IMPACT OF CLINICAL PHARMACIST IN IMPROVING QUALITY OF LIFE IN PATIENTS WITH EARLY STAGES OF CHRONIC KIDNEY DISEASE

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ABSTRACT

Background: Clinical Pharmacists play an important role in evaluating patients' risk of chronic kidney disease (CKD), and earlier intervention can have a major influence on patient outcomes.

Aim: To assess the impact of Clinical Pharmacist-led intervention on medication adherence and improving quality of life in patients with early stages of CKD.

Methods: A prospective interventional study was conducted in general medicine department in tertiary care hospital for a period of 6 months, 150 patients with CKD were included in the study. Patient's adherence to medication was assessed with the help of Morisky Medication Adherence Scale, Quality of life and Impact of clinical pharmacist were assessed with the help of self made questionnaire.

Results: Regarding Quality of life, after receiving patient counselling, the number of patients with high scores increased from 32 (21.34%) during the baseline visit to 77 (51.33%) at the final follow up. In terms of the impact of clinical pharmacists, 86 (57.34%) patients gave us the highest marks, while 36 (24%) gave us ordinary value

Conclusion: By this study, it is concluded that Clinical pharmacists provided patient counselling can help in improving medication adherence and quality of life.

Keywords: Chronic Kidney Disease, Hypertension, Diabetes Mellitus, Quality of Life, Patient Counselling, Clinical Pharmacist

- ## Introduction

Chronic kidney disease, commonly known as chronic renal disease or CKD, is a disorder in which kidney function gradually declines over time. Over 7.8 million persons are thought to be affected by chronic renal disease in India.There are numerous etiologically unique causes of CKD. Currently, diabetes and hypertension are the two main contributors to CKD, although other common contributors include infectious glomerulonephritis, renal vasculitis, ureteral obstruction, genetic changes, autoimmune illnesses, and others. Diabetes and hypertension are currently responsible for 40–60% of CKD cases in India.

This may lead to decreased quality of life due to lack of awareness about their condition and due to their carelessness of not adhering to medication. The most approachable health care providers, such as Clinical Pharmacists play a critical role in determining a patient's disease status and how it affects their everyday life. As a result the Clinical Pharmacist role is primarily focussed on enhancing quality of life and medication adherence. Accordingly, a Clinical pharmacist's main responsibility is to inform patients about their disease status and to help them adjust their lifestyles in order to improve their quality of life.

Clinical pharmacy is one of the newest fields of pharmacy in the twenty-first century. It does not limit a pharmacist's function to sound manufacturing processes, simple procurement, correct preparation, distribution, and drug product control. Additionally, it includes tasks required to fulfill a certain set of social obligations associated to the appropriate therapeutic use of medicines, such as prescribing, distributing, and administering medications, recording professional services, involving patients directly, reviewing drug usage, and providing education, consultation, and counselling.

This paper attempts to explain that Clinical Pharmacists play an important role in evaluating patients' risk of chronic kidney disease (CKD), and earlier intervention can have a major influence on patient outcomes.

- ## Methodology

Study design: Prospective Interventional study

Study site: Study was conducted in the Department of General Medicine at (SVRRGGH) Sri Venkateswara Ramnarain Ruia Government General Hospital, tertiary care teaching hospital, Tirupati**.**

Study duration: 6 months (April 2022 – September 2022)

Study population: Approximately 150 patients

Study materials:

- Informed consent form (ICF)
- Self-Prepared Questionnaire form including MMA scale

- Patient informative leaflets

Study criteria:

Inclusion criteria:

- CKD patients of stages 1, 2 and 3.
- CKD patients with Chronic Hypertension and Chronic Diabetes Mellitus.
- Patients with age group above 18 years of either sex.
- Patients willing to participate in the study.

Exclusion criteria:

- Patients with Incomplete information
- Patients who are unwilling to participate in study
- Patients with End Stage Renal Disease.
- Patients undergoing Dialysis
- Patients who are Pregnant women
- Patients with urinary tract obstructions
- Patients of age group above 80 years

Study procedure:

Patient enrollment and data collection:

Patients who met the inclusion criteria were enrolled. Participants in the study were told about the Nature of the investigation, and their informed consent was secured. Patient information was gathered using an appropriate self-made questionnaire form, a patient interview, prescriptions, and case profiles.

Measuring Medication Adherence:

Medication Adherence scores were calculated using their responses through use of The Morisky Medication Adherence Scale (MMAS-8) by conducting a patient interview. The scale consists of eight questions, the first seven of which have a binary answer (yes/no) indicating adherent or non-adherent behavior. For question 8, a patient can select an answer on a 5-point Likert scale indicating how frequently he or she fails to take his or her medications. To determine the effectiveness of clinical pharmacist counselling regarding medication adherence ,the clinical pharmacist collected patient information via MMAS questionnaire at the baseline and also during the follow-up.

Scale ranges

- Higher scores(8) indicate low adherence
- Moderate scores(6-8) indicate better adherence
- Low scores(<6) indicate high adherence

Based on the score obtained, Medication adherence is determined.

Measuring Quality Of Life:

Patients were interviewed and their responses to an appropriately adapted self-made questionnaire was used to determine their Quality of Life scores. The scale consists of eleven questions which describes General Functional status, Positive Wellbeing and Physical activity. The study Pharmacist conducted the questionnaire at baseline as well as during follow-up to assess the impact of education on patient medication adherence.

Scale ranges:

- Higher scores (20-22) indicating better functioning and well being
- Moderate scores (11-19) indicating poor QOL
- Lower scores (<10) indicating abnormal functioning and worst QOL

Based on the scores obtained, QOL was determined

Measuring Impact of Clinical Pharmacist:

At the end of the session, a self-made 10-item questionnaire was used to measure the impact of the clinical pharmacist through patient interview. There are eight questions, each worth 10 points and two questions contain binary answers (yes/no), with yes receiving 10 points and no receiving 0.

Scale ranges:

- High scores(60-100) imply that patient counseling has a greater impact.
- Moderate scores(50) require improved patient counseling
- Lower scores(0-40) indicate worse patient counseling.

Based on the scores obtained, Impact of clinical pharmacist was determined

Preparation of Patient information Leaflet:

An information leaflet for patients was created. Information regarding Chronic Kidney Disease, its relationship to Hypertension and Diabetes Mellitus, risk factors, symptoms, complications,

therapy, and dietary and lifestyle changes that patients must adhere to are all included in the leaflet.

Follow-up:

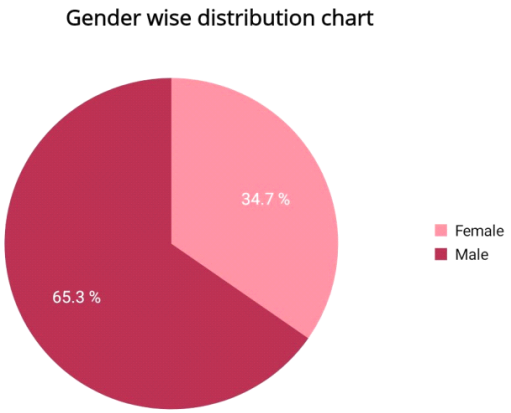
Throughout the six-month period, patients got regular follow-up calls. The clinical pharmacist educates patients about their disease, medications, and important lifestyle changes they would need to make.

3. Results

Subsequent to collection, application of demographic details and scores of self-made questionnaire were entered into the Microsoft Excel-2007 and calculation was made.

TABLE 1: GENDER WISE DISTRIBUTION OF PATIENTS

GENDER	NUMBER OF PERSONS	PERCENTAGE (%)
MALE	98	65.34
FEMALE	52	34.66
TOTAL	150	100%

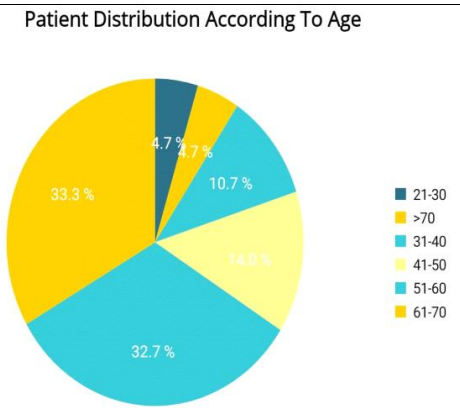


Out of 150 patients maximum number of patients were male 98(65.3%) followed by female were 52(34.7) respectively

TABLE 2: PATIENT DISTRIBUTION ACCORDING TO AGE

AGE(Years)	Total Number Of Patients (%)
21-30	7(4.66%)
31-40	16(10.67%)

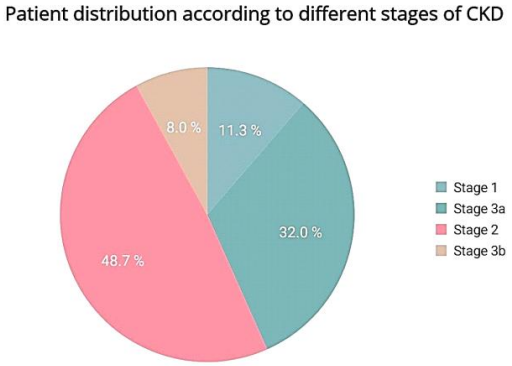
41-50	21(14%)
51-60	49(32.67%)
61-70	50(33.34%)
>70	7(4.66%)
Total	150 patients (100%)



Out of 150 patients, highest number of patients were under the age group of 61-70years were 50 (33.34%), followed by 51-60 years were 49 (32.67%), 41-50 years were21(14%),31-40 were years 16(10.67%),21-30 years were 7(4.66%),>70 years were 7(4.66%).

TABLE 3: STAGES OF CKD

Stages Of CKD	Number Of Patients	Percentage%
Stage 1	17	11.34
Stage 2	73	48.66
Stage 3a	48	32
Stage 3b	12	8
Total	150 patients	100%



Out of 150 patients, highest number of patients are there in stage 2 were 73(48.66%), followed by stage3a were 48 (32%), stage 1 were 17(11.34%), stage 3b were 12(8%) respectively.

TABLE 4: CKD WITH OTHER COMORBIDITIES

COMORBITY	NO OF PATIENTS (%)
HTN+DM	46(30.7%)
HTN	34(22.7%)
DM	20(13.3%)
CVD	17(11.3%)
THYROID	12(8%)
ASTHAMA	11(7.3%)
ANEMIA	10(6.7%)

The majority of patients with other co-morbidities among the 150 patients were HTN+DM, with 46 (30.7%), followed by HTN (22.7%), DM (13.3%), CVD (11.3%), THYROID (8%), asthma (7.3%), and anaemia (6.7%), in that order.

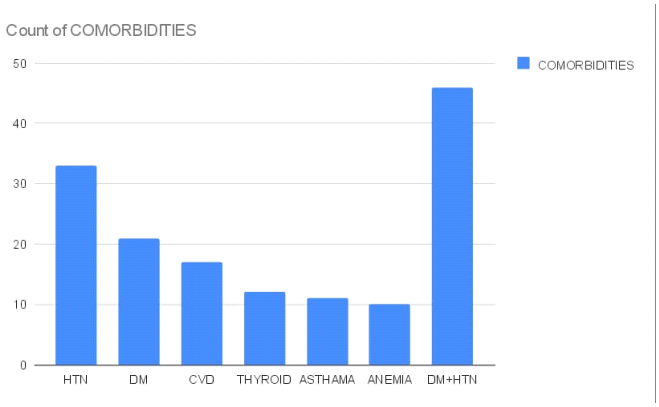


TABLE 5: ADHERENCE TO MEDICATION PRE AND POST COUNSELLING

Adherence	Before counselling Baseline values (%)	Post intervention (after counselling) (%)
High	9(6%)	32(21.34%)
Medium	42(28%)	110(73.33%)
Low	99(66%)	8(5.33%)

Out of 150 patients, good adherence was identified in 9(6%), medium adherence in 42(28%), and low adherence in 99(66%) prior to teaching 32 (21.34%). Patients with high adherence during the baseline visit were 6%, which subsequently increased to 21.34% following patient counseling. Patients with poor and medium adherence during the initial visit were 9 (6%), 42 (28%) and 8 (5.33%), respectively.

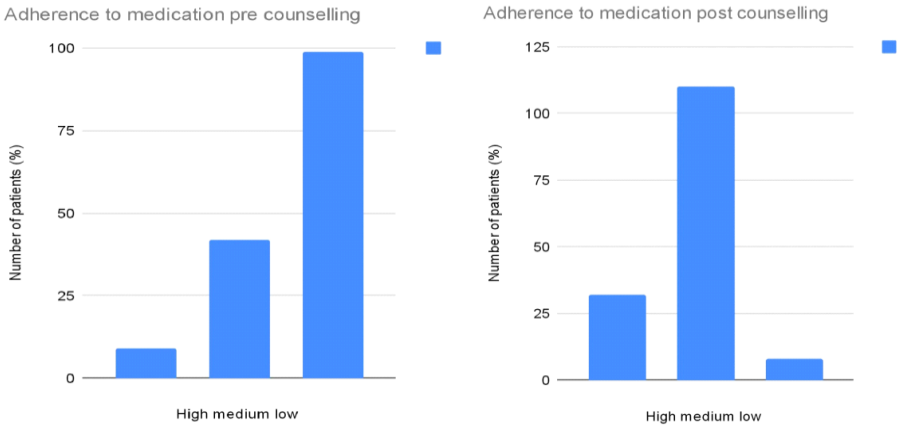


TABLE 6: MEDICATION ADHERENCE PRE AND POST COUNSELLING AMOUNG MALE PATIENTS

Adherence	Medication adherence pre counselling among male patients (%)	Post intervention (after patient Counselling) (%)
High	5(5.10%)	20(20.408%)
Medium	29(29.59%)	72(73.469%)
Low	64(65.31%)	6(6.123%)

TABLE 7: MEDICATION ADHERENCE PRE AND POST COUNSELLING AMONG FEMALE PATIENTS

Adherence	Medication adherence before counselling among female patients (%)	Post-intervention (after patient Counselling (%)
High	4(7.692%)	12(23.077%)
Medium	13(25%)	38(73.077%)
Low	35(67.308%)	2(3.846%)

It was found that small range of significant difference exist between medication adherence in male and female i.e., females were found to be more adhered to medication by 96.1% than male 93.8%.

TABLE 8: MEDICATION ADHERENCE PRE AND POST COUNSELLING IN DIFFERENT STAGES OF CKD

CKD STAGES	HIGH ADHERENCE		MEDIUM ADHERENCE		LOW ADHERENCE	
	Before Counselling	After Counselling	Before Counselling	After Counselling	Before Counselling	After Counselling
Stage 1	0	2	1	14	16	1
Stage 2	5	15	28	55	40	3
Stage 3a	2	9	9	36	37	3
Stage 3b	2	6	4	5	6	1

Out of 150 patients included in our study as shown in Table 15, CKD patients with stage 2 were found to be more adhered than patients undergoing dialysis and patients of other CKD stages.

TABLE 9: AGE WISE DISTRIBUTION OF MEDICATION ADHERENCE PRE AND POST COUNSELLING

Age	ADHERENCE					
	High		Medium		Low	
	Baseline valves before counselling (%)	Post intervention (After counseling (%)	Baseline valves before counselling (%)	Post intervention (After counseling (%)	Baseline valves before counselling (%)	Post intervention (After counseling (%)
21-30	0	3	3	4	4	0
31-40	1	10	5	6	10	0
41-50	2	12	8	8	11	1
51-60	4	24	21	21	24	4
61-70	8	29	11	10	31	11
>70	0	4	3	3	4	0

Individuals aged 61-70 years were less adherent to their medication regimen than others, and medication adherence increased following successful patient education through counselling.

TABLE 9: REASONS FOR MEDICATION NON ADHERENCE PRE AND POST COUNSELLING

Reasons	Pre counselling baseline valves (%)	Post intervention (after counseling) (%)
Forgetfulness	14(9.33%)	05(3.33%)
Pill burden	12(8%)	12(8%)
Concerned about cost	12(8%)	12(8%)
Carelessness	11(7.33)	05(3.33%)
Fear of side effects	07(4.66%)	0
Lack of information	06(4%)	01(0.66%)

The most prevalent cause for non-adherence was forgetfulness (9.33%), pill burden (8%), expense worry (8%), carelessness (7.33%), fear of adverse effects (4.66%), and the least influenced issue was lack of knowledge (4%). After patient education, forgetfulness decreased to 3.3%, carelessness decreased to 3.3%, fear of adverse effects decreased to 0%, and lack of information decreased to 0.66%. But the cost and burden of taking pills remained an issue.

TABLE 10: NUMBER OF PILLS TAKEN BY THE PATIENTS

Number of pills	Number of patients (%)
1 to 5	26(17.34%)
6 to 10	69(46%)
11 to 15	49(32.66%)
>15	6(4%)

In our investigation, it was shown that 26 patients had a daily tablet load of 1 to 5, 69 patients had a pill burden of 6-10, 49 patients had a pill load of 11-15, and 6 patients had a pill load of >15.

TABLE 11: QUALITY OF LIFE OF PATIENTS PRE AND POST COUNSELLING

S.NO	Quality Of Life	Mean Value Before Education	Mean Value After Education
1	Emotional well being	100/9=11.11	12.3
2	Pain	80/9=8.88	9.5
3	Social functioning	73/9=8.11	9.2

4	Physical functioning	86/9=9.5	10.5
5	Energy /fatigue	130/9=14.44	14.96
6	Roll limitation to emotional problem	140/9=15.55	13.5
7	Health change	90/9=10	11
8	General health	60/9=6.66	6.95
9	Roll limitation to physical health	62/9=6.88	7.2

Before and after patient counseling, the quality of life of 150 patients was evaluated. As demonstrated in Table 19, there was a small improvement in the Quality of Life of CKD patients following patient counseling. The domain with the highest average score was Role restriction due to emotional disorder (15.55%), while the domain with the lowest average score was Role limitation due to General health (6.66%).

TABLE 12: QUALITY OF LIFE ASSESSMENT

SCORE RANGES FOR Q /L	**BEFORE COUNSELLING NUMBER OF PATIENTS**	**AFTER COUNSELLING NUMBER OF PATIENTS**
BEST (20-22 SCORE)	32(21.33%)	77(51.34%)
BETTER (11-19 SCORE)	38(25.34%)	53(35.33%)
POOR (<10 SCORE)	80(53.33%)	20(13.33%)

The patient's quality of life was evaluated both before and after counseling. After patient counseling, it was discovered that the Quality of Life of the CKD patients had somewhat improved, as indicated in Table 20. Out of 150 patients, 77 (51.33%) had the highest scores (between 20 and 22), followed by 53(35.34%) who received better results (between 11 and 19), and 20(13.33%) who received worse scores (below 10)

TABLE 13: IMPACT OF CLINICAL PHARMACIST ASSESSMENT

SCORE RANGE OF CLINICAL PHARMACIST ASSESSMENT	NUMBER OF PERSONS	PERCENTAGE(%)
BEST (60-100SCORE)	86	57.34%
BETTER (50 SCORE)	36	24%
WORST (0-40SCORE)	28	18.66%

The impact of the clinical pharmacist was evaluated. Out of 150 patients, 86 (57.34%) patients provided us with the highest scores (60-100), followed by 36 (24%) patients who chose to give us average scores (50), and 28 (18.66%) patients ended up giving us the lowest scores (0-40).

- **Discussion**

Our study included 150 patients as shown in Table 1, males were found to be profoundly affected 98(65.34%) compared to females 52(34.66%). This may be due to lifestyle of the males which differs from females.

As indicated in Table 2, patients were discovered in the age groups of 21 to 30 years (7 (4.66%)), 31 to 40 years (16(10.67%), 41-50 years 21 (14%), 51-60 years 49 (32.67%), 61-70 years 5 (32.9%), and >70 years (7(4.66%). The age range 61-70 years had the highest percentage of patients.

In a study on "Assessment of risk factors and medication adherence of CKD" conducted by Syeda Firdous, Ayesh Siddiqua et al., it was discovered that 41-50 year old patients were more adhered, 92 (30.%), than the remaining age groups [(54)].

As shown in Table 3, 11.34% of those in the current study were in CKD stage 1, 48.66% were in CKD stage 2, 32% were in CKD stage 3a, and 8% were in stage 3b. Stage 2 had the highest percentage of cases.

Siva Kala T, Arepalli Sreedevi, Hari Prasad MV, and Jikki PN conducted a study on "Assessment of knowledge and adherence to therapy among CKD patients," and discovered that 68.9% of patients were in stage 5, 15.53% were in stage 4, and 11% were in stage 3, with 85% of patients on HD [(55)].

As indicated in Table 4, the comorbidity linked with CKD included HTN+DM (30.7%), HTN (22.7%), DM (13.3%), cardiovascular disease (11.3%), thyroid (8%), asthma (11.3%), and anemia (6.7%). In our investigation, it was shown that 46 out of 150 patients had HTN+DM (30.7%).

Olumuyiwa J.F, Peter Ehizokhale Akhideno, Oluwatosin Beatrice Ibiyemi-Fasipe et al. discovered in a previous study on "The burden of polypharmacy and pattern of comorbidities among chronic kidney disease patients in clinical practice" that the main co-morbidities associated with CKD were HTN (83.70%), DM (31.70%), Coronary Heart Disease [56].

As demonstrated in Table 5, out of 150 patients, good adherence was identified in 9(6%), medium adherence in 42(28%), and low adherence in 99(66%) prior to teaching 32 (21.34%). Patients with high adherence during the baseline visit were 6%, which subsequently increased to 21.34% following patient counseling. Patients with poor and medium adherence during the initial visit were 9 (6%), 42 (28%) and 8 (5.33%), respectively.

In a research on "Medication adherence in individuals with advanced Chronic Kidney Disease" done by W. Tesfaye, R. Castelino, et al., 35 patients out of 78 were found to be non adherent (45%), while 55% patients were found to be adhered [57].

In this study as shown in Table 6and 7, it was found that small range of significant difference exist between medication adherence in male and female i.e., females were found to be more adhered to medication by 96.1% than male 93.8%.

A comparable study on "Determinants of compliance behavior among patients undergoing haemodialysis" done by Yoke Mun Chan, Mohd Shariff et al. discovered no significant difference in medication compliance between male and female individuals [58].

Out of 150 patients included in our study as shown in Table 8, CKD patients with stage 2 were found to be more adhered than patients undergoing dialysis and patients of other CKD stages.

As demonstrated in Table 9, individuals aged 61-70 years were less adherent to their medication regimen than others, and medication adherence increased following successful patient education through counselling.

Tangkiatkumjai M, Walker D M, and colleagues did a prior research. et al. on "The relationship between medication adherence and clinical outcomes in CKD patients." It was shown that patients aged 28-39 years reported medication non-adherence at a greater proportion (38%) than those aged 60 and up (21%)11 [59].

As demonstrated in Table 10, the most prevalent cause for non-adherence was forgetfulness (9.33%), pill burden (8%), expense worry (8%), carelessness (7.33%), fear of adverse effects (4.66%), and the least influenced issue was lack of knowledge (4%). After patient education, forgetfulness decreased to 3.3%, carelessness decreased to 3.3%, fear of adverse effects

decreased to 0%, and lack of information decreased to 0.66%. But the cost and burden of taking pills remained an issue.

In a study conducted by Bhupendra Verma, Amrita Singh, J. S. Bishnoi, Anil Kumar Mishra conducted a study on "Adherence to medication in chronic kidney disease". It was found that High cost of medications (72%) and need to take medicines for long durations (59%) were among the most common types of non-adherence. High pill burden and complex dosing schedule were other common causes of non-adherence in this study. Prescription of ≥ 4-5 pills/day has been significantly associated with non-adherence in CKD patients. Fear of adverse effects of medications, lack of knowledge about necessity of individual drug, and lack of knowledge and insight about nature of disease were other important factors [(60)].

In our investigation, as demonstrated in Table:11, it was shown that 26 patients had a daily tablet load of 1 to 5, 69 patients had a pill burden of 6-10, 49 patients had a pill load of 11-15, and 6 patients had a pill load of >15.

Yi-Wen Chiu, Isaac Teitelbaum, and Madhukar Misra did a study on "Pill load, adherence, hyperphosphatemia, and quality of life in maintenance dialysis patients." Oral drugs were shown to lead to a median daily pill burden of 19. The daily pill load was greater than 10 in 91% of individuals, greater than 20 in 47%, and greater than 30 in 17% [(61)].

Before and after patient counseling, the quality of life of 150 patients was evaluated. As demonstrated in Table 12, there was a small improvement in the Quality of Life of CKD patients following patient counseling. The domain with the highest average score was Role restriction due to emotional disorder (15.55%), while the domain with the lowest average score was Role limitation due to General health(6.66%).

The domains with the lowest average score in a study conducted by Keila Batista Alves, Nathalia, and Cristina Sanches on "Is quality of life associated with compliance to pharmacotherapy in patients with chronic kidney disease undergoing maintenance hemodialysis" were physical role functioning (0.0) and emotional role functioning (33.3%). The domain social role functioning, on the other hand, had the highest average score (100.0%) [(62)].

The patient's quality of life was evaluated both before and after counseling. After patient counseling, it was discovered that the Quality of Life of the CKD patients had somewhat improved, as indicated in Table 20. Out of 150 patients, 77 (51.33%) had the highest scores (between 20 and 22), followed by 53(35.34%) who received better results (between 11 and 19), and 20(13.33%) who received worse scores (below 10).

At the end of the project, Table 13 demonstrates the impact of the clinical pharmacist. Out of 150 patients, 86 (57.34%) patients provided us with the highest scores (60-100), followed by 36 (24%) patients who chose to give us average scores (50), and 28 (18.66%) patients ended up giving us the lowest scores (0-40).

In a previous study by Javedh shareef, Kripa G S, et al on Impact of Pharmacists' Counseling on Quality of Life in Patients Undergoing Hemodialysis in a Tertiary Care Teaching Hospital it was observed that the At the 5% level of significance, there is a difference in mean scores in all four domains, indicating that pharmacists' counseling had an influence on enhancing QOL in the intervention group [63].

4. Conclusion

This study found that clinical pharmacist involvement has a significant influence on raising patients' knowledge of their disease and maintaining it by enhancing medication adherence and quality of life. As clinical pharmacists, we counselled patients about their illnesses and drugs, and we were successful in raising patients' awareness of their problems and how to treat them. In order for them to lead healthier lifestyles, we provided them with lifestyle suggestions, nutrition counselling, and exercise instruction. There was a statistically significant improvement in medication adherence and lifestyle management after the follow-up. The importance of counselling in improving the quality of life for CKD patients is highlighted by these outcomes.

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