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ASSESSMENT OF THE IMPACT OF MEDICATION COUNSELLING ON KDQOL SCORE OF PATIENTS WITH CHRONIC KIDNEY DISEASES

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Abstract:

Background*: Chronic Kidney Disease (CKD) is a serious medical and public health problem whose prevalence is increasing worldwide. CKD patients are medically complex, require multiple medications for treatments of their various comorbidities, thus these patients are at risk of drug-related problems (DRPs) that may lead to increased morbidity, mortality, and cost to the healthcare system.* ***Methodology****: This study was a Prospective, Observational Study carried out for a period of six months in tertiary care hospital to assess the impact of medication counselling on the KDQOL of chronic kidney patients. A total of 32 patients undergoing hemodialysis were enrolled into the study who were categorized into test and control groups by randomize method. Patients in the test group received counselling verbally along with the information leaflet, whereas the control group received the counselling only after the end of the study. The QoL of patients were assessed by using Kidney Disease Quality of Life-36 (KDQOL-36) questionnaire at the baseline and at final follow-up.* ***Result****: A statistically significant difference in the domain 4($p< 0.00015$)) and domain 5($p<0.000278$) was found at 2nd follow up period in test group and in contrast, no significant improvement in control group. The impact of pharmacist's medication counselling on QOL in hemodialysis patients had showed significant improvement.in test group compare to control group.* ***Conclusion****: The study suggests that the periodic counselling by a clinical pharmacist at regular intervals has a positive impact on improving the QOL of hemodialysis patients.*

Keywords*: Chronic Kidney Disease, Medication Counselling, KDQOL*

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INTRODUCTION:

Chronic Kidney Disease defines as kidney damage or a glomerular filtration rate (GFR) of less than 60 ml per minute per 1.73 m (body surface area) for three months or more.[1] Currently around 850 million people are affected by various types of kidney disorders. CKD 's global burden is growing, and by 2040, CKD is expected to become the fifth most common cause of years of life lost worldwide.[2]

CKD patients are therapeutically complex, require numerous medicines to treat their various comorbidities, and these patients are at high risk of medication-related problems (DRPs) that may lead to increased morbidity, mortality, and health care costs. Most studies revealed a lack of knowledge, attitude, and practice (KAP) with respect to the drug name; indication, dosage regimen of their medication, disease, and lifestyle changes among hemodialysis (HD) patients with chronic kidney disease (CKD).[3]

Kidney Disease Quality of Life-36 (KDQOL-36) includes both generic and ESRD-specific HRQOL scales. This questionnaire is a globally accepted tool, simple and important for assessing Health related quality of life (HRQOL) in CKD patients as an important outcome and prognostic predictor.[4] Although, over the pass decades' innovative advances in renal replacement therapy (RRT) for treating CKD occurred but there is no clinical improvement achieved**.** When there is no cure for a chronic disease, an essential healthcare goal must be to maximize life quality.[1]

In India the pharmaceutical care concept is not well developed compared to developed countries.[5]Several studies have shown that patient education can retard the progression of renal disease and promote quality of life.[6] The current study was designed to assess the impact of medication counselling on the KDQOL scores of chronic kidney patients.

MATERIAL AND METHODS:

A prospective Observational Study was carried out for 6 months (August 2019 to january2020) at CARE Hospital, Nampally, Hyderabad. The Inclusion Criteria of the study for choosing patient was the age above 18 years, diagnosed with hypertension, diabetics, chronic kidney disease and willing to participate in the study and Patients with other severe debilitating illnesses (stroke, dementia, HIV infection, malignancies, severe complications of heart, lungs, brain, autoimmune disease [e.g. Rheumatoid arthritis], cardiovascular disease, endocrine disease, a history of head trauma and other mental illnesses), hearing impairment/ unable to communicate with researchers or unable to complete the study procedure, Pregnant or lactating women, altered level of consciousness and Patients participating in any other studies which are interventional were excluded from the study.

A sample size of 32 patients (16 patients in the intervention group and 16 patients in the control group) was calculated by using sample size formula for comparison of two means (2-sided), as-summing a standard deviation of 3.58,4.25, using a two-tailed t-test of the difference between means, a power of 90%, and a significance level of 5%. The calculation is based on the assumption that the measurements on environment are normally distributed.

Data was collected using a structured data collection form. Information collected from patient case files included demographic characteristics of the patients, admission unit, co-morbidities, family history, social history, allergies, primary diagnosis, laboratory investigations, drug dosage regimen and KDQoL questionnaires were analysed to calculate the individual scores for test and control group. The statistical significance in the difference in the outcome variables between the groups was calculated by using unpaired t-test. Data was analysed using R studio and MS Excel.

Study methodology was demonstrated in **figure:1**

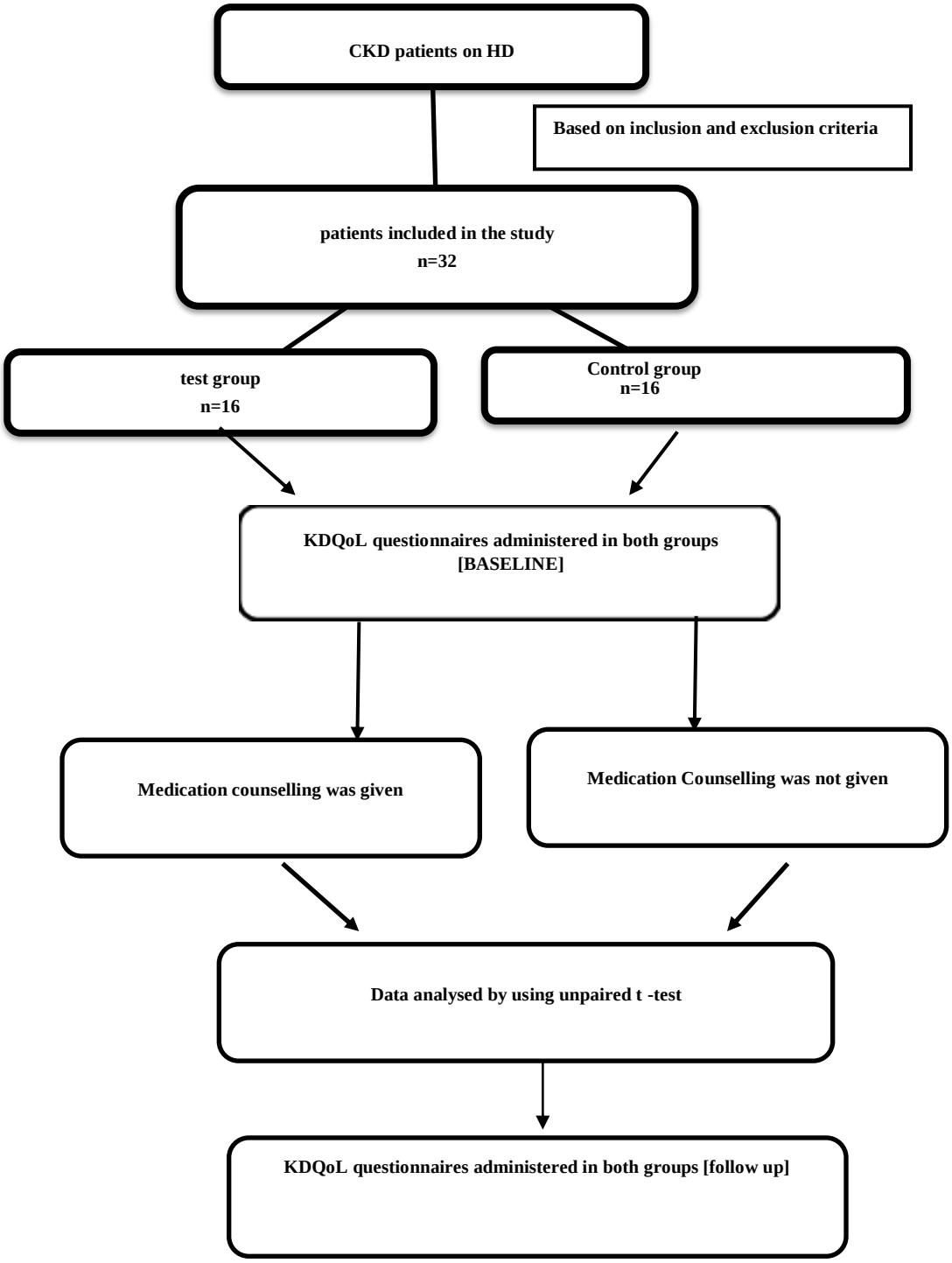

Figure 1: Flow Chart of Study Methodology

RESULT:

There are total 32 patients enrolled in this study based on inclusion and exclusion criteria and all 32 patients completed all the follow-up of this study and there is no drop out in number of patients in the study.

It was found that mean age of study's patients are 55-59 years old and others Baseline characteristics of HD patients are given in **[table no:1].**

	Demographics	TEST GROUP [n=16]	CONTROL group[n=16]
1	Age (mean [STDV])	59.8±9.5	55.3±9.3
2	Gender (NO. OF PATIENTS [% of patients])	Male: 62.5% Female: 43.75%	Male: 68.7% Female: 25%
3	BMI [mean]	23.293	23.3
4	Patient history for CKD	100%	100%
5	Family history of CKD	6.25%	6.25%
6	Educational status • Illiterate • School • Secondary School • University • Graduate	 00 62.5% 18.75% 00 18.75%	 00 50% 18.75% 6.25% 25%
7	Smoking habits • Non smoker • Smoker • Ex-smoker	 75% 12.5% 12.5%	 87.5% 6.25% 6.25%
8	Alcoholic habits • Non alcoholic • Alcoholic • Ex-alcoholic	 81.25% 18.75% 00	 81.25% 12.5% 6.25%
9	Co-morbidities • Yes • no	 100% 00	 87.5% 12.5%
10	Disease specific condition • Hypertension • Diabetics mellitus • both	 31.2% 25% 43.7%	 25% 12.5% 62.5%
11.	Language of counselling Hindi Telugu	 68.75% 33.30%	NONE

Table No - 01: BASELINE CHARACTERISTS OF HD PATIENTS

In this study total forty-nine different types of medication prescribed for CKD HD patients in **[table no: 2]**and patient's medication counselling were given for those medications.

The quality of life of the control and test group were compared for six months and It was found that at the baseline KDQoL- 36 Score of both test and control was significantly impaired and at the end of the study period it was assessed that there was a statistical highly significant improvement in QoL scores seen in the **domain 4 and 5** scores of test group from baseline to second follow up revealed that mean increases from 36.97±11.09 to 48.15±3.99 and 39.68±11.33 to 54.28±3.69 respectively which is statistically significant[$p<0.005$] compare to control group score from baselines to second follow up which didn't show any clinical or statistical significance in scores were given in **[table no:3]**

Table No-02: Details of patient's medication counselling

No.	Drugs used	Number of patients[n=32]	Percentage
1	Amlodipine	9	28.12
2	Aspirin	8	25
3	Aspirin + atorvastatin	3	9.37
4	carvedilol	1	3.12
5	Atorvastatin	6	18.75
6	Betahistine	2	6.25
7	Bisoprolol	7	21.87
8	Calcium + Vit-D3	24	75
9	Calcium carbonate	2	6.25
10	Calcium dobesilate monohydrate	1	3.12
11	Calcium polystyrene sulphonate	1	3.12
12	Cefuroxime	2	6.25
13	Cilnidipine	6	18.75
14	Clonidine	2	6.25
15	Coenzyme Q10	4	12.5
16	Darbepoetin	6	18.75
17	Erythropoietin	23	71.87
18	Folic acid	4	12.5
19	Furosemide	4	12.5
20	Glimepiride	3	9.37
21	Glyceryl trinitrate	1	3.12
22	Inositol nicotinate	1	3.12
23	Insulin	18	56.25
24	Iron	21	65.25
25	Lactulose	6	18.75
26	Levocarnitine	**5**	**15.6**
27	Labetalol	1	3.12
28	Losartan	2	6.25
29	Metoprolol	6	18.75
30	Moxonidine	1	3.12
31	Multi vitamin	13	40.6
32	Nebivolol	1	3.12
34	Ondansetron	1	3.12
35	Pantoprazole	25	78.1
36	Paracetamol	4	12.5
37	Potassium chloride	2	6.25
38	Prazosin	1	3.12
39	Pregabalin	3	9.37
40	Prucalopride	1	3.12
41	Sevelamer	3	9.37
42	Sodium bicarbonate	3	9.37
43	Sodium picosulphate	1	3.12
44	Thyroxine	1	3.12
45	Torsemide + Spironolactone	5	15.6
46	Clopidogrel	3	15.6
47	Rosuvastatin	3	9.37
48	telmesartan	1	3.12
49	Lactoferrin	2	6.25

Table No -03: Kidney Disease Quality of life scores of test and control group

KDQoL	Control (Mean±SD	Test (Mean±SD)	t-value	p-value	Significance
Domain-1 [Symptom/ Problem List]					
Baseline	76.43±12.49	69.22±17.86	1.29411	p>0.005	Not Significant
2nd Follow Up	74.48±11.17	71.56±15.04	0.62283	p>0.005	Not Significant
Domain-2 [Effects of Kidney Disease]					
Baseline	61.72±20.30	63.48±21.88	-0.51833	p>0.005	Not Significant
2nd Follow Up	59.77±19.23	65.51±21.08	-0.80578	p>0.005	Not Significant
Domain-3 [Burden of Kidney Disease]					
Baseline	30.08±29.25	23.44±30.09	0.62239	p>0.005	Not Significant
2nd Follow Up	30.47±39.69	23.44±31.08	0.65558.	p>0.005	Not Significant
Domain-4 [Sf-12 Physical Composite]					
Baseline	41.33±7.98	36.97±11.09	1.24906	p>0.005	Not Significant
2nd Follow Up	39.69±6.70	48.15±3.99	-4.33761	p<0.001	Highly Significant
Domain-5[Sf-12 Mental Composite]					
Baseline	43.39±8.96	39.68±11.33	1.01161	p>0.005	Not Significant
2nd Follow Up	44.23±9.05	54.28±3.69	-4.11489	p<0.001	Highly Significant

DISCUSSION:

CKD has been chosen in this study because its impact on quality of life [QOL] is an important outcome measure in patients on dialysis .[10-17] The major therapeutic goal is to improve the daily functioning ability of these patients so that they can enjoy life up to its full possible extent. This study illustrates how physical, psychological, social functioning, environmental, and general health were affected in CKD patients.

In this study, HRQoL was evaluated using the generic and disease-specific validated KDQoL-36 scale as opposed to the previously conducted HRQoL studies of HD patients using the generic specific HRQoL scales such as SF-36, Karnofsky Performance Status, EQ-5D and WHO-Bref.[3,7,8,11,12,17].

In our study Male predominance is noted over females this may be due to lack of physical activity, stress, lack of family support etc. to females. These findings were consistence with the study conducted on QoL haemodialysis patients [7,14,15,16] and contrast to other study where female predominance over male [9]. In our study greatest number of patients were in the age group of 55 to 59 years compare to previous study where majority of patients in the age groups of 41-50 [14] and 51-60 years.[15] In view of the result, BMI may not influence CKD condition. The results revealed that all patients [n=32, 100%] had a history of CKD ranging from 0 to 5-year duration which is similar to previous study.[14]

Our findings are similar with previous study where majority of patients did not have family history of CKD.In our study, a larger number of patients were e ducated, but they were not aware of risk factors and complications that can be overcome by educating the community about disease, which was consistent wit h earlier research. In this study smoking were not associate with CKD contrast to previous studies which showed association between smoking and CKD. [1] In this study alcohol were not associate with CKD contrast to previous studies which showed association between alcohol and CKD .[1] The results showed that among 16 patients, [n=11, 68.75%] of patients were counselled in Hindi language and [n=5, 33.30%] of patients were counselled in telugu language. As Hyderabad is a multilingual city majority of people speak Hindi, Urdu, telugu and other languages. The result shows that patients having CKD are followed by HTN [(n=26, 81.30%) followed by DM (n=19, 59.40%). similar result shown by previous studies where hypertension is a major risk factor for CKD followed by DM [9, 14,15,16] presented in **table no:01**

Majority of the patients were prescribed with calcium, vitamin d3, Erythropoietin, iron supplement and multivitamin [**table no-02**] because CKD led to deficiency of synthesis of erythropoietin, imbalance in calcium and phosphate levels and multivitamin because patients need to be well nourished. Results from previous studies indicate that patients with hemodialysis have insufficient knowledge and understanding of their medications. [17]

These results were comparable with the studies of patient counselling, patient education, and pharmaceutical care intervention in the HRQoL of patients with HD. [19,20,24,33,34,35,38] The *Abraham et al* study evaluated the impact of patient counselling in HRQoL of HD patients in India at 6 and 12 months. The increase in HRQoL scores was observed in the test group in comparison to the control group in "physical, psychological, environmental and social domains".[8,16] The study conducted by *Thomas et al* assessed the impact of HD patient counselling at 6 months in India on HRQoL patients. In the test group, the increase in HRQoL scores was observed by 2 per cent compared to the control group. [8] The study conducted by *Mateti UV et al* on pharmaceutical care intervention significantly improved the HRQoL scores over time in the domains noticed regarding "physical functioning, general health, emotional well-being, social functioning, list of symptoms / problems and kidney disease effects" .[3] The study conducted by *Balasubramanian T et* al to assess the effects of patient counselling on health-related quality of life among end stage renal disease hemodialysis patients. In India, at six months. Increased QOL scores were highly significant for components of physical and renal disease. [12] The study conducted by *Dashti-Khavidaki et al*, assessed the impact of HD patients at six months in Iran on pharmaceutical care in HRQoL. In the test group, the increase in the scores of HRQoL domains was observed in "role-emotional, mental health, social functioning and general health dimensions" compared to control group. [13]

Our study findings showed improvement in domain 4 and domain 5 scores which represent physical and mental composite respectively. Improvement in physical and mental composite score after counselling may result in clearance of all misconceptions about allopathy drugs, details of each indication of drugs, purpose, strength, side effects associated with drugs and how to report any side effects and how important is to adherence on medication in improving QoL in CKD disease and related to improvement of the self-esteem of HD patients. Our study result showed that pharmacists medication counselling aid to improve of heath related quality of life of CKD patient.

Our study is having many limitations includes small sample size, monocentric study design and Only a single follow-up after counselling was taken because of the limited study period that limit the applicability of results to CKD population undergoing treatment because these patients may require continuous follow-up of several months or even years. Medication adherence was not measured.

CONCLUSION:

Chronic kidney disease (CKD) is a condition with progressive loss of renal function and a worldwide public health problem with an increasing incidence and prevalence, poor outcomes, and high cost. Haemodialysis's patients show a substantial reduction in HRQOL in all health domains. It is a major challenge for healthcare providers to develop various strategies to help improve the HRQOL as part of a well-designed Hemodialysis [HD] care program. In this study during the final follow-up, it was observed that between the groups there was a difference in mean scores in the SF-12 physical and SF-12 Mental Composite Domains Which implies that pharmacist education and counselling has led to clinically significant improvement in the QoL of intervention group as compared with that of control group. We believed that incorporating clinical pharmacist during CKD management through pre-dialysis education programmes will improve patient understanding of disease and adherence that could be translated into improved quality of life, improved prognosis and reduced burden of health care. The study also suggests that the periodic counselling by a clinical pharmacist at regular intervals has a positive impact on improving the QoL of haemodialysis patients.

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