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IMPACT OF CLINICAL PHARMACIST ON MEDICATION ADHERENCE AND QUALITY OF LIFE IN CHRONIC KIDNEY PATIENTS

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ABSTRACT

CKD is the very common chronic disease occurring in the today's world, which is deliberately in need of the continuous monitoring and treatment throughout one's life. The main effect is fall on the quality of life i.e. lack of education, changes in lifestyle and low level of understanding on the management of the disease. The main objective was to look out the impact of the clinical pharmacist and its lead collaborative care on QOL and medication adherence. It was a prospective and observational study. 200 patients were enrolled, only 116 were reported and participated in this study. Interventional group received patients received pharmaceutical care V.IZ. patient counseling, Patient information leaflet(PIL), and frequent noticeable changes. In the baseline, first follow up and second follow ups, medication adherence and QOL were assessed by using Morisky Medication adherence scale and reports, whereas COOP/WONCA QOL questionnaire in both the groups. The results showed that MMAS scores p values 0.007**, 1.000, <0.0001**, 0.007, 0.014 and 0.000 at the baseline, first and second follow-ups respectively. The QOL score p values of physical component scale and mental component scale showed highly significant. This study concluded that the impact of clinical pharmacist provided patient counseling had a positive impact on medication adherence and QOL.

KEYWORDS: Ckd, Observational study, Medication adherence, Quality of life.

1. INTRODUCTION

CKD is a worldwide public health problem and is now recognized as a common condition that is associated with an increased risk of cardiovascular disease and chronic renal failure (CRF). In India, the prevalence and incidence of kidney failure is treated by dialysis and transplantation have increased from 1988 to 2004. This could be due to rapid increasing prevalence of diabetes and hypertension CKD which has turned out the major cause of morbidity and mortality, particularly at the later stages. The same study clearly explained about the importance of public health and medical issues like high hospital rates and increased health costs.[1]

According to WHO, Medication adherence is defined as "the extent to which a person's behavior taking medicine corresponds with agreed recommendations from a health care provider."[World Health Organisation, 2003].[2] It acts as the important link between the treatment and therapeutic efficacy in the medical care.[3] There are two methods to calculate this one is direct method and the other is indirect method. Direct method includes measurement of concentration of drug and its metabolite, detection of the blood sample, moreover drug formulation methods also. These are expensive and difficult to calculate in short period of time for the health care provider. Indirect method is simple as it targets at asking patient about the prescribed medication, assessment of the clinical response, pill counts, patient questionnaire etc. These all details will help the health care provider for the estimation of medication adherence.[4]

Quality of life is a broad concept. We can evaluate both positive and negative aspects of life. They stand out as valid indications and proof for prospective study in order to attain good outcome.[5,11]

This study was carried out in Vijayanagar institute of medical sciences, Bellary in General Medicine department inorder to know the impact of clinical pharmacist on medication adherence and quality of life in ckd patients.

2. MATERIALS AND METHODS

The study technique used here is the prospective randomized study conducted in the Vijay Nagara Institute of medical sciences and Research centre for a period of six months in the general medicine department.

Study criteria

Inclusion criteria

- Patients diagnosed with CKD
- Patients of either of the sex above 30 years

Exclusion criteria

- Patients unable to comply with protocol requirements
- Pregnancy and breast feeding patients

Source of data

Inpatient

Patient case records, medication charts, laboratory reports

Outpatient

Prescriptions

Forms Used

Informed consent form[ICF], Data collection form, Patient informed leaflet[PIL], Morisky 8 medication adherence form, quality of life form and Patient satisfaction questionnaire[PSQ].

Study Procedure

According to eligibility, patients and their family members were informed regarding proposed study details. Patients and their family members were informed about procedure in proposed work and right to withdrawal from study at any moment. In addition, patients can leave the study at any time. The patient's data concerning the reason for withdrawal before completing the treatment were registered and archived for statistical evaluation. Specific reasons for withdrawal of study were:

(1) Voluntary withdrawal from the patient

(2) Development of exclusion criteria during the study or other safety reasons

(3) Non-compliance of the protocol.

The intention-to-treat principle were kept at all times and all subjects were analyzed according to their allocated treatment group. A screening log was also maintained, documented the total number of patients invited for participation, number randomized in the study, screen failures and reasons for screen failures.

Participant information sheet (PIS) in the local language (Kannada, Telgu, Hindi) were provided to all the eligible patients prior to randomization. PIS document provided detail of purpose of this study, measurement and procedures involved, benefits of participation in the study.

The interested participants were explained about the consent details, a brief introduction about the study and its purpose, the procedures involved in the study such as screening, randomization, interventions, benefits, confidentiality terms, the rights of the participant and trial contact information. Patient understanding for the PIS- Informed Consent form (ICF) were cross verified. Concerns or queries regarding the study was also addressed.

Upon agreeing to participate after going through the PIS and ICF forms, two copies of the ICF was signed by the patient and the investigator on the same date. The participants who were unable to read and write was asked to provide their thumb-print impression, plus signature of an impartial witness was also taken. The participant were provided a copy of a signed consent form and the other signed copy of ICF was also filled in the patient study file and stored at the participating site. The researcher was ensured the proper collection and storage of the participant consent forms.

Patients were assigned to the intervention or the control group through a computer-generated randomization designed by a blinded person. After randomization and allocation, the intervention group patients were given pharmaceutical care along with the usual care delivered by clinical pharmacist at the study sites and those allocated to the control group would receive usual care.

Patients who met the inclusion criteria were informed about the study and they were enrolled after their consent. The control group (patients and their families) would receive usual care. Randomization would take place during week zero (baseline) and patients would meet again with the Clinical pharmacist every two months (2nd and 4th month). At each appointment, variables related to the study like effectiveness, safety, adherence, quality of life, were assessed.

PSQ was prepared by selecting the suitable questionnaire and expert to know the impact of the clinical pharmacy services. The obtained data were subjected to statistical analysis.

Statistical Analysis

Descriptive statistical analysis has been carried out in this study. Results were part of continuous and categorically measurements which were presented as mean±SD and in number(%). significance was assessed at 5% level of significance.[12,15]

3. RESULTS

A total of 200 patients were approached and explained about the study procedure and the pattern of the study chronologically, out of which 116 patients agreed to participate in the study. Few patients were dropped out because of negligence, left the place, illiteracy, and age factor. The total number of the patients who had completed the study was 116[58C + 58 I]. The basic demographic variables of patients showed, at the age group of 61-70[34.4%] and above 70[31%] years was found to be more in the control group and in the interventional group. In gender wise, males were more, 41[70.06%] and 32[55.17%] than the females, 17[29.39%] and 26[44.82%] in both control and the interventional group. we considered only the two parameters for the demographic analysis here.

Clinical variable analysis

The clinical variable of the patients showed that only 31[55.3%] had alcohol habit in the control group and non-alcoholics were found to be 31[55.3%] in the interventional group. Non smokers were found more in the both the groups. The hypertension, diabetes mellitus, anemia were the more co-morbid conditions and there is no suggestive of family history of disease in both the groups.

Comparison of Medication Adherence reporting scale scores

The distribution of medication adherence scores of MMAS statistically showed a strongly significant value by using mann whitney u test in SPSS ssoftware, in both the baseline and second follow-up, i.e. 0.007** and <0.001** for MMAS and for MARS the p values are 0.000,0.082,0.003,0.0164,0.102,0.036,0.000 and 0.000 from questions 1-8 at the second follow-up. The overall distributive total of MARS score p value at the second follow-up was 0.000.

Quality of life score domain

The quality of life domain scores were comparatively distributed based on physical fitness, daily activities, social activities, feelings, change in health and overall health of the patients at the baseline, first and second follow –ups. Results was 0.006**, 0.012**, <0.001**, 0.054,

0.193, 0.11*, <0.001**, 0.039 and 0.005**, <0.001**, <0.001**, 0.008**, showing highly significant activity. this method was approached by GRAPH PAD PRISM and that to by chi-square test.

Patient satisfactory questionnaire analysis

The patient satisfactory questionnaire involved about the pharmacist and the role of the disease management based on the certain scoring ie. 33.73±4.3[max score 45] for the clinical pharmacy services and 18.38±1.88[max score 25] for types of counsellings. The dairy cards were returned by only few patients at the end-up of the follow-ups.

Table No. 01: Patient demographic details based on age and gender.

Variables	Control group		Interventional group	
1.AGE IN YEARS	**N**	**%**	**N**	**%**
21-30	0	0.00	0	0.0
31-40	06	10.34	0	0.0
41-50	08	13.73	18	31.0
51-60	10	17.2	14	24.1
61-70	16	27.5	20	34.4
≥ 70	18	31.0	06	10.34
2.GENDER				
MALE	41	70.06	32	55.17
FEMALE	17	29.3	26	44.82
TOTAL	58	100	58	100

***Patient demographic details.**

***Table 2: Shows clinical variables of chronic kidney disease patients along with co morbid conditions.**

Clinical variables	Control group		Interventional group	
1. ALCOHOL	**N**	**%**	**N**	**%**
NO	27	46.5	31	53.5
YES	31	53.5	27	46.5
2. SMOKING				
NO	33	56.8	35	60.2
YES	25	43.2	23	39.7
3. COMORBIDCONDITION				
ANAEMIA	22	37.9	12	20.6
HYPERTENSION	09	15.5	10	17.2
DIABETIS MILLITUS	06	10.3	04	06.8
OTHERS	04	06.8	02	03.4
TOTAL	58	100	58	100

Clinical variables and co morbid factors of CKD.

***Table 3: Shows that comparision of morisky medication adherence scale.**

MMAS	Control group	Interventional group	Pvalue
BASELINE	**2.43 ± 0.62**	**2.01 ± 0.83**	**0.007****
I FOLLOW UP	**3.01 ± 0.61**	**3.01 ± 0.54**	**1.000**
II FOLLOW UP	**3.19 ± 0.81**	**4.00 ± 0.37**	**<0.001****

Over all Comparision of MMAS scale done using SPSS software i.e. Mann whitney test between control group and interventional group where the Pvalue is <0.001 for both groups as it is statistically highly significant.

***Table No. 4: Comparision of control group and interventional group of CKD patients answered for our questions taken from Morisky medication adherence scale.**

MMAS	Control group	Interventional group	Pvalue
1Q: I forgot to take Medicine			
BASELINE	**3.25 ± 1.43**	**3.01 ± 1.26**	**0.0086**
I FOLLOW UP	**3.25 ± 1.26**	**4.17 ± 0.76**	**0.032**
II FOLLOW UP	**3.88 ± 1.21**	**4.87 ± 0.19**	**0.000**
2Q: at times I miss out to date			
B	**4.82 ± 0.29**	**4.35 ± 0.7**	**0.139**
I	**4.76 ± 0.46**	**5.01± 0.00**	**0.422**
II	**4.71 ± 0.56**	**5.01±0.00**	**0.174**
3Q: I stop taking medication			
B	**3.63 ± 1.24**	**3.16 ± 1.26**	**0.116**
I	**4.14 ± 1.11**	**4.18 ± 0.75**	**0.368**
II	**4.32 ± 0.99**	**5.02 ± 0.00**	**0.004**
4Q: Forgetting medication			
B	**4.92 ± 0.39**	**4.65 ± 0.8**	**0.129**
I	**4.88 ± 0.59**	**5.00 ± 0.00**	**0.322**
II	**4.81 ± 0.69**	**5.00 ± 0.00**	**0.164**
5Q: Did you take medication yesterday			
B	**4.88 ± 0.59**	**4.77 ± 0.82**	**0.561**
I	**4.81 ± 0.69**	**4.92 ± 0.39**	**0.464**

II	**4.69 ± 0.88**	**5.00± 0.00**	**0.062**
6Q: Taking medication when disease is under control.			
B	**3.73± 1.24**	**3.15 ± 1.26**	**0.106**
I	**4.12 ± 1.21**	**4.28 ± 0.85**	**0.458**
II	**4.42 ± 0.95**		
7Q: Taking medication is inconvenient?			
B	**3.65± 1.23**	**3.08± 1.16**	**0.089**
I	**3.65 ± 1.23**	**4.27 ± 0.87**	**0.036**
II	**3.88 ± 1.14**	**4.96 ± 0.20**	**0.000**
8Q: Do you remember taking medication			
B	**4.92± 0.39**	**4.85 ± 0.61**	**0.592**
I	**5.00± 0.00**	**5.00± 0.00**	**0.00**
II	**5.00 ± 0.00**	**5.00 ± 0.00**	**0.00**
TOTAL:-			
B	**42.02± 12.01**	**40.05± 12.6**	**0.007**
I	**42.46± 11.96**	**44.58 ± 11.06**	**0.014**
II	**42.81 ± 13.38**	**44.96 ± 10.20**	**0.000**

Morisky medication adherence scale comparing patients.

***Table No. 5: Shows the change in physical fitness, feelings, dailyact, social act, change in health and overall health both in control and interventional group as per COOP WONCA CHARTS. Here P value is statistically significant for feelings, daily act and social activities.**

QOL	Control group	Interventional group	P value
PHYSICAL FITNESS			
BASELINE	**48.06 ± 21.36**	**25.88 ± 30.88**	**0.005****
I FOLLOW UP	**50.00 ± 24.30**	**36.33 ± 25.09**	**0.031***
II FOLLOW UP	**57.48± 28.67**	**70.03 ± 20.64**	**0.004****
FEELINGS			
B	**52.87 ± 11.93**	**37.75 ± 15.60**	**<0.001****
I	**49.48 ± 14.91**	**47.08 ± 16.29**	**0.447**
II	**47.52 ± 15.2**	**70.12 ± 12.54**	**<0.001****
DAILY ACT			
B	**50.73 ± 10.31**	**46.00 ± 20.45**	**0.191**
I	**59.62 ± 12.30**	**50.96 ± 18.34**	**0.07**
II	**49.00 ± 17.61**	**70.23 ± 12.68**	**<0.001****
SOCIAL ACT			
B	**48.96 ± 12.19**	**40.64 ± 22.29**	**0.011****
I	**52.92 ± 16.79**	**49.77 ± 19.29**	**0.227**
II	**55.67 ± 18.87**	**70.99 ± 14.03**	**<0.001****
CHANGE IN HEALTH			
B	**50.00 ± 23.45**	**27.88± 31.09**	**0.006****
I	**54.81 ± 28.30**	**38.46 ± 27.09**	**0.043***
II	**50.85± 28.74**	**72.04 ± 19.34**	**0.005****

OVER ALL HEALTH			
B	**52.88 ± 13.33**	**46.23 ± 16.10**	**0.039***
I	**54.95 ± 12.60**	**50.00 ± 14.14**	**0.289**
II	**56.85± 14.59**	**70.71± 12.11**	**0.001****

Table No. 06: PSQ about the pharmacist provided clinical pharmacy services and types of counselings repectively.

PSQ	CKD
QUESTION OF CLINIICAL PHARMACY SERVICES	**M ± SD**
Q,NO :1 understanding of CKD	**3.65±0.41**
Q,NO : 2 Timing of follow up	**3.01±1.19**
Q,NO : 3 Time for discussion	**3.03±0.99**
Q,NO : 4 Trust on pharmacist	**3.85±0.61**
Q,NO : 5 Rating on CKD medication	**4.25±0.61**
Q,NO : 6 Participation in the study	**3.66±0.75**
Q,NO : 7 Use of study	**4.10±0.43**
Q,NO : 8 Effect of advice by pharmacist	**3.02±0.10**
Q,NO : 9 Role of pharmacist	**4.00±0.46**
OVER ALL	
Q,NO : 10 Explanation of CKD	**4.10±0.33**
Q,NO : 11 Explanation on the purpose of medicine	**3.62±0.75**
Q,NO : 12 Advice on how best to take medicine	**3.11±0.51**
Q,NO : 13 Explanation on possible side effects	**4.04±0.46**
Q,NO : 14 Disease/drug pills and dairy card	**3.22±0.61**
TOTAL	**20.38 ± 2.88**

DISCUSSION

In this study, only 116 students were accepted and participated because maximum people had an afraidness to give the consent, location difficulty in follows- ups and what the pharmacist can do. The consented people were participated and few people were dropped off due to negligence, illiteracy.

The results show a very good improvement from the baseline to the second follow up. This strongly proved that there is a clinical pharmacist influence/positive impact on patient counseling [i.e. INTERVENTION MADE AND PROVIDED PILS]. these were noted based upon the previous reported studies V.1.2[‘’A STUDY ON IMPACT OF CLINICAL PHARMACIST INTERVENTIONS ON MEDICATION ADHERENCE AND QUALITY OF LIFE IN RENAL HYPERTENSIVE PATIENTS (Ramanath et al’’].

The assessment of medication adherence scores by MMAS clearly proved that there was a better improvement in the medication adherence behaviour of patients both in control and interventional groups. Due to repeated follow ups, the control group showed little improvement i.e. p value was estimated to be 0.007 in the baseline study, 0.014 in the first follow-up and 0.000 in the second follow-up as it indicates not much change in the study.

However there was a very good improvement in interventional when compared to control group i.e. p value was estimated to be 0.007 in the baseline study 1.000 in the first follow up and <0.001 in the second followup as it indicates that it is statistically strongly significant because of which the intervention group patients provided with counseling PILS, and frequently reminding them and makes them to strongly adapt to think about the disease management. This was previously reported in [‘’INTERVENTION TO IMPROVE PATIENT ADHERENCE WITH CKD AT TERITIARY CARE TEACHING HOSPITAL (Palaniswamy et al..)].

The co releative results of the baseline to the second follow-ups show that there is good improvement in the medication adherence and the various factors influencing for the non adherence rate was replaced from the baseline to the II follow up. Hence we can say that the adherence behavior directly influences on QOL of a chronic CKD patient. This was taken from [‘’A STUDY ON IMPACT OF CLINICAL PHARMACIST INTERVENTIONS ON MEDICATION ADHERENCE AND QUALITY OF LIFE IN RENAL HYPERTENSIVE PATIENTS (Ramanath et al)’’].

The various QOL domain scores as per [‘’COOP WONCA CHARTS’’] showed a good improvement whwn compared the baseline to I follow up and from I follow up to II follow up and the baseline to II follow up. Individually if we would look at, the overall QOL was improved.

How ever we cant consider this in case of CKD as continuos monitoring is constantly required. This was reported as per [‘’QOL OF CKD PATIENTS TREATED AT AN OUT PATIENT CLINIC’’(cavalcanta et al, 2005)].

The dairy cards were provided to control and interventional group patients as a remainder to their medications returned back were less.it may be due to forget fullness, lack of education and negligence. If returned, there may be chances of showing more important in the management of disease.

About 70% of the patients were satisfied about the pharmacist provided clinical pharmacy services and types of counseling was observed. This shows that definitely in the area of clinical pharmacy, it has evoked the role of pharmacist by providing good impact aand need to find out reason and strategy to show much more improvisation.

We have fabricated biosynthesized gold nanoparticles based *in situ* drug delivery systems using LM leaf extract as a source of natural anticancer compounds such as Apigenin, Eupatorine, Cirsilineol, Eupafolin and Hispidulinetc using green chemistry approach. The green synthesized gold nanoparticles have found to be highly stable for long time and biocompatible towards *in vitro* and *in vivo* systems. Interestingly, b-Au-LM-1 has found to have enhanced anticancer activity than pristine LM extract in different cancer cells. Detailed mechanistic studies have been carried out and have found that b-Au-LM-1 can inhibit the cancer cells through multi-regulatory actions mainly by ROS mediated apoptosis pathway. The results altogether demonstrate that, the biosynthesized gold nanoparticles based drug delivery systems consisting with natural anticancer phytochemicals fabricated by eco-friendly and cost effective approach can be the alternative medicine for cancer therapeutics in near future.

5. CONCLUSIONS

In the present study, the clinical pharmacist interference / intervention among the Bellary population has a very strong proliferation impact in creating awareness about the disease and its maintenance by increasing their MH and QOL.

In the study one, we proved that by randomized technique V.I.Z. division into control and interventional group showed how effectively patients were involved in the study. It also

showed the combined and effective relation between the pharmacist and the patient from the base line studies to all the follow ups.

We have done a simple and clear approach, ingenious and an ideal method to emphasize the role of clinical pharmacist in the chronic kidney disease through parameters like MH and QOL.

When evaluating the long term outcome of CKD patients, the optimal timing of the assessment is essential because the emotional domain seem to improve slowly both in males and females. This study also showed data QOL and MH in one patient was substantially reduced after 6 month follow up as opposed to baseline study. Moreover the follow up time is too short for a reliable assessment of recovery in CKD patients since patients often need a longer time to get accustomed to new and more restricted circumstances. This study also concluded that pharmacist involvement is very important in the chronic kidney diseases prevention and also management of certain population for increasing QOL by preventing recurrence of the disease, its progression and minimizing of the hospital admissions.

Future Perspective

- We can implement the public health activities and clinical practice enabling the detection of CKD by using objective measures.
- Incidence and prevalence of CKD.
- We can also estimate the total protein and albumin, GFR and other factors that increase transiently which is the threshold for the definition of CKD.
- Additionally we can also develop the pharmacist role in optimizing the drug therapy, laboratory monitoring and medication reconciliation.
- We can also emphasize our study on the improvement of the Medicare prescription of drug and modernization services of CKD which is to optimize the therapeutic outcomes and medication safety.
- Considering the above advantages the role of clinical pharmacist and its lead collaborative care on QOL and MH place a critical role in the health care system.

However, the major issues and challenges should be addressed properly and new care model should be evaluated to improve the QOL and MH for the safety purpose. Hence pharmacist are ideal member of the health care wing to address the education and the communication gap between patient, provider and the health care system.

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