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Evaluating the effectiveness of pharmacist-led interventions on medication adherence in chronic disease management

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ABSTRACT

Chronic kidney disease (CKD) is a public health concern due to its increasing prevalence, multiple prescribed medications, multiple emergency visits and hospital admissions that is a burden on healthcare resources. The study was conducted to assess the rate & pattern of occurrence of drug related problems (DRPs) and clinical and economic outcomes of pharmacist interventions in CKD patients. This was a randomized, controlled, prospective, open labeled study that included patients diagnosed with chronic kidney disease of any stage who are admitted to a tertiary care hospital or visiting the ambulatory dialysis centre. Test group were actively followed by intervening pharmacist to identify DRPs and necessary changes to drug therapy and/or monitoring parameters were performed. A direct cost associated with pre-determined variables like medication prescribed, lab investigation/s ordered, length of hospital stay and adverse drug effects per admitted inpatient between control and interventional groups was evaluated and compared. The control group received usual medical care provided by healthcare professionals. Clinical pharmacist interventions can significantly improve disease control measures, improve health related quality of life, and reduce costs of drug therapy. Employing clinical pharmacists in hospitals is beneficial to patients as well as can reduce healthcare costs.

Keywords: *Pharmaceutical, medicine, healthcare delivery systems.*

1. INTRODUCTION

Chronic kidney disease (CKD) is a progressive disease of declining kidney functions where the nephrons of the kidney are damaged and/or stop functioning and this process is spread over a long period, maybe several months to years. In CKD, the reduction in kidney function is irreversible with a progressive decrease in the glomerular filtration rate, which eventually ends in end-stage renal disease (ESRD). Renal replacement therapies (RRTs) like haemodialysis (making use of an artificial kidney), peritoneal dialysis (using the peritoneal membrane to remove accumulated waste from blood), and renal transplantation are the means of survival once ESRD sets in (1). It is estimated that 750 million persons across the globe are affected by kidney disease making it a global public health problem (2). The burden of kidney disease, as well as its detection and management differs worldwide based on socio-economic setting and it is influenced by local cultural and political factors (2). Though several countries have established national data collecting systems like registries for CKD & ESRD, there are inconsistencies in collected data particularly from low- and middleincome countries. High quality data with respect to patients with CKD and not on any mode of renal replacement therapy is limited (2). World Health Organization‟s (WHO) Global burden of disease 2015 study estimates that reduced glomerular filtration rates directly contributed to over a million deaths, and close to twenty million disability-adjusted life-years (DALYs) and loss of life years of about 18 million from cardiovascular diseases. The growing number of people with CKD, the number of people progressing to end stage, and the resulting financial load of managing the disease in both first world as well as emergent nations has thrown light upon preventing occurrence of CKD and minimizing the risk factors.(17). According to a National Health and Nutrition Examination Survey (NHANES) report, in the United States, overall prevalence of CKD (stages 1- 5) gradually increased from 14.2% (2001-2004) to 14.8% (2013-2016) and CKD stage 3 is most prevalent (18). In Europe, CKD prevalence varied from 4.1% reported in a Swiss study (Swiss Bus Santé study) to 25.5% in a German study (the Northeast German SHIP study) (5). Quality of data from Africa being poor, exact estimates are not reported. A systematic review from Africa reported CKD prevalence from 2-42% from the community-level studies, 11-90% in patients with diabetes, and 13-51% in patients with hypertension (13). A saudiarabian study reports 6.5% prevalence of renal insufficiency, 5.4% of diabetic nephropathy, and 1.4% of chronic kidney disease patients among hospitalized inpatients (17). (6). In India, a population based survey has reported an incidence of 151 per million population in Central India (8), reduced GFR was found in 13% of population (14),

other studies report between 0.8% to 4.8% of reduced GFR (10). (11). According to an Indian CKD registry report published in 2012, among approximately fifty-two thousand registered CKD patients, 48% had ESRD, 16% had CKD of undetermined etiology, hypertensive nephrosclerosis and glomerulonephritis were causes of CKD in 13% and 14% of CKD patients respectively, and the most common cause was diabetic nephropathy (31% of patients). (15). A 5 year follow-up epidemiological study observed that kidney disease patients progressed to ESRD at yearly rates of 23% for those with polycystic kidney disease, 10% for those with glomerulonephritis and 12% for those with diabetic nephropathy, but the risk of death before ESRD was 2-fold higher among diabetic nephropathy patients than those with cystic kidney disease. (4). (9).

Primary research questions were

- Can provision of Clinical Pharmacist services in chronic kidney disease patients lead to better health-related outcomes in this patient population?
- Can the outcomes of such services be quantified?

2. BACK GROUND OF THE STUDY

CKD is a complex disease with multiple comorbidities and attendant complications. Evidence has accumulated over the years and we now know that the disease is associated with significant morbidity and mortality risks. What makes the disease deadlier is that the metabolic complications associated with it that include mineral and electrolyte imbalance, metabolic acidosis, anemia, and renal osteodystrophy among others may remain asymptomatic for a long time. It is proven now that these complications can significantly affect the physical, and emotional health of a person. A list of other complications of CKD include, cardiovascular disease, secondary hyperparathyroidism, bone and mineral metabolism disorder, uremia and bleeding complications, gout secondary to accumulation of uric acid, and malnutrition due to poor appetite associated with uremia (14). So, the management of CKD does not involve only controlling the progression of disease and treat underlying disorder but also provide therapy for controlling complications of the disease. (7). Treatment in CKD consists of medications to treat the symptoms of the disease as well as counteract the accumulation of various metabolic wastes as well as mineral and electrolyte disturbances. Most commonly, diuretics that remove excess water from body, phosphate binders to prevent excess absorption of phosphorous from the gut, bone medications like calcium and vitamin D, antihypertensive medications to control hypertension caused by excessive secretion of renal hormones (to maintain adequate blood supply to kidneys), statins to combat cardiovascular risk, medications to lower potassium blood levels, and medications to treat anemia are commonly prescribed (1). It is common for patients to be admitted to emergency with serious uremic symptoms that requires immediate and urgent haemodialysis using a temporary vascular access to make the patient stable. Even though, ultimately RRTs are required to sustain life, they have a significant impact on the length and the quality of life of the person . National, European, and global standards and guidelines for management of CKD are available for the health care professional to refer in caring for the patient. Some of the available standards or guidelines include European renal best practice (ERBP), National Institute for Health and Care Excellence (NICE) guidelines for management of CKD in adults, and Kidney Health Australia – Caring for Australasians with Renal Impairment (KHA-CARI) guidelines. The Indian Society of Nephrology (ISN) CKD guidelines by the Indian CKD Guideline Workgroup (ICKDG) (http://isn-india.org/images/CKD_1.pdf) is available for our country.

- To initiate Pharmacist-Psychiatrist Collaborative Medication Therapy Management services.
- To design and validate the patient education materials for selected psychiatric diseases.
- To assess the impact of collaborative Medication Therapy Management services on clinical, humanistic and economic outcomes.

3. METHODOLOGY

Study Hypothesis: Pharmacist-provided healthcare services to chronic kidney disease patients will have positive impact on disease control and better health-related outcomes in patients with chronic kidney disease.

Study design: This was a randomized, controlled, prospective, open-labeled, interventional study.

A descriptive or observational study describe the characteristics of a population or an event or circumstance being studied, but does not provide information regarding how and when the characteristics occurred. So this type of research design is not appropriate to answer the research question. Retrospective studies have limitations in terms of completeness of data, and so a prospective study is a good choice. Among analytical studies, since the study population consisted of patients with chronic kidney disease, a case-control study and cohort study were not suited. Also, since the study required some kind of intervention by way of pharmacist providing pharmaceutical care services, and to really assess the impact of these services there was a need for two groups, an experimental and a comparison group, an interventional study design was chosen. Since randomization eliminates bias when grouping patients, a randomized, controlled, interventional study was chosen.

Study site: The study was conducted in Nephrology, Medicine, Surgery and Orthopaedic Units of a tertiary care hospital in

Mysore.

Sample Size Calculation: Choosing paired t-test as a suitable statistical test to investigate the research question, the sample size was calculated. Assuming a standard deviation value of 12, keeping the level of significance at 1%, power of the study at 90%, and minimum detectable significance between two groups as 1, a sample size of 1877 for each group was obtained and secured.

Statistical analysis: Demographic details are depicted in numbers and percentages. Identified DRPs are classified according to PCNE classification and reported denoting PCNE codes with numbers and percentages in both test and control groups. Pharmacist interventions are reported denoting PCNE codes with numbers and percentages in both test and control groups. Parametric data are reported with means and standard deviations. Disease control measures between test and control groups was analyzed using twotailed t-test with significance set at 0.05. Scoring template provided by RAND corporation was used to convert responses of patients into scores. (16). Responses from questions that address specific health status of the patient are averaged together and reported as average scores for the five different domains of the KDQoL (Symptom/Problem list – 12 items, Effects of kidney disease – 8 items, Burden of kidney disease – 4 items, Physical and Mental Health Composite – 12 items). HRQoL values are compared between test and control groups using two-tailed t-test with significance set at 0.05. Predictors of HRQoL was assessed using independent t test (two groups) and ANOVA (for more than two groups). Domain-wise predictors of HRQoL with various demographic characteristics of the study population was assessed using multiple regression analysis.

4. RESULTS

Among 4065 patients (2025 in Test group and 2040 in Control group) included for analysis, 3997 (98.5%) were inpatients and 68 (1.5%) were ambulatory patients on maintenance haemodialysis. Demographic details of study population is depicted in Table 1. There were more males in the study population (56%), and majority (~40%) of patients belonged to age group 50-59 years followed by age group 30-49 years (~37%). The average age of the study group was 53 years (range:16-91). Study patients received an average of 7 medications per patient and majority of them (~30%) had middle or high-school education. Close to 30% of study subjects were in CKD stage 4 followed by stage 3 (~25%), almost half of the population belonged to lower middle class on Kuppuswamy's socio-economic scale.

Table 1: Demographic Details of Study Subjects

Parameter	Test (%) (n = 2025)	Control (%) (n = 2040)	Total (%) (n = 4065)	P value
Males	1140 (56.2)	1146 (56)	2286 (56.2)	0.889
Females	885 (43.7)	894 (44)	1779 (43.8)	
Age				0.022
<18	1(0.05)	1 (0.05)	2 (0.05)	
18-29	45 (2.2)	66 (3.23)	111 (2.7)	
30-49	779 (38.4)	723 (35.4)	1502 (36.9)	
50-59	814 (40.1)	825 (40.4)	1639 (40.3)	
60-79	216 (10.6)	265 (12.9)	481 (11.8)	
≥ 80	170 (8.39)	160 (7.8)	330 (8.1)	
Average Age	51.56 ± 15.87 (range – 17- 90)	49.32 ± 16.46 (range – 16- 91)	53.52 ± 15.54 (range – 16-91)	0.11
Education	427 (21)	580 (28.4)	1007 (25)	< 0.001
Illiterate Upto 5 Grade	519 (25.6)	480 (23.5)	999 (24.5)	
6-10 Grade Pre-University Graduate and	554 (27.3)	686 (33.6)	1240 (30.5)	
above	475 (23.4)	274 (13.4)	749 (18.4)	
	50 (2.4)	20 (0.9)	70 (1.7)	
Average number of medications prescribed	8.10 ± 3.67 (range – 3-17)	6.60 ± 2.83 (range – 2-17)	7.34 ± 3.35 (range – 2-17)	0.024

CKD Stages	280 (13.8)	298 (14.6)	578 (14.2)	
Stage 1	311(15.3)	330 (16.1)	641 (15.7)	
Stage 2	530 (26.1)	499 (24.4)	1029 (25.3)	0.647
Stage 3	590 (29.1)	583 (28.5)	1173 (28.8)	
Stage 4	314 (15.5)	330 (16.1)	644 (15.8)	
Stage 5				
No of Co- morbidities 0	180 (8.8)	170 (8.3)	350 (8.6)	
1	215 (10.6)	227 (11.1)	442 (10.9)	
2	485 (23.9)	478 (23.4)	963 (23.7)	
3	561 (27.7)	578 (28.3)	1139 (28)	0.758
4	510 (25.1)	501 (24.5)	1011 (24.9)	
>4	74 (3.65)	86 (4.2)	160 (3.9)	
Kuppuswamy SES	18 (0.8)	22 (1)	40 (1)	
Upper (> 25)	34 (1.6)	14 (0.7)	48 (1.1)	
Upper Middle (16-	985 (48.6)	1014 (49.7)	1994 (49)	
25)	945 (46.6)	913 (44.7)	1858 (45)	0.001
Lower Middle (11-	48 (2.4)	77 (3.8)	125 (3.9)	
15)				
Upper-lower (5-10)				
Lower (<5)				

Prescribers asked information pertaining to drug therapy to the pharmacist to improve patient care. Among them, queries pertaining to Drug-Drug interactions (n=12) and Dose adjustment (n=10) were more. Number and category of queries asked by prescribers are shown in Fig 1.

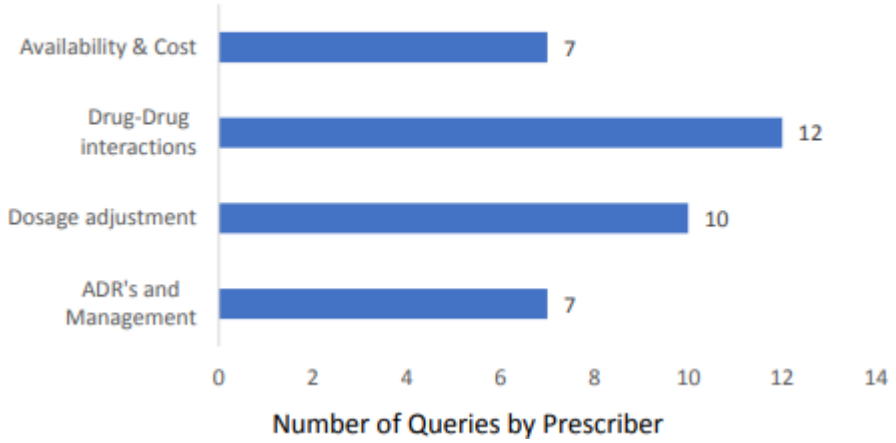

Figure 1: Information Sought by Prescriber

The significance of pharmacist interventions were classified as Minor, Moderate or Major based on the ability of intervention to enhance effectiveness of therapy, reduce patient morbidity or treatment costs and reduce hospital stay. A total of 53.6 % of interventions were found to have moderate significance, 35% to have major significance, and 8% to have minor significance. Effect of interventions on morbidity, treatment costs or hospital stay could not be determined for about 4% of interventions. The significance of interventions is shown in Fig 2.

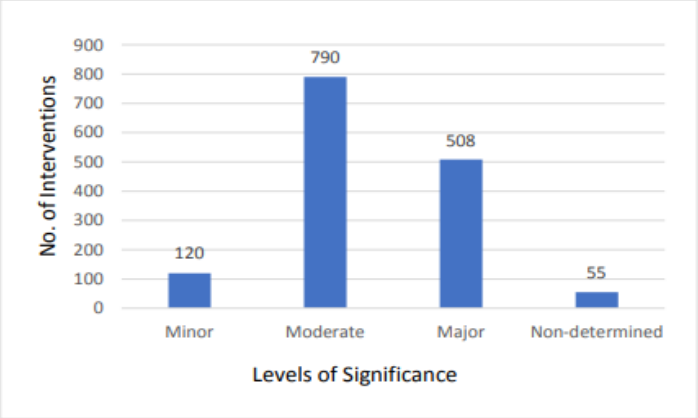

Figure 2: Significance of Pharmacist Interventions

Level of Decision making by pharmacist for interventions was categorized based on level of involvement. It was seen that majority of the interventions [968 (75.3%)] belonged to Level 2 Corrective, while few of them were Level 3 Consultative [136 (10.5%)] and Level 4 Proactive [139 (10.8%)]. A small number were annotative [42 (3.2%)]. Level of decision making by pharmacist is shown in Fig 4.

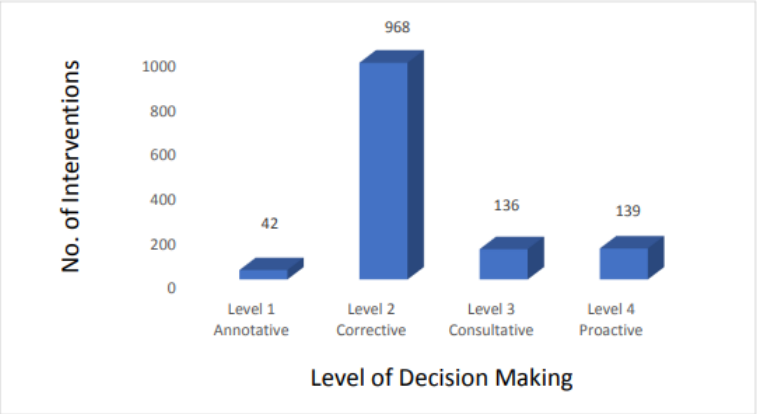

Figure 3: Level of Decision Making by Pharmacist

Drug stopped and new drug started were most common interventions performed, followed by dose and frequency changes. Prescribers requested information regarding drug-drug interactions, and dose adjustment the most. More than half of interventions were of moderate significance and pharmacist level of decision making was corrective action in 75% of cases. 96% of pharmacist interventions were solved. Time taken by pharmacist to identify a problem, suggest recommendations and document the same was 39 minutes. The total time taken by pharmacist to make 1285 interventions was 57,825 minutes.

5. CONCLUSION

CKD is a complex disease with multiple comorbidities, multiple prescribed medications, and attendant complications that can affect the physical and emotional health of the individual. The research project aimed to evaluate clinical and economic consequences of clinical pharmacist intervention in CKD patients. The study found that clinical pharmacist interventions can significantly improve disease control measures, improve health related quality of life, and reduce costs of drug therapy. Employing clinical pharmacists in hospitals is beneficial.Our study was designed to study the kind of drug related problems that occur among chronic kidney patients and the impact of interventions performed by pharmacists in solving the problems. As far as we are aware, this is a unique study that took a holistic look at the problems, interventions, impact on patients' health as well as on the cost of pharmacist interventions in patients with kidney disease. Though there are several studies that have focused on problems related to drugs and recommendations by pharmacist or provision of pharmaceutical care in this population as well as systematic reviews that have documented the outcomes of such studies, most have only characterized the problems and interventions or only looked at the costs or a couple of parameters that reflect disease control in the patient.

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