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# Research Article

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# Prevalence of Depression, Adherence, and Quality of Life in Advance Chronic Kidney Disease and Hemodialysis Patients: A prospective follow-up Study

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# **Background:**

Many patients with end-stage renal disease (ESRD) have poor physical and mental health, little is known about these health domains in individuals with advanced chronic kidney disease (CKD). The study aimed to study how symptoms, depression, and health-related quality of life (HRQoL) differed between ESRD and CKD patients.

# **Methodology:**

Patients with ESRD and those with advanced CKD are included in the study. The Morisky Lewis Greens Adherence measures, Hamilton Depression Rating Scale, and KDQOL-SF-36 were used to assess patients' adherence, depression, and HRQoL, and these health domains were compared between patient groups.

#### **Results:**

A total of 314 patients participated in the study, the mean age of participants was 54.64±15.33. Hypertension and diabetes remained the predominant comorbid conditions with prevalence rates of 64.2% and 74.6%, respectively which is significantly higher level of depression observed, which also deteriorates follow-up periods in both groups of patients. The anemic condition remained the major problem among patients with ESRD. The results show thay the overall HRQoL domain and scale parameters were deteriorating the follow-up period. Scores on the SF-36 Physical Component Summary and the SF-36 Mental Component Summary were similar.

# **Conclusions:**

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Patients with ESRD and advanced CKD have similar symptom burdens, depression rates, and poor HRQoL. Given the well-known impairments in both patient groups, the findings of this study highlight the significant decline in the physical and psychological well-being of CKD patients.

**Keywords:** Chronic Kidney Disease, Heath related Quality of life, Depression, Hemodialysis, Medication Adherence.

#### 1. INTRODUCTION:

Advanced Chronic Kidney Disease (CKD) is a public health problem globally and can lead to conditions including kidney failure, and cardiovascular problems[1]. In different regions of the world, CKD has reached an epidemic rate in people with ages ≥20 years who are most affected by this disease. The total number of men & women with CKD was 225.7 million and 271.8 million respectively till 2010 [2]. According to the new research, the global prevalence of CKD was 9.1% in 2017(697.5 million cases). Women and girls (9.5 %) had a greater age-standardized global prevalence of CKD than men and boys (7.3%). China (132.3 million) and India (115.1 million) accounted for about a third of all CKD cases, with ten countries having more than ten million cases and 79 nations having more than one million cases[3].

Alongside the improvement in the dialysis process and advancement in therapy, the prevalence of CKD continues to upsurge in most countries. It is higher in Japan at approximately 2000 per million populations and in developing countries of Africa and Asia[4], it varies from 100-400 per million population (PMP)[5]. Although the reliability of the data received from low and middle-income countries (LMICs) is uncertain as experts usually believe that CKD prevalence allover the world is about 150 PMP [6].

The impact of CKD is higher in low-income countries with the highest prevalence rate[7, 8]. The treatment affordability is challenging with CKD leading to higher mortality[9]. CKD is a chronic medical condition for many different reasons[10]. Increasing prevalence over the last few decades makes it a major healthcare concern in industrialized countries[11]. It is predicted to increase continuously over the next few decades. Given this health condition, there is a need for clinical interventions to deal with these economic consequences .[12]

Considering the high incidence of CKD and the challenges posed by the patients undergoing dialysis to partially rehabilitate one's life is very crucial. Patients have to suffer from different kinds of emotional and physical challenges during the procedure[13]. Survivals are not only the goal of putting the patient on strenuous dialysis procedure, instead, it is also a matter of improvement and increasing the quality and years of a healthy life. Understanding the deterioration of the patient's health-related HRQoL is the most crucial aspect which can affect the burden and mortality in these patients[14, 15]. Therefore, it is important to evaluate all such parameters while dealing with the critical condition of CKD patients. This study was conducted to emphasize the usage of tools to measure the HRQoL of patients, as well as treatment outcomes.

In Pakistan, advanced CKD and end-stage renal failure is the most common cause of morbidity and mortality. According to the National Kidney Federation Registry, a total of 5935 patients were admitted to different dialysis units across country[16].

There is a significant upsurge seen in the prevalence of advanced CKD all over the world. It is important to evaluate what could be the factor that could impact the quality of treatment and design a patient support program to increase the patient involvement in the self-management of the disease condition. The study aimed to provide insight into the utilization of tools to access the level of depression and medication adherence. Another objective was to measure how medication adherence and depression could impact the overall HRQoL of patients with advanced CKD.

# 2. MATERIAL AND METHODS:

# **Study Design:**

This was a multicenter prospective follow-up study conducted within 2 districts Rawalpindi and Islamabad in 3 major tertiary care hospitals, i.e., Federal Government Polyclinic Hospital, Islamabad, Pakistan Institute of Medical Sciences, Islamabad, and District Headquarter Hospital Rawalpindi, Pakistan.

#### **Inclusion and Exclusion Criteria:**

All patient who aged >18 years with advanced CKD and CKD Stage 5 on hemodialysis were enrolled in the study. Patients, who were diagnosed with any malignancy or other limitation that thwart them to participate in this study, were excluded.

# **Sampling**

The sample size was calculated using the Sample Size Determination in Health Studies software provided by the World Health Organization (WHO). A randomized sampling approach was used, the reported decreased eGFR prevalence in the Pakistan region report was 15-20%. The sample size calculated was 27, which enabled us to estimate the prevalence of decreased eGFR to within 5% of the true value with 95 percent confidence using an expected population proportion of 25%, a relative precision of 0.05, and a 95 percent confidence interval (CI).

# **Tools:**

To achieve the purpose of the study, the following tools were used.

# Sociodemographic Data Sheet

It was designed by principal investigators of the study to assess the relevant socio-demographic variables, e.g., age, gender, education status, duration of CKD treatment, and comorbidity condition.

# **Laboratory Investigation Assessment datasheet**

To assess the pre-study serum potassium, calcium and phosphorus, hemoglobin, and urea levels. The same laboratory investigation was also assessed after the completion of the follow-up visit at 6 months duration. These laboratory values were retrieved from the available medical record of patients.

# Assessment of depression, HRQoL, and Medication adherence:

The study comprised different pre-validated questionnaires that were administered to achieve the objectives of the study.

# **Kidney Disease Quality of Life-Short Form (KDQOL-SF-36)**

The Urdu version of the KDQOL-SF-36 is a reliable and validated version for assessing HRQoL in kidney disease patients on dialysis in Pakistan[17]. The KDQOL-Physical SF-36's Health Composite Summary (PCS), Mental Health Composite Summary (MCS), and Kidney Disease Composite Summary (KDCS) domains can be measured using the HRQoL scores for physical functioning, physical disabilities, pain, emotional wellness, social functioning, and energy. The KDQOL-36 has five measures, including two basic HRQoL scales (12 items) from the SF-12 version 1 and three kidney-specific scales (24 items total). In the general population, the SF-12 PCS and MCS are assessed using a T-score methodology (mean=50, SD=10), with higher scores indicating improved HRQOL.

# Hamilton Depression Rating Scale Urdu Version (HAM-D-U)

Hamilton Depression Rating Scale was used in patients who speak Urdu. The HAM-D-U is an effective tool used for determining the magnitude of depression. Internal accuracy (Cronbach alpha 0.71), test-retest reliability, and inter-rater reliability were reasonably good for the Urdu version of the HAM-D (HAM-D-U)[18]. A score of 0–7 on the HAM-D-U is considered normal (or in clinical remission), but a score of 20 or more (showing at least moderate severity). Interpretation of HAM-D-U scores is as follows: Not depressed: 0–7, Mild (subthreshold): 8–13, Moderate (mild): 14–18, Severe (moderate): 19–22, Very severe (severe): >23

# Morisky Lewis Greens Adherence scales (MLGS)

The Morisky Levine Green adherence questionnaire (MLGS) was used to evaluate medication adherence. It is a four-item questionnaire with high reliability and validity that has proven to be particularly useful in chronic conditions such as hypertension, kidney disease, and other cardiovascular diseases<sup>20</sup>. It assesses both deliberate and accidental adherence using criteria such as forgetfulness, carelessness and stopping the drug while feeling better and worse. Each question in the survey was answered with a 0 or 1 response. The total score of the four elements represents the degree of prescription adherence. Medication adherence is indicated by a score of 4, while non-adherence is indicated by a score of less than 4. The questionnaire was translated into Urdu using the standard forward-backward process, yielding a Cronbach alpha of 0.570, which is within the appropriate range (0.45–0.9)[19, 20].

# **Ethical Approval and consent to participate**

The Bio-Ethics Committee (BEC) of Quaid-i-Azam University Islamabad had permitted this observational prospective study in Tertiary Care Hospitals (BEC-FBS-QAU2017-13). The study was also approved by the Ethical Review Board of Shaheed Zulfkar Ali Bhutto Medical University (1-1/2015/ERB/SZABMU). Informed consent was taken from all the participants included in this study. The study was conducted as per the Declaration of Helsinki. The current study was reported according to "The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)" guidelines

#### Statistical tool

Primary data was recorded in Microsoft Excel 2010 and secondary data was generated with anonymous patient coding. Data was analyzed using the SPSS® (IBM version 20) was used to analyze the data. Continuous variables were reported in means and standard deviations, whereas categorical variables were reported in frequencies and percentages. The Chi-squared test was conducted to see if there was any correlation between categorical variables.

#### 3. RESULT

#### **Patient Characteristics**

During the study recruitment period, a total of 400 patients were enrolled in the study at the treatment sites. Eighty-six patients were those who didn't meet the eligibility criteria and were excluded. In total, 314 patients participated in the study and completed KDQOL, HAM-D-U, and MLGS. Figure 1 shows the schematic flow of the study. In the total 314 patients, 39.8% (n=125) was CKD Stage 4, 9.2% (n=29) with stage 5 not on hemodialysis yet and 50.9% (n=160) were of CKD Stage 5 on hemodialysis.

The demographic characters of the participants in the study were displayed in *Table 1*. The mean age of the participants was 54.64±15.33. The majority of the participants in the study were female with a major proportion of the study population was from the age group of 41-60 years. Population with BMI in normal range was 53.0%. The study population selected via convenience sampling comprised of different disease levels, treatment approaches, and disease durations.

The comorbidity conditions among the study populations is depicted in *Figure 2*. Among the CKD population, diabetes and hypertension were the most prominent underlying comorbid conditions, i.e., 62% and 55%, respectively. Nineteen percent of the population had various etiological factors e.g., proteinuria, cigarette smoking, chronic anemia, illicit drug use. Most of the patients had a family history of kidney disease and usually had a strong history of heart diseases. There were also a large group of people who had unknown etiology and represent almost 30% of the study population.

# **Laboratory Parameters:**

There was a significant deterioration in the laboratory parameters and its impact was also analyzed in the patients' overall HRQoL. In correlation analysis, there were certain laboratory parameters that affected the overall HRQoL composite score significantly. Statistical analysis suggested that hematological and serum iron studies were those laboratory parameters that had statistically significant impact on the Mental Composite Score (p-Value <0.05). Contrary to the fact the Physical composite Score was significantly affected by the parameters like hematological serum iron and renal function concentration in the blood this can be seen in *Table 2*.

# **Depression**

We used 21 items Hamilton Depression Rating Scale (HAM-D-U) to determine the pre-study and post-study analysis of depression levels in the study population.

It was observed that throughout treatment there was no educational or counseling support provided to any of the patients. Analysis of the depression data given by 314 patients in the pre-assessment questionnaire and 244 in the post-assessment questionnaire. There were 45 patients who refused to fill post-study HAM-D-U.

The frequency distribution of the depression assessment at baseline found that there was a significant high depression level in both CKD populations (Figure 3). There were only a few cases in which there was a normal to moderate level of depression.

Upon the follow-up visit it was observed that there was a significant increase in the depression level among the study population. In both the study populations, respondents indicated a higher level of depression compared to their previous state. However, further analysis with the Pearson Chi-square test found that there was no significant difference between the baseline and post-study depression levels (p-value >0.05).

# **Medication Adherence**

Around 38.8% (n = 122) of the 314 participants scored 4 and had high adherence, while the majority (61.2%, n = 192) belonged to a non-adherent population with a score of less than 4. In addition, the findings revealed that there was no statistically significant relationship between adherence and gender, age, marital status, education level, smoking status, or the number of medications (p > 0.05).

# **Quality of Life**

A total of 314 patients completed the KDQOL-SF-36 questionnaire on a baseline visit. As shown in *Table 3*, even though patients with ESRD had a lower level of the physical score as compared to those having advanced CKD, there were no significant differences seen in the SF-36 PCS scale (31.28±7.91 versus 36.28±8.41, P=0.68). However, the overall mental health composite measured by MCS at baseline was lower for the ESRD population significantly as compared to the CKD population, i.e., 36.66±6.57 and 48.66±5.44, respectively (P=0.009).

For the KDQOL-SF-36 domain, Mental Health Composite was the factor that affected the study population the most, which showed a statistically significant level in both the study groups (p-value <0.05). The other major KDQOL-SF-36 domains which impact on both the populations were Physical Functioning, Role Limitations-Physical, Emotional Wellbeing as well as Energy and fatigue evident from *Table 3*.

In the follow-up visit, 244 patients agreed to respond to the given questionnaires. A total of 35 patients with ESRD and 10 CKD patients did not respond in the post-study. In the post-analysis, there was a noteworthy deterioration seen in KDQOL-SF-36 domains and scale parameters among patients with advanced CKD.

ESRD patients scored significantly lower than advanced CKD patients in Problem's list/Symptom, Burden of Kidney Disease, and Mental Health composite domains (p <0.05). In the KDQOL-SF-36 scales, there were significant deterioration in Physical function, Emotional well-being, and Energy level in patients with advanced CKD (p <0.05).

#### DISCUSSION

The study was conducted in major two cities of Pakistan and is the first-ever follow-up study that investigates the point of concern for patients with advanced CKD and ESRD on HD. According to the results of this study, targeted patients with advanced CKD who are not on chronic renal replacement therapy have a similar overall burden of symptoms and depression and a poor HRQoL. Results derived in this research have a slew of clinical ramifications for both patients and care providers.

Despite studies showing that patients with ESRD have poor physical and psychosocial health, the clinical, medication, and/or patient-related factors that cause symptoms, depression, and poor HRQoL in the targeted patient population are not known. Patients tend to develop symptoms, depression, and poor HRQoL if they lose a large amount of weight even without losing kidney function. Therefore, it is critical to determine if this is due to metabolic disturbances, retained uremic contaminants, comorbid medical conditions, anxiety about the existence of CKD and the possible need for renal replacement therapy in the future, or other causes to administer adequate care. Due to the utilization of the different tools for the development of detailed analysis, the results derived in this study have significant implications for CKD patients.

The study of Ajeebi and his colleagues showed that patients with advanced CKD can likely be unaware of the effects of chronic renal replacement therapy on their physical and mental health. Following this school of thought, it is evident that a variety of patients need chronic dialysis for a drastic lifestyle change[21]. Based on results derived in this study, it is concluded that many people with CKD notice a significant difference in their physical and/or psychosocial well-being during the transition period of the disease. Due to the development of these in-depth results, the current study will be helpful for future studies conducted on the subject.

In the United States, about 500,000 patients undergo chronic renal replacement therapy, many of them are treated with hemodialysis. Although previous research summarised that in this group, bothersome symptoms and depression are often undertreated, it is currently unclear as per the cited study, whether CKD patients experience an equal treatment of symptoms[22].

The results derived in this research have led to the development of the conclusion that patients with advanced CKD are treated for anemia, bone disease, electrolyte abnormalities, and hypertension identically as patients of ESRD. This sourced the interpretation that regardless of this, renal clinicians are needed to be mindful of the high prevalence of symptoms and depression in the large population of patients with CKD. This is crucial for the administration of effective symptom-alleviating and antidepressant treatments.

On the other hand, in the case of patients with ESRD complaints of sleep problems, muscle cramps, dry mouth, and light-headedness are largely frequent. Even though these discrepancies did not reach statistical significance after several comparisons, there is biological plausibility to

such differences that warrants further investigation. In light of the results, it is evident that patients with ESRD have posted lower scores on the SF-36's physical function subscale. Although there were no variations in PCS scores because of this observation. This as per the referred study does provide preliminary insight into subdomains of HRQoL that may differ between these two populations<sup>24</sup>. In a study conducted on the patient undergoing kidney transplantation and those who were on hemodialysis or peritoneal dialysis, the findings provided evidence that there was a significant improvement in the HRQoL over the span of one year[23]. The comparison between the derived findings and the existing research material concluded that patients with CKD and ESDR are equally treated for health issues including anaemia, depression, sleeplessness, and bone and muscle diseases which lead to the deterioration of their quality of life. Therefore, in the context of end-stage renal disease, patients should be informed about the estimate of their life expectancy, based on known predictive factors of mortality and the advantages and disadvantages of dialysis treatments. According to the study of Nataatmadja et al., (2021) the study of among 3,000 patients with an average age of 73 years, 60% of them regretted having started dialysis rather than having opted for conservative treatment[24]. As far as possible, the decision to initiate dialysis in patients with end-stage renal failure must therefore be made personally between the patient, his family, the attending physician, and the referring nephrologist. Thus, the aim is to assess the existing treatment options and the patient's preferences, considering the prognosis of life, the desired quality of life, the degree of autonomy, and the comorbidities present. In particular, it allows the patient to make a free and informed choice between the various existing therapeutic options and thus ensure better adherence and provide greater satisfaction with care.

Chronic renal diseases are frequent in the population but often remain difficult to demonstrate clinically, as their symptoms are crude[25]. It is thus not uncommon for patients to develop end-stage renal failure, having presented very few symptoms or only vague and not very specific symptoms (fatigue, inappetence, etc.). In large population studies, it was found that only 23% of people with chronic kidney disease (CKD) were aware of their diagnosis[26]. According to the study of Live & Zhang (2019), chronic kidney disease is in most cases secondary to hypertension, diabetes, immunological disease, etc. Nevertheless, there are several kidney diseases that, although rare, could be diagnosed early, thanks to typical clinical and biological signs (red flags). However, even these diseases are often underdiagnosed, further prolonging the diagnostic error of these patients and their early management[27-29].

According to the World Health Organization (WHO), depression, the fifth leading cause of disability in the world in 1996, is expected to become the second in 2020. This situation is mainly due to the frequency of resistance and chronic forms of unipolar depression. In the presence of a chronic and resistant depressive syndrome, the expert psychiatrist will assess the effects of the treatments implemented, pharmacological and, where appropriate, psychotherapeutic[30]. While the chronic nature of depression can be reasonably assumed based on the history, clinical evaluation, and available medical documents, reliable information is often lacking on which to

conclude that depression is resistant. The following possibilities can be considered when the patient does not benefit from an optimum treatment:

- The antidepressant was prescribed at an insufficient dose.
- The measurement of plasma level did not control the adherence to the drug treatment.
- The medication was not changed despite the lack of therapeutic benefit[31].

If there is evidence of resistance to pharmacological treatment, the clinical type of depression should be identified. Moreover, there are different depressive syndromes capable of responding to specific pharmacological agents (sad, psychotic, atypical, bipolar depression)[32]. Their implementation is the responsibility of the specialist in the form of complex algorithms intended to help the practitioner in his therapeutic decisions. Their implementation is the responsibility of the specialist in the form of complex algorithms intended to help the practitioner in his therapeutic decisions. Their implementation is the responsibility of the specialist. However, these recommendations have low symptomatic remission rates for resistance and chronic depression, even when treated. The development of genetic, neuroanatomical, or neurochemical markers could provide tools for selecting the most appropriate therapeutic option in a "personcentered" approach[33].

It was also observed that the Physical and Mental health composite tends to deteriorate in patients with advanced CKD and ESRD. Previous studies reported that patients with moderate to progressing kidney disease had lower PCS than that of MCS[34]. There was a previous study conducted among CKD Stage1-4 patients reported the same findings that PCS and MCS score was (32.1 ±8.1 and 40.6 ±11.1) respectively. The severity of the disease, particularly in individuals with ESRD, has a considerable impact on HRQoL, according to the current study. This link has also been discovered in other investigations such as HRQoL scores are already compromised in patients with intermediate CKD, according to Mapes and his colleagues and HRQoL values deteriorate over time in dialysis patients[35].

The general demographic features of our ESRD sample were close to those of the US ESRD population, while the study's CKD cohort had a higher proportion of men than the total population of CKD patients. The result supported the above-mentioned study as it was discovered that the rate of depression was observed to worsen with time; a linear increase was identified from baseline till the 2nd administration of the questionnaire 6 months later. Possible causes for this finding are likely to be lifelong dialysis therapy with at least 3 dialysis operations per week, patients taking too many medications at once, the economic strain on patients and their families, and changed familial and social ties. In a group of chronic HD patients, depression symptoms increased linearly, a link was discovered to exist between poor sleep quality, unemployment, pruritus, hypoalbuminemia, and diabetes, and depressive symptoms.

The critical judgment of the findings and the prior research suggested that the patients suffering from the CKD and ESDR are likely to develop mental health issues due to the prolonged effects of illness which are found to identically be suitable for the progression of this mental health issue.

In addition, the treatment of hemodialysis patients includes all possible measures to reduce the impact of symptoms encountered in end-stage renal disease[32]. These symptoms are particularly pain, pruritus, nausea, headache, fatigue, anxiety, and depression. Eighty percent of patients suffered from chronic kidney pain and went to dialysis related to underlying complications of mental health, especially depression. It has been stated in the study of Duane et al. that diseases affecting the kidneys are frequent but remain asymptomatic for a long time, leading to a diagnostic delay with consequences for the management of the patient [29]. However, certain warning signs, whether cutaneous, articular or related to electrolyte abnormalities, should put the chip in the ear and guide the practitioner to the renal origin of the pathology. Therefore, certain rare diseases affecting the kidneys are discussed here based on clinical vignettes, emphasizing the biological and clinical signs that lead to their diagnosis[36]. Moreover, mental health depends on individual, genetic and hormonal factors, but also relational, community, and societal factors. Patients of CKD and ESRD of all ages suffer from certain mental disorders more frequently, with more comorbidities. This also has an impact on their physical health and family and social balance. Specificities exist at the clinical level, as well as concerning the use of psychotropic drugs, their side effects, and adherence to care. The role of the primary care physician is essential for the prevention and detection of mental disorders in CKD and ESRD patients for their psychological support, guidance, and follow-up[33].

As examined above study, it can say that furthermore, the relationship between CKD and ESRD is supported by multiple observations, suggesting a major role of depression in the overall epidemiology of CKD and ESRD. Hence there are some practical implications for the prevalence of dialysis patients: chronic and resistant forms of depression are frequent and represent a major public health problem, depression is generally considered resistant to pharmacological treatment after the failure of two antidepressants of a different class, prescribed ineffective doses for a sufficient time, in certain biological and psychological characteristics linked to the person, as well as various social and environmental factors, are likely to favor the chronicity of depression, and in current practice, an unfavorable development is often the result of poor compliance with the treatment of appropriate medication[37]. Therefore, there is no specific replacement therapy for renal function for the elderly, despite the hemodialysis (HD) or peritoneal dialysis (PD) can constitute a radical change in mental health and reduce depression. Thus, support at the end of life, with adequate psychological, social, and spiritual support for the patient and his family, is essential to cure CKD and ESRD patients.

#### CONCLUSIONS

The patients on maintenance dialysis for ESRD and those with severe CKD have significant burdens of physical and mental symptoms, depression, and low HRQoL. Given the

significant and well-known declines in physical and psychological well-being among patients with ESRD receiving hemodialysis, findings drawn in this research imply that these health-related areas should receive special attention in the vast and expanding population of patients with advanced CKD.

#### **Limitations:**

The current study only has a 6-month follow-up, the study findings should be regarded with caution. Research presented by Preljevic and his peers concluded that women had a higher risk of mental health issues such as depression than men<sup>28</sup>. However, it is not assessed in the research as limited consideration of the demographics of targeted patients. To corroborate the current study's findings, a multicentre investigation with a large sample size and extended follow-up period is required. In addition to this, future research in this domain needs to consider the comparison of mentioned health-related domains in a much wider and broader sample of patients with ESRD and CKD, including those with severe comorbid illnesses.

# **Conflict of Interest:**

None

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# **Figures**

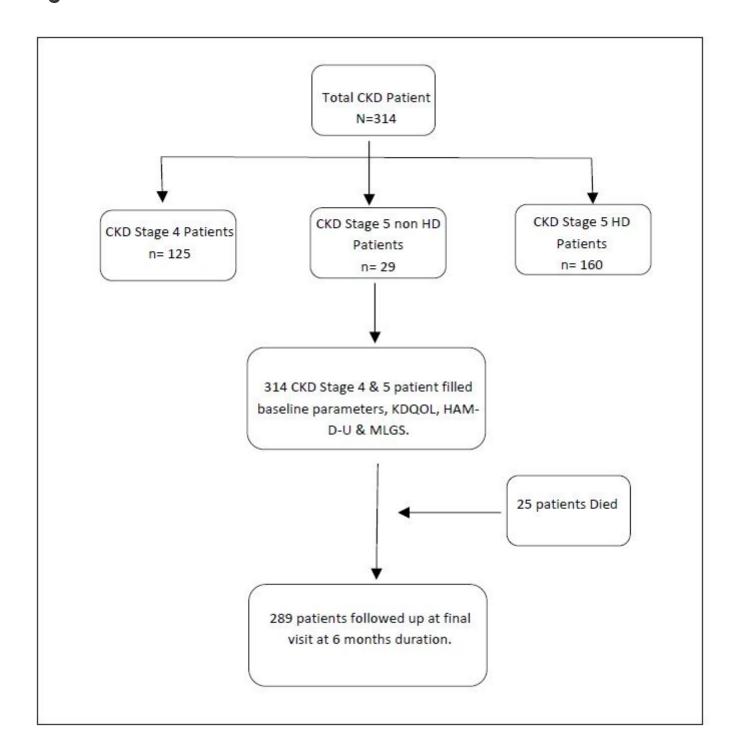


Figure 1
Schematic Diagram

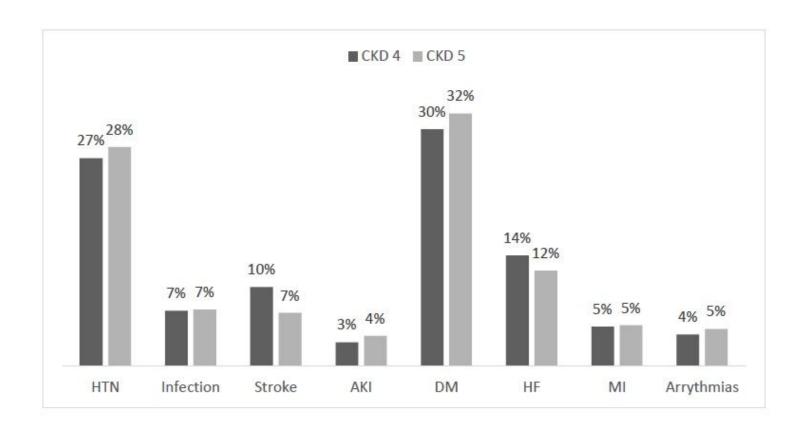
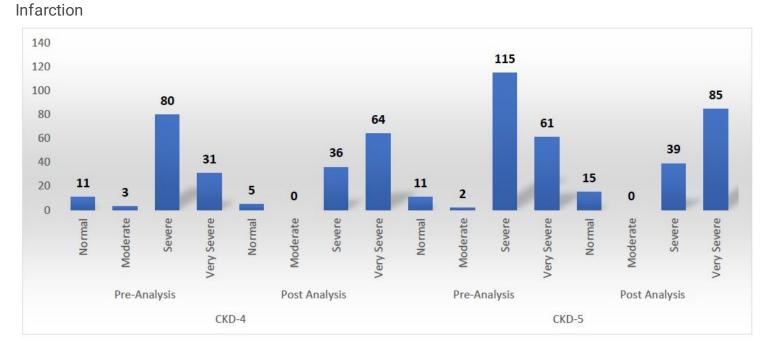


Figure 2

Comorbidity conditions among the study groups. \*CKD4: Chronic Kidney Disease Stage 4 and 5, HTN: Hypertension, AKI: Acute Kidney Infection, DM: Diabetes Mellitus, HF: Heart Failure, MI Myocardial



Depression level distribution (frequency) among study groups pre- and post-study.

Figure 3

# **Supplementary Files**

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• TableFile.pdf