

EVALUATING THE IMPACT OF CLINICAL PHARMACISTS ON MEDICATION RECONCILIATION AND QUALITY OF LIFE IN CKD PATIENTS: A CROSS-SECTIONAL OBSERVATIONAL STUDY

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ABSTRACT

Context: Chronic kidney disease (CKD) is associated with high medication burden, renal dose-adjustment requirements, drug-related problems and reduced quality of life. Pharmacist-led medication reconciliation may identify discrepancies and support safer nephrology care.

Aim: To evaluate the role of pharmacists in identifying medication discrepancies and to examine the relationship between medication burden, adherence and quality of life among CKD patients.

Settings and Design: A cross-sectional observational was prepared for adult CKD stage 3-5 patients in a secondary care hospital setting. 106 patients were enrolled in this study.

Materials and Methods: Eligible patients were adults aged 18 years or above with CKD stage 3-5 receiving at least two chronic medicines. Medication history, current prescription, clinical variables, CKD stage, dialysis status, comorbidities, medication discrepancies, KDQOL-36 domain scores and MMAS-based adherence categories were documented. Medication discrepancies were classified as omission, commission, duplication, dose error, renal dose issue, drug-drug interaction, documentation error and adverse drug reaction.

Statistical Analysis: Descriptive statistics, chi-square tests, Welch t-test, one-way ANOVA, Pearson correlation and multiple linear regression were used. The chart was rechecked using Python 3.11 with SciPy and stats models.

Results: The dataset included 106 patients; mean age was 56.6 +/- 10.1 years. Stage 5 CKD was present in 43 (40.6%) patients. Polypharmacy, defined as five or more medicines, was observed in 90 (84.9%). At least one discrepancy was present in 83 (78.3%). CKD stage was significantly associated with discrepancy presence (chi-square=28.69, p<0.001), and medication burden was associated with adherence category (chi-square=65.73, p<0.001). Mean overall quality-of-life score was lower among patients with discrepancies than among those without discrepancies (48.8 +/- 11.4 vs 62.4 +/- 9.2; t=5.91, p<0.001).

Conclusion: This study concludes that pharmacist-led medication reconciliation is clinically relevant in high-burden CKD care.

KEYWORDS: Drug-Related Side Effects and Adverse Reactions; Medication Errors; Medication Therapy Management; Nephrology; Patient Safety; Polypharmacy; Renal Insufficiency.

INTRODUCTION

Chronic kidney disease (CKD) is a disease in which the kidneys become less effective at filtering blood. Global burden estimates show that CKD contributes substantially to disability and premature mortality. Indian evidence indicates that the prevalence is increasing in community-based studies. Modern guidelines on CKD recommend taking steps to prevent the worsening of the disease. (3)

In CKD, several factors can convert an ordinary discrepancy into clinically significant harm for routine medication. These include reduced renal clearance, alteration in pharmacodynamics, dialysis schedule and multi-morbidity. According to recent literature, patients with CKD have a need for structured processes of medication management that incorporate kidney function and patient/caregiver-centred counselling based on indication, dose, monitoring and follow-up. At the

health-system level, the WHO medication-safety policy will continue to target high-risk situations, polypharmacy, and care transitions as key areas of action. (5)

Polypharmacy is common in CKD due to the need for treatment for hypertension, diabetes mellitus, anaemia, mineralo-bone disease, fluid overload, cardiovascular risk and symptom control. Evidence in the literature suggests that there is a high global prevalence of polypharmacy in CKD. Patient-reported evidence shows that major polypharmacy is associated with lower health-related quality of life in non-dialysis CKD. (6,7)

Medication reconciliation compares patient's best possible medication history with current orders, followed by documentation and resolution of discrepancies with the aim of a patient's safety. The clinical pharmacists have received training to collect medication history, screen for drug interactions, identify renal dose problems, recognize adherence barriers, and relay recommendations to the clinical team. According to evidence from hospital-based CKD, clinical pharmacist is capable of discovering and solving drug related problems. Other recommendation is outpatient nephrology pharmacy standard entails the participation of a pharmacist in comprehensive medication management. (8,9)

METHODS AND MATERIALS

Research design and configuration.

This is a cross sectional observational original-article draft written based on B. Pharm thesis protocol. The location for the study (setting) was a secondary care hospital located in Tumakuru, Karnataka, India, that involved nephrology/dialysis services and Department of Pharmacy Practice activities. The design was descriptive and analytical; no treatment allocation or intervention was planned.

Study sample.

The study population included any adult patient greater than or equal to 18 years with a documented CKD stage 3-5 on two or more chronic medicines. Patients who were admitted to the intensive care units, patients who were unable to give medication history due to diminished capacity or communication limitations, and patients under care for less than one month were excluded. The number of sample size proposed for the uploaded thesis was 106 participants. The chart also contained 106 coded records.

Experiment size.

The calculation of sample size was done using $n = Z^2 pq / d^2$. With $Z=1.96$, $p=0.50$, $q=0.50$ and $d=0.10$, a minimum size of 96.04 was arrived at which was rounded off to 96. After adding the ten per cent for non-response or incomplete data the final number was approximately 106 patients.

Collection of data in possession.

Data sources were intended to be patient interviews; medication strips; previous prescriptions; discharge summaries; medication charts; and available laboratory parameters. Pharmacist-led reconciliation consisted of creating the best possible medication history, comparing that to the current prescription, identifying discrepancies, and documenting clinical recommendations. The process was consistent with the present-day CKD medication-management priorities, which include assessment of renal dosing, avoidance of nephrotoxic medicines, interaction screening and adherence councils. (3,4,9)

The discrepancies in medication were categorised as omission, commission, duplication, dose error, wrong frequency, wrong route, drug-drug interaction, adverse drug reaction, contraindicated medicine and renal dose adjustment issue or documentation error. Quality of life was represented by the outputs of the KDQOL-36 domain in the thesis draft; adherence was represented by the MMAS-based high, medium and low categories.

Data analysis.

Frequencies and percentages were used for categorical variable summaries. Average and standard deviation was taken as continuous variable to establish associations between categorical variables Chi-square tests were used. Welch t-test compared overall quality-of-life score between patients with and without disallowed trials. One-way ANOVA analyzed quality-of-life score by stage CKD. We assessed the relationship between medication count and discrepancy count. We looked at several predictors of overall quality-of-life score using multiple linear regression. The adherence category was coded 0=low, 1=medium and 2=high. A < 0.05 p-value was considered statistically significant. The master chart was rechecked on Python 3.11 using pandas, SciPy and stats models.

RESULTS

The following results are based on the actual hospital findings. The dataset contained 106 adult CKD stage 3-5 patients. The mean age was 56.6 $\pm$ 10.1 years, and 58 patients (54.7%) were male. Most patients were aged 41-60 years, followed by those older than 60 years. Urban residence was recorded in 61 patients (57.5%). The clinical profile showed a mean medication count of 7.9 $\pm$ 3.2 medicines and mean overall quality-of-life score of 51.8 $\pm$ 12.3.

Table-1: Demographic and clinical profile of the study population (n=106).

Variable	Category/Statistic	n (%) or mean $\pm$ SD
Age group	18-40 years	6 (5.7)
Age group	41-60 years	59 (55.7)

Variable	Category/Statistic	n (%) or mean +/- SD
Age group	>60 years	41 (38.7)
Sex	Male	58 (54.7)
Sex	Female	48 (45.3)
Residence	Urban	61 (57.5)
Residence	Rural	45 (42.5)
Mean age	Years	56.6 +/- 10.1
Medication count	Medicines per patient	7.9 +/- 3.2
Discrepancy count	Discrepancies per patient	1.6 +/- 1.4
Overall QoL score	KDQOL-derived overall score	51.8 +/- 12.3
Dialysis status	Yes	43 (40.6)

Stage 5 CKD was the largest subgroup (43, 40.6%), followed by stage 4 (35, 33.0%) and stage 3 (28, 26.4%). Hypertension was the most frequent comorbidity, followed by anaemia and diabetes mellitus. Polypharmacy, defined as five or more medicines, was observed in 90 patients (84.9%); 36 patients (34.0%) had 10 or more medicines.

Table-2: CKD stage, comorbidities and medication burden.

Parameter	Category	n (%)
CKD stage	Stage 3	28 (26.4)
CKD stage	Stage 4	35 (33.0)
CKD stage	Stage 5	43 (40.6)
Comorbidity	Hypertension	85 (80.2)
Comorbidity	Diabetes mellitus	58 (54.7)
Comorbidity	Cardiovascular disease	39 (36.8)
Comorbidity	Anaemia	67 (63.2)
Comorbidity	Dyslipidemia	31 (29.2)
Medication burden	2-4 medicines	16 (15.1)
Medication burden	5-9 medicines	54 (50.9)
Medication burden	>=10 medicines	36 (34.0)

At least one medication discrepancy was documented in 83 patients (78.3%). Omission was the most frequent discrepancy category, followed by dose error, drug-drug interaction and renal dose issue. These findings indicate that reconciliation workload was concentrated around clinically relevant prescription-list and kidney-function-related discrepancies.

Table-3: Medication discrepancies and drug-related problems identified.

Finding	Category	Frequency
Discrepancy presence	No discrepancy	23 (21.7%)
Discrepancy presence	At least one discrepancy	83 (78.3%)
Discrepancy type	Omission	48 (27.6% of discrepancies)
Discrepancy type	Dose error	35 (20.1% of discrepancies)
Discrepancy type	Drug-drug interaction	27 (15.5% of discrepancies)
Discrepancy type	Renal dose issue	26 (14.9% of discrepancies)
Discrepancy type	Documentation error	21 (12.1% of discrepancies)
Discrepancy type	Duplication	7 (4.0% of discrepancies)
Discrepancy type	Commission	7 (4.0% of discrepancies)
Discrepancy type	ADR	3 (1.7% of discrepancies)
DRP action	Adherence problem requiring counselling	76
DRP action	Dose review/interaction monitoring / therapy review	67

The 199 pharmacist recommendations across five major action groups. Acceptance was highest for documentation corrections and patient counselling/adherence support, although all categories had acceptance rates above 77%.

Table-4: Pharmacist interventions and recommendation acceptance.

Recommendation type	Total recommendations	Accepted n (%)	Pending/not accepted
Dose adjustment	61	48 (78.7)	13
Drug discontinuation/duplication review	14	11 (78.6)	3
Interaction monitoring	27	21 (77.8)	6
Patient counselling/adherence support	76	60 (78.9)	16
Documentation correction	21	17 (81.0)	4

The mean overall QoL score was 51.8 +/- 12.3. The burden of kidney disease domain had the lowest mean score, while the symptoms/problems domain had the highest mean score. Medication adherence was high in 30 patients (28.3%), medium in 55 patients (51.9%) and low in 21 patients (19.8%).

Table-5: Quality-of-life and adherence outcomes.

Outcome	Category/domain	n (%) or mean +/- SD
KDQOL-36	Symptoms/problems	60.9 +/- 12.9
KDQOL-36	Burden of kidney disease	45.6 +/- 14.3
KDQOL-36	Effects of kidney disease	49.7 +/- 14.0
KDQOL-36	Physical component	46.1 +/- 13.2
KDQOL-36	Mental component	54.6 +/- 13.8
KDQOL-36	Overall QoL	51.8 +/- 12.3
Adherence	High	30 (28.3)
Adherence	Medium	55 (51.9)
Adherence	Low	21 (19.8)

CKD stage was significantly associated with discrepancy presence (chi-square=28.69, df=2, p<0.001). Medication burden was significantly associated with adherence category (chi-square=65.73, df=4, p<0.001). Patients with at least one discrepancy had lower mean overall QoL scores than those without discrepancies (48.8 +/- 11.4 vs 62.4 +/- 9.2; Welch t=5.91, p<0.001). One-way ANOVA showed a significant QoL difference across CKD stages (F=74.12, p<0.001). Medication count was negatively correlated with QoL (r=-0.71, p<0.001) and positively correlated with discrepancy count (r=0.44, p<0.001).

Table-6: Key association, correlation and regression results.

Analysis	Statistic	p-value	Interpretation
CKD stage vs discrepancy presence	Chi-square=28.69; df=2	<0.001	Significant association
Medication burden vs adherence category	Chi-square=65.73; df=4	<0.001	Significant association
QoL by discrepancy status	Welch t=5.91	<0.001	Lower QoL with discrepancies
QoL across CKD stages	F=74.12	<0.001	QoL decreased with advanced stage
Medication count vs discrepancy count	r=0.44	<0.001	Moderate positive correlation
Medication count vs overall QoL	r=-0.71	<0.001	Negative correlation
Discrepancy count vs overall QoL	r=-0.60	<0.001	Negative correlation
Regression model for QoL	R ² =0.769; adjusted R ² =0.757; F=66.40	<0.001	Model significant
Regression coefficient: CKD stage	Beta=-5.95	<0.001	Advanced stage associated with lower QoL
Regression coefficient: medication count	Beta=-0.62	0.028	Higher count associated with lower QoL
Regression coefficient: adherence score	Beta=6.24	<0.001	Better adherence associated with

Analysis	Statistic	p-value	Interpretation
			higher QoL

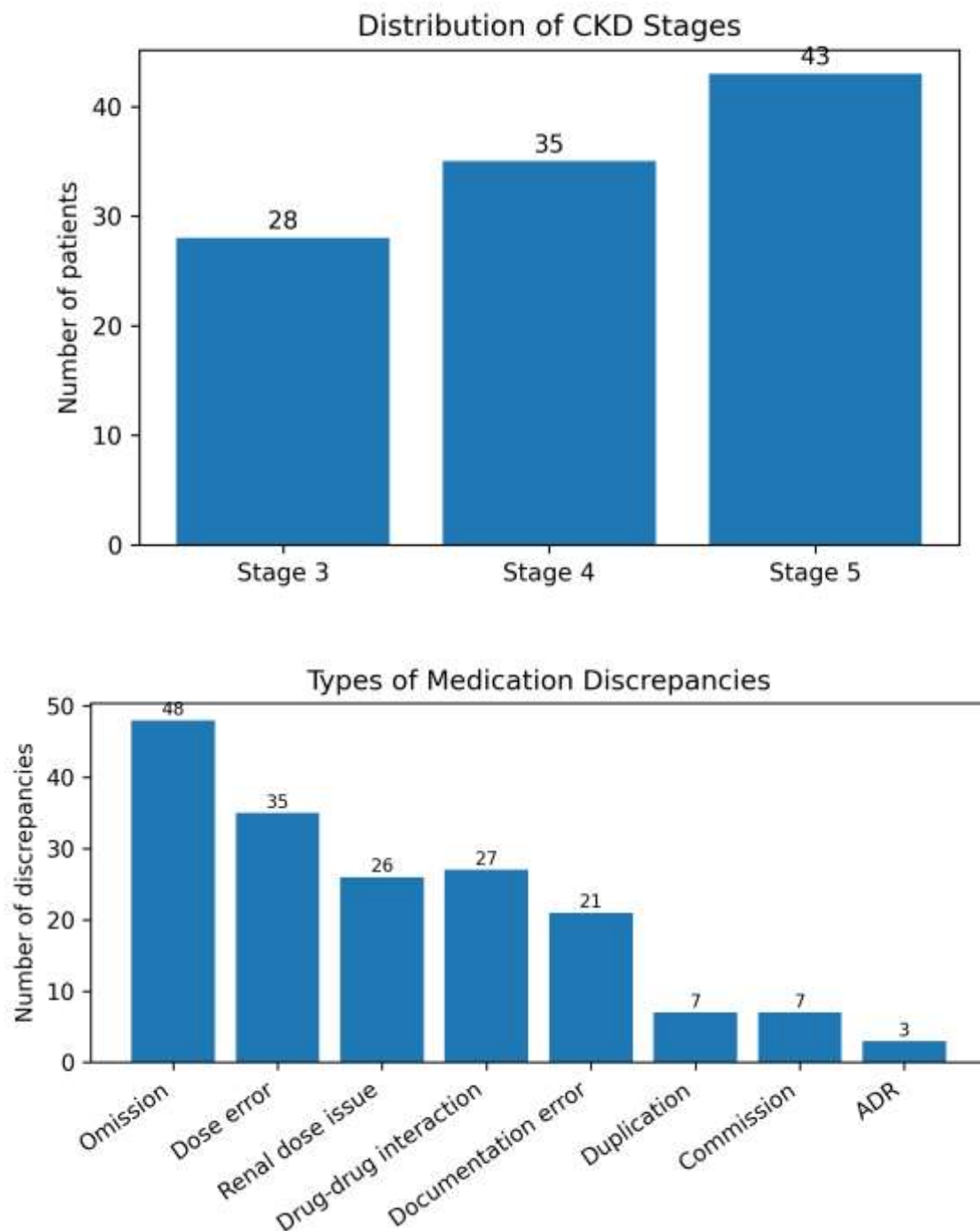


Fig-1: Distribution of CKD stages in the dataset.

DISCUSSION

In this data CKD patients, a high medication burden, frequent discrepancies, intermediate adherence challenge and lower quality of life were seen. The pattern is clinically plausible, as CKD stage 3-5 patients are often prescribed multiple therapies for one or more kidney disease, cardiovascular risk, diabetes, anaemia, mineral-bone disease and dialysis-related needs.

The prevalence of polypharmacy aligns with the trends seen in contemporary CKD literature. According to Naseralallah et al., polypharmacy is common among CKD populations. Major polypharmacy and hyper polypharmacy are associated with lower HRQoL in non-dialysis CKD patients, according to Adjero et al. In the current analysis, the number of medications was also negatively correlated with overall quality of life and positively correlated with the count of discrepancies.

Omissions, as well as errors in doses, interactions and renal doses were most common. CKD impacts drug exposure, which affects the risk-benefit balance of several medicines including antimicrobials, antidiabetics, anticoagulants, analgesics and other high-risk drugs. Zhang et al. similarly found that there were drug-related issues on CKD patients

who were admitted to the hospital and evidenced clinical pharmacist intervention. This reinforces that medicine reconciliation is a clinical process which relates to security rather than just administration. (8)

The role of the pharmacist goes beyond detecting discrepancies. Standards for outpatient nephrology describe activities of pharmacists such as comprehensive medication management, education and monitoring and interdisciplinary collaboration. Any recent interpretations of KDIGO guidance focused on pharmacists note the importance of optimising medications and implementing new recommendations surrounding chronic kidney disease (CKD). They should also focus on delivering patient-centred care. (11)

The analysis indicated that patients with discrepancies showed lower QoL. Due to its cross-sectional design, it cannot be determined whether the discrepancies lower QoL, whether lower QoL increase the risk of discrepancy or whether both are outcomes of advanced disease and treatment burden. The interventional literature has biological and practice-based plausibility. Evidence from various studies highlights that pharmacist interventions can lead to an improvement in selected clinical outcomes of CKD. A randomised trial recently reported a reduction in drug-related problems and quality-of-life score improvement following pharmacist-led care. (12,13)

Medication burden also linked adherence to therapy. Patients receiving ten or more medicines had low adherence as per the collected data. Mohammadnezhad and colleagues have indicated that medication therapy management provided by clinical pharmacy improved adherence and self-care outcomes. Similarly, Wickramasinghe and co-authors noted that utilization of clinical pharmacy services improved adherence and QoL in pre-dialysis CKD patients. According to these studies, counselling, regimen explanation, teach-back and follow-up are of practical value in patients with a high medication burden.

CONCLUSION

This cross-sectional observational study demonstrates that the active integration of clinical pharmacists in the multidisciplinary care of patients with CKD. The study indicates that pharmacist-led medication reconciliation is a worthwhile clinical pharmacy service for high medication burden CKD patients. There was a high level of medication discrepancies which were associated with CKD stage, adherence category and quality-of-life score. Given the high burden of polypharmacy and complex treatment regimens in polypharmacy and complex treatment regimens in this population, incorporating clinical pharmacist-led-medication management into standard nephrology care protocols is strongly recommended to improve overall patient safety and clinical outcomes.

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Conflict of Interest:

There is no Conflict-of-interest from all authors.

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