervention and control group. PCNE classification 9.0V was used for categorizing problems and causes of DRPs. **Results:** Patients in the intervention group (n=109) and the control group (n=109) had a mean age of 51.3±14.8 years, with 61.47% being male and 38.53% being female. A total of 110 DRPs were identified (intervention group=54.45%; control group=44.54%; p=0.25). The commonly identified DRPs included unnecessary drug treatment (In: 31.14%; C: 40.82%), untreated indication (In: 26.3%; C: 24.49%), treatment safety problem (In: 8.2%; C: 6.12%). The acceptance rate for pharmacists' recommendations by physicians was 62.3% in intervention group. The value of pharmaceutical care was significantly reflected in the achievement of the therapeutic outcomes 39.34% of the DRPs were completely solved, 14.75% were partially solved, 27.87% were not solved in the intervention group compared with the control group. **Conclusion:** This study shows that DRPs are common among renal disorder patients in India as multi-drugs are involved in the treatment. Patients in the intervention group experienced fewer DRPs and better medication-related outcomes compared to those in the control group, who did not receive such intervention. Adding a clinical pharmacist in urology and nephrology department has provided a significant impact in preventing DRPs and improving outcome of intervention provided.

Key words: DRPs, PCNE classification, renal patients, pharmacist intervention.

INTRODUCTION

Kidney disease and urinary Tract disorders are increasing globally and rising faster in developing countries. Global disease burden estimates suggest that kidney and urinary tract diseases result in around 830,000 deaths and 18,467,000 disability-adjusted life years each year, making them a significant health concern ranking them 12th among causes of death (1.4%) and 17th among causes of disability (1.0 %) [1].Pharmacotherapy is an essential strategy for treating renal disorders, and often involves multiple medications being used simultaneously and also impaired kidney function can change the pharmacokinetics and pharmacodynamics of a drug that is largely removed by renal excretory systems. This results in the accumulation of toxic levels of the drug or its metabolites [2,3] which might lead to drug-related problems (DRPs).

According to Pharmaceutical Care Network Europe (PCNE), a DRP is "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes" [4]. Several classification systems of DRP have emerged, among them the Pharmaceutical Care Network (PCNE), which has been the most widely used internationally in hospital clinical practice [5]. According to PCNE DRP that is detected can be classified as potential (if they have the prospect of causing harm) and manifest (if they did cause harm to the patient) [6].

The fundamental role of clinical pharmacists is to deliver pharmaceutical care. During their routine practice, Early detection and prevention of DRPs among patients with kidney dysfunction in developed countries has been made possible by the incorporation of clinical pharmacy services and the application of evidence-based guidelines [7, 8]. Clinical pharmacists' impact on reducing DRPs rates at the patient level has been extensively studied in developed countries. In India, there are very few studies showing the value of clinical Pharmacist recommendations [9].

This study aims to provide a comprehensive analysis of the impact of pharmaceutical care interventions in reducing DRPs among renal disorder patients. By examining current practices and evaluating the effectiveness of various intervention strategies, the study seeks to offer practical recommendations for healthcare providers to enhance patient care and safety in this vulnerable population.

MATERIALS AND METHODS

It was a Randomized Controlled study which was conducted at multispecialty hospital in Erode.

The duration of the study was six months and conducted between February 2024 to July 2024.

Study Site: Sudha Institute of Medical Science, Erode (SIMS) which is a 300 bedded multi-specialty hospital at Erode. Approximately about 35 patients are admitted in Urology and Nephrology department each month. Urology and Nephrology unit at SIMS offers specialized care focused on kidney and urinary health. Equipped with advanced technology, the unit provides comprehensive services from urology and nephrology diagnostics to complex treatments.

Inclusion criteria: Patients ≥ 18 years old with primary urological and Nephrological conditions.

like CKD, renal failure, UTI, nephritic syndrome, renal calculi, ureteric calculus, PUJ obstruction. Extended hospital stays for > 24 hours 24 hours for adequate data collection who were able to provide informed consent.

Exclusion criteria: Patients with advanced malignancies, uncontrolled diabetes, severe cardiovascular diseases, active infections or history of organ transplantation affecting kidney function and patients with severe mental or cognitive impairment, pregnant and lactating women. The study was conducted after obtaining permission from the Sudha Institute of Ethical Committee, Erode, Tamil Nadu (Ref. no: ECR/948/Inst/TN/2018/RR-22).

Study Method: A specialized data collection form was designed for collecting the patient details. The patients were randomly categorized into intervention and control group. PCNE classification 9.0V was used for categorizing problems and causes of DRPs. Interventions were provided only to the intervention group and the acceptance rate was evaluated. The obtained outcome was compared between intervention and control group.

Statistical Analysis: The data obtained was entered into MS Excel. Descriptive Statistics can be used to describe the data. Categorical variables - Frequencies and percentages, Continuous variables – Mean, standard deviation (to summarize the data) Chi-square test was performed to compare the impact of patient care between intervention and control group.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
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RESULT AND OBSERVATION

Table 1: Baseline Patient Demographics:

Patient demographics	Intervention (n=109)	Control (n=109)	p- value
AGE			
male	72	62	0.89
female	37	47	0.034
GENDER			
male	72	62	0.314
female	37	47	
NO. of COMORBIDITIES			
0	47	53	0.548
1	38	34	
2	20	15	
3	4	7	
DIGNOSIS			
Ureteric calculus	34	27	0.144
Renal Calculus	18	33	
VUJ Calculus	9	4	
PUJ Calculus	4	1	
CKD	7	11	
Renal Failure	4	2	
UTI	17	12	
Urosepsis	4	7	
Pyelonephritis	12	12	
NO. of DRPs			
Present	61	49	0.25
Absent	48	60	

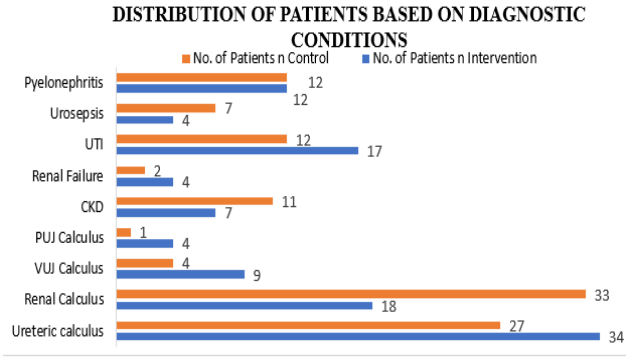

Figure 2: Distribution of Patients Based on Diagnostic Condition

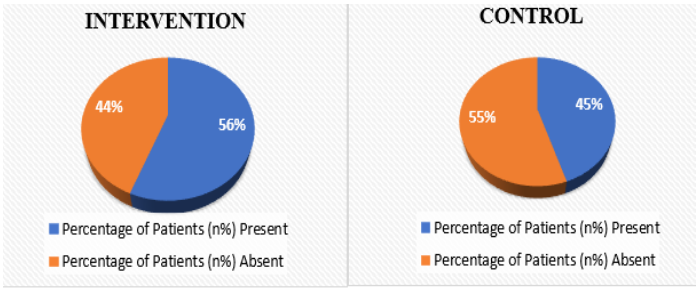

Figure 3: Distribution of DRP According to PCNE

Table 2: Number of drugs prescribed:

No. of drugs prescribed	Intervention	Control	p - value
3	5	1	0.00005
4	15	7	
5	15	16	
6	17	24	
7	16	21	
8	20	14	
9	6	12	
10	3	5	
11	4	2	
12	1	1	
13	2	1	
14	1	1	
15	0	1	
16	0	2	
17	2	0	
18	1	1	
19	0	0	
20	1	0	

Table 3: PCNE classification for DRPs:

PCNE Classification	Intervention (n=61) n(n%)	Control (n=49) n(n%)	p - value
PROBLEM DOMAIN			
P1: Treatment effectiveness	31 (50.82)	24 (48.98%)	0.8708
P2: Treatment Safety	5 (8.2)	3 (6.12%)	
P3: Others	25 (40.98)	22 (44.9%)	
CAUSE OF DRP			
C1: Drug selection	29 (47.54)	33 (67.35)	0.317
C2: Drug form	1 (1.64)	0	
C3: Dose selection	9 (14.75)	18 (36.73)	
C4: Treatment duration	3 (4.92)	4 (8.16)	
C5: Dispensing	6 (9.84)	4 (8.16)	
C6: Drug use process	6 (9.84)	7 (14.29)	
C7: Patient related	40 (68.85)	31 (63.27)	
C8: Patient transfer related	2 (3.28)	0	
C9: Others	8 (13.11)	4 (8.16)	
PLANNED INTERVENTION			
I0: No intervention	0	49 (100)	<0.001
I1: At prescriber level	48 (78.69)	0	
I2: At patient level	15 (24.59)	0	
I3: At drug level	13 (21.31)	0	
I4: Other intervention or activity	4 (6.56)	0	
ACCEPTANCE OF INTERVENTION			
A1: Intervention accepted	38 (62.3)	0	<0.001
A2: Intervention not accepted	15 (24.59)	0	
A3: Others	8 (13.11)	49 (100)	
OUTCOME			
O0: Not known	11 (18.03)	0	<0.001
O1: Solved	24 (39.34)	0	
O2: Partially solved	9 (14.75)	0	
O3: Not solved	17 (27.87)	49 (100)	

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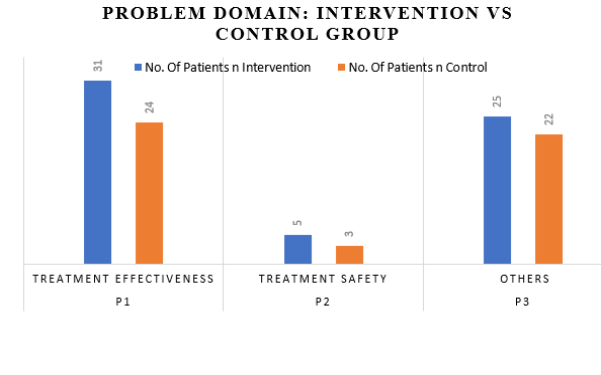

Figure 4: Problem Domain: Intervention vs Control Group

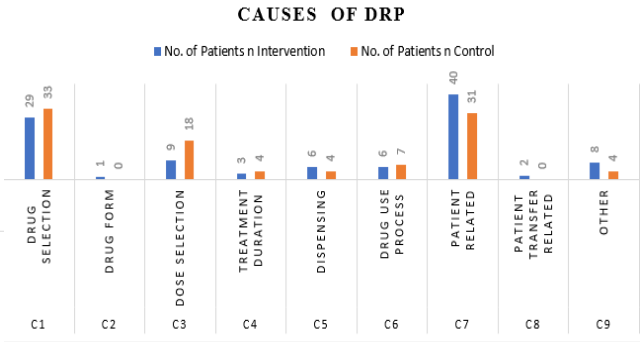

Figure 5: Causes of DRP

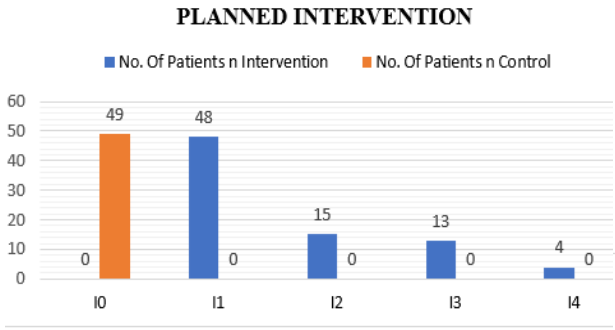

Figure 6: The Planned Intervention:

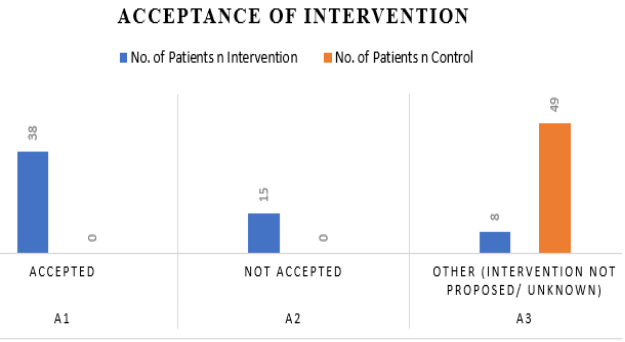

Figure 7: Acceptance of Intervention

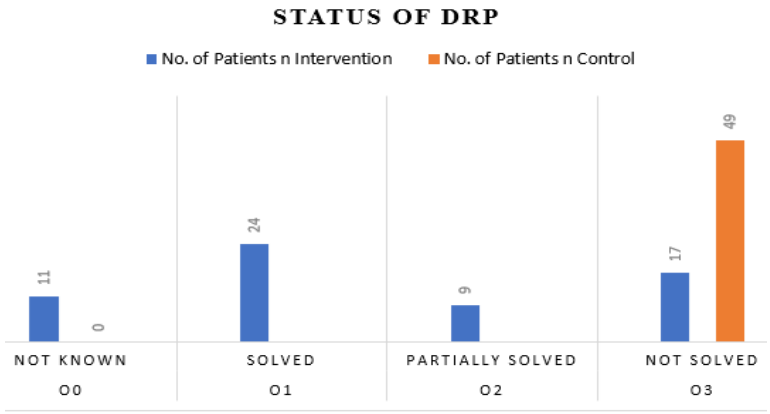

Figure 8: Outcome of Intervention:

DISCUSSION

To the best of our knowledge, it is the first Randomized Controlled Trial conducted in India to categorically evaluate DRPs using PCNE classification, and to identify factors associated with the occurrence of DRPs in the urology and nephrology unit of a tertiary care hospital in India. It is one of the few comparative studies conducted on renal patients.

In our study total of 218 patients with the average age of 51.3±14.8 (51±15 in intervention group and 51.7±14.57 in control group, table 1) who fulfilled the inclusion criteria were evaluated for DRP (109 in the intervention group and 109 in the control group). The study population constituted 61.47% male (Intervention group: n=72 and control group n=62) and 38.53% female patients (Intervention group: n=37 and control group: n=47). The demographic and clinical characteristics were similar in both groups, with no statistically significant differences shown (p>0.05, table 1). Salah AbuRuz *et.al* conducted a similar randomized controlled trial with the patients admitted in the surgical ward in which the patients in the intervention group (n=63) and the control group (n=60) had a mean age of 55±14.4 years, with 52.0% being women [10].

Most of the patients in both the study groups i.e., intervention and control group suffered from other comorbid conditions including hypertension, type 2 diabetes mellitus, renal calculi, coronary artery disease (Table 1). Patients with zero comorbidities were found to be 43.12% in intervention group and 43.12% in control group. Patients with one and two comorbidities were found to be 34.86% and 18.35% in intervention group and 31.2% and 13.76% in control group. Interestingly for patients with three comorbidities the control group (6.42%) has almost double the percentage of patients compared to the intervention group. The number of comorbidities were similar in both groups, with no statistically significant differences shown ($p>0.05$, table 1).

Most of the study population was diagnosed with ureteric calculus prevalence was higher in intervention group (31.19%) than in control (24.77%), followed by renal calculus (Intervention= 16.51%, Control= 30.28%), UTI (Intervention= 15%, Control=11.01%), pyelonephritis equal in both the groups (11.01%), CKD (Intervention= 6.42%, Control=10.09%), VUJ calculus (Intervention= 8.26%, Control=3.67%), Urosepsis (In= 3.67%, C= 6.42%), Renal failure (Intervention= 3.67, Control= 1.83) and PUJ obstruction (Intervention= 3.67, Control= 0.92) (Figure: 2). The diagnostic conditions were similar in both groups, with no statistically significant differences shown ($p>0.05$, table 1).

The occurrence of DRP increased in patients prescribed with drugs greater than 5 ($n \geq 5$). The large number of identified drug-related problems can be partly attributed to the high quantity of medications the patients are using. Since patient with renal disorder particularly CKD patients are usually prescribed with a greater number of drugs, there is more possibility of occurrence of DRPs. In a recently released meta-analysis study conducted by Alruqayp WS *et.al* that solely looked at CKD patients who were hospitalized, the prevalence of DRP was found to be between 12 and 77% [11].

The problems identified were categorized into three types. Majority of the problem was due to unnecessary drug treatment (Intervention: 31.14%; Control: 40.82%) followed by untreated indication (In: 26.3%; C: 24.49%), treatment safety problem (Intervention: 8.2%; Control: 6.12%) (Table 3). In a prospective observational study conducted by Julius Kyomya *et.al.*, the most common DRPs were 'Untreated symptoms or indication' (35.6%) followed by 'adverse event (possibly) occurring' (28.3%), and 'effect of drug treatment not optimal' (23.3%) [12]. The type of DRPs were similar in both groups, with no statistically significant differences shown ($p>0.05$, table 3) (Figure: 4).

The major causes of DRPs identified in our study were patient related (Intervention: 65.57%; Control: 63.27%), drug selection related (Intervention: 47.54%; Control: 67.35%), dose selection related (Intervention: 14.75%; Control: 36.73%), inappropriate outcome monitoring (Intervention: 13.11%; Control: 8.16%), drug use process (Intervention: 9.84%; Control: 14.29%), dispensing process related (Intervention: 9.84%; Control: 8.12%), inappropriate treatment duration (Intervention: 4.92%; Control: 8.16%), patient transfer related (Intervention: 3.28%), drug form related (In: 1.64%). The causes of DRPs were similar in both groups, with no statistically significant differences shown ($p>0.05$) (Table 3) (Figure: 5).

Intervention was planned only to the intervention group and no intervention in control group which creates a significant difference. The intervention planned were categorized into three levels: at prescriber level (60%), at patient level (18.75%), at drug level (16.25%) and other interventions planned constituted 5%. In a different retrospective study conducted by Althomali A *et.al.*, among all the interventions made, the majority were suggested regarding 'indication' (45.7%), including the addition of drugs, drugs with no indications, and duplication [13] (Table 3) (Figure: 6).

The 62.3% interventions were accepted by the physician, 24.59% were not accepted and the acceptance rate is unknown in 13.11% (Table 3) (Figure: 7). The acceptance rate was different in both groups, with statistically significant differences shown ($p<0.0001$, table 3) since no intervention is provided in intervention group. In a different study by Garedow *et.al.*,[14]81.6% and Pehlivanli *et.al.*,[15] 91.7% of interventions were accepted which is comparatively higher than our study. This might be due the lack of knowledge regarding the importance of Pharmacist intervention and its effect on preventing DRPs.

The outcome obtained in our study after providing intervention to the intervention group (Table 3) were found that, 39.34% of the DRPs were completely solved, 14.75% were partially solved, 27.87% were not solved and outcome status of 18.03% was not known in intervention group (Table 3) (Figure: 8). The DRPs in control groups were not solved as no intervention was provided. The patient in intervention group had better therapeutic outcome and reduced number of stay in hospital when compared to the control group. The outcome was different in both groups, with statistically significant differences shown ($p<0.0001$, table 3).

Taking into consideration the global scenarios the importance of pharmaceutical care intervention is increasing in the developing countries like India. The decision-making and their level of involvement had shown interesting results that potentially optimize the betterment of patient care [16]. Prospective interventional study conducted by Pehlivanli *et.al.*, finding implies that drug-related problems could have a negative impact on the efficacy and safety of the treatment as well as be a factor that raises the cost of care by extending the patient's stay in the hospital. This may indicate implementation of clinical pharmacy services in the nephrology ward has a great impact on optimized therapy and preventing DRPs thereby reducing the unnecessary cost sent by the patient on

treatment [17]. Our study added to the literature supporting previous studies related to DRPs in renal dysfunction patients and supporting the important role of clinical pharmacists in the provision of pharmaceutical care.

CONCLUSION

This study shows that DRPs are common among renal disorder patients in India as multi-drugs are involved in the treatment. The current study identified that 50.46% patients experienced DRPs. The most commonly identified DRPs were related to unnecessary drug treatment, untreated indication, treatment safety. The major cause of DRPs was related to patient factor, drug selection, dosage selection and inappropriate outcome monitoring. The comparative analysis between the intervention and control groups demonstrated that pharmaceutical care interventions had a significant positive impact. Patients in the intervention group experienced fewer DRPs and better medication-related outcomes compared to those in the control group, who did not receive such intervention. Adding a clinical pharmacist in urology and nephrology department has provided a significant impact in preventing DRPs and improving outcome of intervention provided.

Acknowledgment:

Firstly, I'd like to express my thanks to Dr. K Sudhakar, Managing Director, Sudha Hospitals continuous support of this research work. My sincere thanks also go to Professor Dr. Anandhasayanam A helped me in all the time of research ideas and guidance.

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How to cite this article:
Kannan Subramaniam et al. Ijppr.Human, 2024; Vol. 30 (9): 90-98.

Conflict of Interest Statement: All authors have nothing else to disclose.

	Kannan Subramaniam Professor & HOD Department of Pharmacy Practice, SSM College of Pharmacy
	Agnes Kanimozhi A Pharm D Research Scholar SSM College of Pharmacy
	Aishvariya D.A Pharm D Research Scholar SSM College of Pharmacy
	Dhananjayan M Pharm D Research Scholar SSM College of Pharmacy
	**Anandhasayanam A** Professor Department of Pharmacy Practice SSM College of Pharmacy

Sangameswaran B
Principal
SSM College of Pharmacy,