International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Effectiveness of Patient Counselling and Patient Information Leaflet (PIL) on Medication Adherence in Chronic Kidney Disease (CKD) Patients in a Tertiary Care Hospital

Prajwal H[1], Megha H M[1], Amrutha M[2], Abhijith Kumar Dalal[3], Dr. Yashoda K[4]

[1,2]Bpharm students, Department of pharmacy practice, SJM College of Pharmacy, Chitradurga, Karnataka, India
[3,4]Assistant Professor, Department of pharmacy practice, SJM College of Pharmacy, Chitradurga, Karnataka, India

Abstract
Chronic Kidney Disease (CKD) is a long term illness that requires regular treatment and steady use of medicines. Poor adherence to medication frequently causes a disease to deteriorate, which in turn results in more hospital visits and a decrease in the quality of life. This research assessed the impact of patient counselling and the implementation of a Patient Information Leaflet (PIL) on the enhancement of medication adherence in CKD patients in a tertiary care hospital. A total of 60 CKD patients were randomly divided into two groups- one got regular care and other received pharmacist counselling with a bilingual PIL. The levels of adherence were determined using the Simplified Medication Adherence Questionnaire for CKD (SMAQ-CKD). After the counselling sessions, the percentage of poorly adherent patients noticeably fell to 6.7 percent in the intervention group from 80 percent, while those highly adherent increased from 0 to 40 percent ($p < 0.000001$), In contrast, the control group had shown only a low level of improvement ($p = 0.035$). Our results indicate that medication adherence is significantly improved among the CKD patients by pharmacist counselling with a PIL in both languages. This highlights the importance of pharmacist's role as a part of the multidisciplinary renal care team.

Keywords: Chronic Kidney Disease, Simplified Medication Adherence Questionnaire for CKD, Patient Information Leaflet.

1. Introduction

Chronic Kidney Disease (CKD) is a major contributor to declining global health and premature death. Consequently, this situation poses a severe challenge to healthcare systems, particularly in developing countries. It is characterized as any structural or functional changes of the kidneys resulting in health abnormalities for a duration of three months or more [1].As per estimates, CKD is responsible for 10-15% of the adult population worldwide, but in India, this figure has raised to 17%, thus, posing a hefty load on healthcare resources [2,3].

The leading causes of CKD are diabetes mellitus and hypertension, and these two conditions alone make up nearly 70% of the total cases [4]. The treatment of CKD is a challenging one and may include various types of medicine, dietary changes, fluid control, and eventually, dialysis or a kidney transplant. It is undoubtedly difficult for many patients to comply with such long-term treatment regimens. Previous studies have shown that between 30% and 60% of CKD patients who fail to take their medications as prescribed [5].

Poor adherence is affected by several factors such as forgetfulness, complex dosing schedule, high cost of treatment, side effects and poor understanding of the diseases [6,7]. Non-adherence not only increases the rate of CKD progression to end-stage renal disease (ESRD) as well as hospitalization and a decrease in quality of life overall [8]. The World Health Organization estimates that only about 50% of chronic ill patients in developed and developing countries follow their long-term treatments [9].

In southern parts of India, especially in Karnataka, the burden of CKD is on the rise due to lifestyle transition, increased prevalence of non-communicable diseases and delayed diagnosis of the disease [21,22]. Recent studies performed in hospital-based settings in Bengaluru, Davanagere and Chitradurga have seen prevalence rates for CKD ranging from 14% to 19% and most of these patients were found to have been diagnosed at the late stages of their disease [21,22]. Rural and semi-urban populations are particularly vulnerable because of the limited access to healthcare facilities, lack of financial resources and lack of awareness in kidney health [23,24]. Educational status also plays a major role - patients with limited literacy or low health awareness would often not be able to understand prescriptions, dietary restrictions or follow-ups on a regular basis [23,24].

Pharmacists, as one of the most accessible healthcare professionals, can play an important role in bridging the communication gap between doctors and patients. Through regular counselling, reinforcement of medication schedules and provision of clear educational materials the pharmacists can assist patients in a better understanding of their disease and treatment plan [10-12,25]. Patient Information Leaflets (PILs) are a good form of education and can be used as a quick and reliable source of information for patients to refer to when they are at home. In multilingual areas such as Karnataka, bilingual PILs (written in both English and Kannada) can help in countering the language barriers and enhance treatment adherence [24,26-28].

Although several international studies shown that patient counselling can improve adherence and quality of life in CKD patients but there is limited published data from the Indian and Karnataka context [21,22,27]. Hence, this study was undertaken to assess whether pharmacist counselling supported by a bilingual Patient Information Leaflet could improve medication adherence among CKD patients attending the nephrology department of Basaveshwara Medical College and Hospital, Chitradurga, Karnataka.

2. Methodology

Study Design and study site

The prospective cohort study took place at the Department of Nephrology, Basaveshwara Medical College and Hospital, Chitradurga, Karnataka. The research was done for three months following the approval from the Institutional Ethical Committee. The primary objective was to evaluate the effectiveness of pharmacist counselling and a bilingual Patient Information Leaflet (PIL) on medication adherence among patients with chronic kidney disease (CKD) [21,22].

Study population and sampling.

A total of 60 CKD patients aged 18 years or older were included in the study from both inpatient and outpatient nephrology units [1,2], after obtaining written informant consent. Patient with cognitive impairment, psychiatric disorders, multiple organ failure or dissatisfied participants were supposed to be excluded from this study. Participants were divided into to 2 equal groups in a random manner. Participants in the control group, consisting of 30 individuals, maintained their standard outpatient care. The intervention group of 30 participants received structured counselling by a pharmacist on disease knowledge, lifestyle modifications, and adherence to their medications, along with a bilingual PIL in English and Kannada for use at home when necessary (8). This sample size was calculated with the formula for a sensitivity to compare the mean difference of the two independent group to each other in a 95% confidence level and 80% statistical power. Assuming adherence improvement rates depicted in other studies [13,14] we have estimated that we would need to involve 30 subjects per group.

Data Collection Procedure

Data were gathered by using structured data collection form as it contains some sociodemographic information (age, gender, education, residence, occupation), clinical parameters (CKD stage, comorbidities, and medication profile), and responses from medication adherence questionnaire. Baseline (pre-counselling) data was recorded during the first visit of the patient. Pharmacist-led counselling sessions were delivered individually and targeted the understanding of disease, adherence to treatment, modification of diet and lifestyle [10-12,25].

Each participant in the intervention group received a bilingual PIL, both English and Kannada designed to improve their understanding and recall the information [24,26–28]. A repeat measurement of medication adherence was done after 2 weeks with a follow-up data collection.

Study Tools

The level of medication adherence was assessed using the Simplified Medication Adherence Questionnaire for CKD, a previously validated tool to measure factors such as forgetfulness, intentional discontinuation or time of medication intake [5,6,9]. According to the scores obtained, patients were allocated in three levels of adherence:

- High adherence: ≥8
- Moderate adherence:5-7.9
- Low adherence:<5

Statistical Analysis

All statistical procedures were run using IBM Statistics-SPS, version 29. Categorical variables were presented as percentage and continuous data as the mean+-SD. The Wilcoxon signed-rank test was used for within-group comparisons, and the Mann–Whitney U test was used for between-group comparisons. Statistical significance was set at a p-value of less than 0.05 [29,30].

3. Results

Among the 60 participants, 36 (60%) were males and 24 (40%) were females with the average age of 52.4 ± 13.6 years. The majority of participants (66.7%) were from the rural areas. The most common comorbid conditions were hypertension (80%) and diabetes mellitus (60%).The Education level appeared to be a significant association with adherence, $p = 0.01$. The levels of adherence for the patients with greater education were better than individuals with only primary education through to no formal education. Other variables like gender, age, employment status and residence did not show a

significant association, p>0.05. Initially, Most of the participants (65%) were considered to be moderately adherent, while 25% reported low adherence and 10% high adherence at baseline. After 2 weeks, the intervention group saw a phenomenal change in medication adherence, with low adherence reduced from 80% to 6.7%, moderate adherence was increased from 20% to 53.3%, and high adherence was increased from 0% to 40%. However, the control group only experienced small changes over the same period, low adherence was slightly decreased from 70% to 60%, and high adherence was merely slightly increased, from 0% to 6.7%. The statistical analysis has verified that the changes in the intervention group were significant both intragroup ($p < .000001$) and intergroup when compared with the control group ($p < .000001$), whereas the changes in the control group were slight ($p = 0.035$).. Statistical analysis confirmed that improvements in the intervention group were substantial both within the group ($p < .000001$) and when compared with the control group ($p < .000001$), while the changes observed in the control group were modest ($p = 0.035$).

Table 1: Distribution of demographic details and its correlation with medication adherence of study sample (N= 60)

Parameter	Frequency (n)	Percentage (%)	Chi-square Value	p-Value
Gender				
Male	36	60	1.95	0.38
Female	24	40		
Age				
18–29 years	6	10		
30–49 years	15	25	6.44	0.376
50–69 years	18	30		
≥70 years	21	35		
Employment Status				
Employed	45	75	1.26	0.534
Economically inactive	12	20		
Unemployed	3	5		
Education Status				
Illiterate	15	25		
Primary	8	13.3	12.94	0.01
Secondary	20	33.3		
Graduate	12	20		
Postgraduate	5	8.3		
Residence				
Rural	40	66.7	0.87	0.65
Urban	20	33.3		

Co-morbidity				
Hypertension	48	80	1.73	0.421
Diabetes Mellitus	36	60	0.63	0.741
Anemia	27	45	0.73	0.694
Cardiovascular Disease (CVD)	21	35	1.21	0.546
CKD Stages				
Stage 1	2	3.3	2.08	0.35
Stage 2	5	8.3		
Stage 3	16	26.7		
Stage 4	15	25		
Stage 5	22	36.7		

Table 2: Patients adherence levels before and after the Intervention

Sl. no	Group (n)	Adherence Level	Baseline n (%)	Follow-up n (%)	Test Value	p-Value
1	Control (n=30)	Low Medium High	21 (70%) 9 (30%) 0	18 (60%) 10 (33.3%) 2 (6.7%)	Wilcoxon W = 130	0.035
2	Intervention (n=30)	Low Medium High	24 (80%) 6 (20%) 0 (0)	2 (6.7%) 16 (53.3%) 12 (40)	Wilcoxon W = 0	<0.00000001
3	Control vs Intervention	High adherence (Follow-up)	Control: 2(6.7%)	Intervention: 12 (40%)	Mann–Whitney U = 118	<0.000001

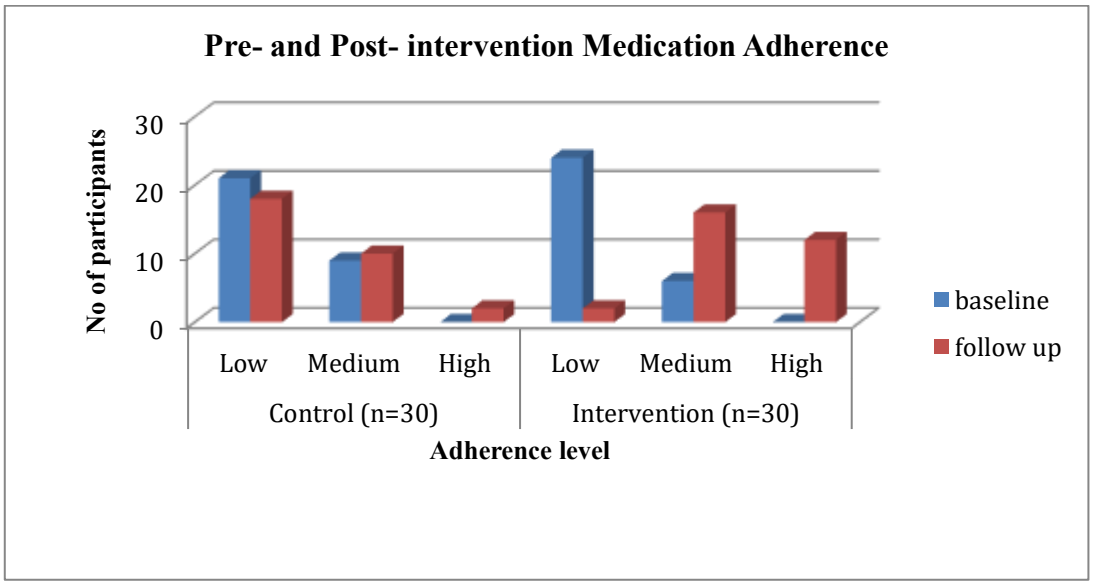

Figure3: Pre- and Post-Intervention Medication Adherence in Control vs Intervention

4. DISCUSSION

Our study was focused on determining the impact of a bilingual Patient Information Leaflet (PIL) supported pharmacist counselling on medication adherence in patients with chronic kidney disease (CKD). The results clearly demonstrate that pharmacist participation had a strong and positive effect on how consistently patients followed their prescribed medications. At the start of the study, adherence levels were poor for both the control and intervention groups, which is in line with reported literature indicating that for many CKD patients, adhering to regular medication routines is problematic [5-8]. After pharmacist counselling and distribution of bilingual PILs there was a marked and statistically significant improvement in adherence in the intervention group. This result is in support of those of Baby et al. (2017), Okoro et al. (2023) and Amin et al. (2023) which found equal results that the pharmacist led counselling increases patient's knowledge of medication, enhances their confidence and helps in the cascade of medication management to patients [10-12].

One of the important observations in our study was the effect of education level on the adherence behaviour. Patients with higher education showed better understanding of their condition as well as an increased willingness to clarify doubts when attending counselling sessions. In contrast, less literate patients or patients who are not able to read English often did not understand complex prescriptions and dosage schedules. For such patients, the bilingual PIL was especially useful and helped them remember the medication instructions and dietary guidelines that were discussed during counselling. This observation is consistent with Subramaniam and Suresh (2024) and Banerjee and Kumar (2020), as they also found language- and literacy sensitive patient education materials to improve comprehension and adherence [24,28]. A few of the people in our study stated that reading the leaflet in Kannada helped them to feel more confident and independent in managing their treatment. These findings address an urgent need of such tailor-made educational interventions with a special focus on rural areas of Karnataka where health literacy and CKD awareness among the beneficiaries is low [21,22,24].

Our results are also supported by the study carried by Ghosh and Gupta (2021) and Patel and Desai (2022) that improvement in self-care, motivation and quality of life among CKD patients post pharmacist-guided education programme [25,26]. Common barriers such as forgetfulness, complex drug regimens and inadequate understanding previously discovered by DiMatteo (2004) and Sontakke (2015) were also found in our participants [7,20]. Continuous counselling and follow-up interactions played an important role to overcome these challenges.

From a regional perspective, the results of this study are similar to the results of Jha and Srinivas [2023] and Thomas and Rajesh [2022] in disproportion in Karnataka, which demonstrated that pharmacist interventions led to significant improvement in adherence in CKD and other chronic diseases [21,22]. By combining personalized counseling with bilingual educational materials, this approach is a very efficient tool to close those gaps which were caused by language, literacy and communication with patient-providers. The improvement in adherence in our study is both statistically significant and clinically meaningful and solidifies the vital role of the pharmacist in the management of chronic disease. Similar international studies have shown that structured pharmacist interventions have contributed to improved treatment adherence, clinical control, and excellent clinical outcomes with chronic illnesses such as hypertension, diabetes, and CKD [10-12,29,30].

The findings from our study show the importance of pharmacist counselling in comprehensive CKD management. Involving pharmacists in routine care can significantly improve patient understanding and adherence, especially with the supported by bilingual or multilingual educational materials.

CONCLUSION

In summary, our study demonstrates that pharmacist counseling combined with a bilingual PIL is useful to help CKD patients to better follow their medication. This approach helps patients to understand their medicines and take them more constantly which serves to change the way they manage their condition to a better extent. Making pharmacist a routine component of healthcare for kidney disease may help patient take more responsibility for their treatment and could cut into hospitalization and disease progression. Future studies with larger numbers of patients and longer follow up will help confirming such findings and allow exploration of other factors affecting patient behaviour in the management of CKD. [12]

REFERENCES

1. Bargman J.M., Skorecki K. Chronic Kidney Disease. In: Harrison's Principles of Internal Medicine, 19th ed., McGraw-Hill; 2015.
2. Modi G.K., Jha V. The incidence of end-stage renal disease in India: a population-based study. Kidney Int. 2006; 70: 2131-2133.
3. Singh A.K. et al. Epidemiology and risk factors of CKD in India – SEEK study. BMC Nephrol. 2013; 14: 114.
4. Kaveh K., Kimmel P.L. Compliance in haemodialysis patients. Am J Kidney Dis. 2001; 37: 244-266.
5. WHO. Adherence to Long-Term Therapies: Evidence for Action. Geneva; 2003.
6. Griva K. et al. Non-adherence in peritoneal dialysis: a systematic review. PLoS One. 2014; 9(2): e89001.
7. DiMatteo M.R. Variations in patients' adherence: 50 years of research. Med Care. 2004; 42: 200-209.
8. Li S. et al. Self-reported adherence and CKD progression. Am J Kidney Dis. 2018; 71(2): 210-219.
9. Hala I., NasrAllah M., Mohamed M. Educational program and adherence in CKD stage 5 patients. J Educ Practice. 2015; 6: 21-33.
10. Baby B.E. et al. Evaluation of the impact of pharmaceutical care on adherence in CKD. Int J Pharm Pharm Sci. 2017; 9(1): 63-66.
11. Okoro R.N. et al. Pharmacist intervention in improving adherence in CKD. Afr J Nephrol. 2023; 26(1): 127-134.
12. Amin R. et al. Effectiveness of regional language PILs in CKD. Int J Nephrol. 2023.
13. Paneerselvam G.S. et al. Effectiveness of mobile apps in improving adherence among CKD patients. J Med Internet Res. 2025; 27:e53144.
14. Tripathi R.K. et al. Drug treatment awareness among CKD patients. Int J Basic Clin Pharmacol. 2023.
15. Sahu P., et al. Adherence to treatment in dialysis patients. Int J Basic Clin Pharmacol. 2019; 8(6): 1334-1338.
16. Chauke G.D. et al. Factors influencing poor medication adherence in chronic diseases. BMC Public Health. 2022.
17. Varghese C.S. et al. Medication adherence and quality of life in CKD. J Drug Deliv Ther. 2024; 10(3-S).
18. Nunes J.W. et al. Patient education and decision support in CKD. Am J Kidney Dis. 2025.

19. Frankenfield D.L. et al. Cost-related non-adherence in ESRD. Am J Health Syst Pharm. 2011; 68: 1339-1348.
20. Sontakke S. et al Barriers to drug therapy adherence in CKD. Indian J Pharmacol. 2015; 47(6): 668-671.
21. S. Jha, R. Srinivas, "Pharmacist-led patient education and medication adherence in chronic kidney disease," Indian Journal of Pharmacy Practice, 2023, 16(2), 98–104.
22. L. Thomas, K. Rajesh, "Impact of patient counseling on treatment outcomes among renal disease patients," International Journal of Research in Pharmaceutical Sciences, 2022, 13(4), 2875–2882.
23. N. Verma, P. Kumar, "Medication adherence among CKD patients: a systematic review and meta-analysis," BMC Nephrology, 2023, 24(1), 55–66.
24. M. Subramaniam, T. Suresh, "Bilingual patient information leaflets: an approach to improve comprehension in rural populations," Asian Journal of Pharmaceutical and Clinical Research, 2024, 17(3), 121–127.
25. A. Ghosh, R. Gupta, "Role of clinical pharmacists in enhancing medication adherence among CKD patients," Journal of Clinical and Diagnostic Research, 2021, 15(12), FC05–FC09.
26. R. Patel, S. Desai, "Effect of pharmacist interventions on quality of life in CKD patients," Saudi Journal of Kidney Diseases and Transplantation, 2022, 33(1), 45–53.
27. E. Joseph, M. A. Fernandes, "Determinants of medication non-adherence in Indian CKD patients: a hospital-based study," Indian Journal of Nephrology, 2024, 34(3), 210–218.
28. T. Banerjee, A. Kumar, "Developing culturally tailored information leaflets for chronic diseases," Patient Education and Counseling, 2020, 103(8), 1605–1613.
29. S. Roy, P. Menon, "Educational interventions for improving adherence in CKD: a randomized controlled trial," Nephrology Nursing Journal, 2021, 48(5), 421–429.
30. V. Reddy, N. Chatterjee, "Pharmaceutical care interventions and adherence improvement in dialysis patients," Clinical Therapeutics, 2022, 44(7), 1123–1132.