ASSESSMENT OF QUALITY OF LIFE IN DIALYSIS AND NON-DIALYSIS CHRONIC KIDNEY DISEASE PATIENTS

Dissertation submitted to

The Tamil Nadu Dr. M.G.R. Medical University, Chennai-32

In partial fulfillment of the award of the degree of

MASTER OF PHARMACY IN
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Submitted by
REG.No.261540210

Under the Guidance of
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EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled **"Assessment Of Quality Of Life In Dialysis And Non-Dialysis Chronic Kidney Disease Patients"**submitted by the student bearing **[REG.No.261540210]** to **"The Tamil Nadu Dr. M.G.R. Medical University"**, Chennai, in partial fulfillment for the award of Degree of **Master of Pharmacy** in **Pharmacy Practice** was evaluated by us during the examination held on.....

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DECLARATION

I do hereby declared that the dissertation **"Assessment of Quality Of Life in Dialysis and Non-Dialysis Chronic Kidney Disease Patients"**,submitted to "**The Tamil Nadu Dr. M.G.R Medical University"**, Chennai, for the partial fulfillment of the degree of **Master of Pharmacy** in **Pharmacy Practice,** It is a bonafide research work has been carried out by me during the academic year 2016-2017, under the guidance and supervision of **Dr. N. Venkateswaramurthy, M.Pharm., Ph.D.,** Professor, Head, Department of Pharmacy practice, J.K.K. Nattraja College of Pharmacy, Kumarapalayam.

I further declare that this work is original and this dissertation has not been submitted previously for the award of any other degree, diploma, associate ship and fellowship or any other similar title. The information furnished in this dissertation is genuine to the best of my knowledge.

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INDEX

1. INTRODUCTION

Chronic kidney disease is a general term for heterogeneous disorders affecting the structure and function of the kidney. The variation in disease expression is related partly to cause and pathology, severity, and rate of progression. Since the introduction of the conceptual model, definition, and staging of chronic kidney disease 10 years ago,[1-4] guidelines have recommended a shift from kidney disease being recognized as a life threatening disorder affecting few people who need care by nephrologists, to a common disorder of varying severity that not only merits attention by general internists, but also needs a concerted public health approach for prevention, early detection, and management.[4-6] Although guidelines had an important effect on clinical practice, research, and public health, they have also generated controversy.[4,7]

Definitions and outcomes

The definition of chronic kidney disease is based on the presence of kidney damage (i.e., albuminuria) or decreased kidney function (i.e., glomerular filtration rate [GFR] <60 mL/min per 1·73 m²) for 3 months or more, irrespective of clinical diagnosis.[1,8-9] Because of the central role of GFR in the pathophysiology of complications, the disease is classified into five stages on the basis of GFR: more than 90 mL/min per 1·73 m²(stage 1), 60–89 mL/min per 1·73 m² (stage 2), 30–59 mL/min per 1·73 m² (stage 3), 15–29 mL/min per 1·73 m² (stage 4), and less than 15 mL/min per 1·73 m² (stage 5). Findings from experimental and clinical studies have suggested an important role for proteinuria in the pathogenesis of disease progression.[10] Epidemiological studies have shown graded relations between increased albuminuria and mortality and kidney outcomes in diverse study populations, in addition to, and independent of, low GFR and risk factors for cardiovascular disease.[11-16] Kidney failure is traditionally regarded as the most serious outcome of chronic kidney disease and symptoms are usually caused by

complications of reduced kidney function. When symptoms are severe they can be treated only by dialysis and transplantation; kidney failure treated this way is known as end-stage renal disease. Kidney failure is defined as a GFR of less than 15 mL/min per 1·73 m^2, or the need for treatment with dialysis or transplantation. Other outcomes include complications of reduced GFR, such as increased risk of cardiovascular disease, acute kidney injury, infection, cognitive impairment, and impaired physical function.[17-20] Complications can occur at any stage, which often lead to death with no progression to kidney failure, and can arise from adverse effects of interventions to prevent or treat the disease.

Chronic kidney disease: global dimension and perspectives[21]

Epidemiology of chronic kidney disease

According to the 2010 Global Burden of Disease study chronic kidney disease was ranked 27th in the list of causes of total number of global deaths in 1990 (age-standardized annual death rate of 15·7 per 100 000), but rose to 18th in 2010 (annual death rate 16·3 per 100 000).[22] This degree of movement up the list was second only to that for HIV and AIDS. The overall increase in years of life lost due to premature mortality (82%) was third largest, behind HIV and AIDS (396%) and diabetes mellitus (93%). An analysis of data on cause of death in the USA and Australia by Rao and colleagues[23] showed that a substantial pro portion of individuals who had died from diabetes had renal failure, but the cause of death was coded as diabetes without complication. In western countries, diabetes and hypertension account for over 2/3 rd of the cases of CKD.[24] In India too, diabetes and hypertension today account for 40-60% cases of CKD.[25] Reported mortality from diabetes-related renal disease was estimated to be four to nine times less than the actual rate.

The incidence and prevalence of end-stage kidney disease differ substantially across countries and regions. More than 80% of all patients receiving treatment for end-stage kidney disease are estimated to be in affluent countries with large elderly populations and universal access to

health care.[26] The lower figures reported from poor countries are largely due to patients not being accepted into renal replacement therapy (RRT) programmes, although where economies are growing, the numbers of patients being accepted for RRT are rising strikingly.[27] Projected worldwide population changes suggest that the potential number of cases of end-stage kidney disease will increase disproportionately in developing countries, such as China and India, where the number of elderly people are expanding. This effect will be enhanced further if the trends of increasing hypertension and diabetes prevalence persist, competing causes of death such as stroke and cardiovascular diseases are reduced, and access to treatment improves. In contrast to clinically apparent advanced-stage chronic kidney disease, precise calculation of the burden of less symptomatic or asymptomatic early-stage chronic kidney disease, which accounts for 80–90% of all cases, is difficult.[28]

Although data on early-stage chronic kidney disease from different parts of the world, they are confounded by heterogeneity in the populations screened, methods used to determine glomerular filtration rate, and proteinuria assays. The estimates are usually based on a single-time measurement rather than on sustained demonstration of abnormality. Even within countries, subgroups are at increased risk of developing chronic kidney disease, disease progression, or both, including black and Asian people in the UK, black, Hispanic, and Native Americans in the USA, and Indigenous Australians, South American Aborigines, Maori, Pacific, and Torres Strait Islanders in New Zealand, and First Nation Canadians.[29-31]

Demographic characteristics

The demographics of people with chronic kidney disease vary widely worldwide. The mean age of 9614 patients presenting with stage 3 chronic kidney disease in India was 51·0 (SD 13·6) years,[32] whereas in 1185 patients in China it was 63·6 (14·7) years.[33] In India, patients with chronic kidney disease of unknown origin were younger, poorer, and more likely to present with advanced chronic kidney disease than were

people with known causes[32]. Young adults aged 20–50 years in sub-Saharan Africa mainly develop chronic kidney disease owing to hypertension and glomerulonephritis[34]. In the USA, African American and Hispanic people reach end-stage kidney disease at younger ages than white people (mean age 57 and 58 years vs 63 years).[29]

Causes

Diabetes and hypertension are the leading causes ofchronic kidney disease in all developed and many developing countries but glomerular-nephritis and unknown causes are more common in countries of Asia and sub-Saharan Africa. These differences are related mainly to the burden of disease moving away from infections towards chronic lifestyle-related diseases, decreased birth rates, and increased life expectancy in developed countries.[35] By contrast, infectious diseases continue to be prevalent in low-income countries, secondary to poor sanitation, inadequate supply of safe water, and high concentrations of disease-transmitting vectors.[36] Environmental pollution, pesticides, analgesic abuse, herbal medications, and use of unregulated food additives also contribute to the burden of chronic kidney disease in developing countries.[37] Rapid urbanisation and globalisation have accelerated the transition in south Asian and Latin American countries, which has led to an overlap of disease burdens, with continued high prevalence of infectious diseases and an increasing prevalence and severity of lifestyle disorders, such as diabetes and hypertension.[37-39] Genetic factors also contribute. Variations in MYH9 and APOL1 are associated with non-diabetic chronic kidney disease in individuals of African origin.

Identification of chronic kidney disease

Identification and staging of chronic kidney disease rely on measurement of glomerular filtration rate and albuminuria. Calculation of actual glomerular filtration rate by measurement of external filtration markers is cumbersome and impractical. Values are, therefore, estimated on the basis of creatinine concentrations in plasma. Creatinine concentrations

in serum might also be affected by creatinine generation (dependent on muscle mass and dietary intake), tubular secretion, and extra renal removal and, therefore, variations between populations are expected. The Modification of Diet in Renal Disease study (MDRD) and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine equations have correction factors for African Americans. Chinese, Japanese, and Thai investigators found that the MDRD equation underestimated the absolute glomerular filtration rates in populations from those countries and developed new equations or correction factors.[40-42] The applicability of these modified equations to similar populations, such as the South Asians and most indigenous races, has not been widely explored. The accuracy of equations is affected by the reference method used to measure glomerular filtration rate. The MDRD and CKD-EPI equations were developed with ^{125}I-iothalamate clearance as the gold standard, the Chinese MDRD equation uses ^{99}mTc-diethylenetriaminepenta-acetic acid (^{99}mTc-DTPA) clearance, and the Japanese MDRD equation uses modified inulin clearance. In a head-to-head comparison study,^{99}mTc-DTPA clearance gave 10 mL/min per 1·73 m² higher values than did inulin clearance.[43] These different approaches might substantially alter outcomes, as noted in the Japanese general population when two equations were used.[44]The characteristics of the population assessed during equation development can also affect accuracy. If an equation is developed in patients with advanced chronic kidney disease, output values are generally low.[45] If the same equation were applied to the general population, an artificially high prevalence of low glomerular filtration rates would be seen. This feature led to the development of the CKD-EPI equation.[46] The average glomerular filtration rate reference values for the MDRD and CKD-EPI cohorts assessed for equation development were 39·8 and 68·0 mL/min per 1·73 m², respectively. The MDRD equation showed 7·8% prevalence of chronic kidney disease in the National Health and Nutrition Examination Survey population, but the CKD-EPI showed a 6·3% prevalence.[46] The 2012 KDIGO guideline suggests use of the CKD-EPI equation to calculate estimated glomerular

filtration rates in adults. Specific pediatric equations, which require knowledge of height, should be used to estimate glomerular filtration rates in children. Older equations, the most popular of which is the Cockroft-Gault formula, continue to be used in some areas. The accuracy of estimated glomerular filtration rate and albuminuria assessments is affected by biases in creatinine and urine albumin assays. Laboratories in many developing countries do not report estimated glomerular filtration rate values. Accurate assessment of differences by ethnic origin, region, or both, will require validation of existing equations for estimated glomerular filtration rate against the same glomerular filtration rate reference method and creatinine assay. In the meantime, the CKD-EPI equation is recommended to calculate estimated glomerular filtration rate, with recognition of the possibility of misclassification in some clinical settings and populations.

Risk factors

Chronic kidney disease is viewed as part of the rising worldwide non-communicable disease burden. Hypertension, diabetes mellitus, and obesity are among the growing non-communicable diseases and are important risk factors for chronic kidney disease. The global prevalence of hypertension in adults was estimated to be about 26% (972 million cases) in 2000,[47] with most cases (639 million [66%]) being in developing countries. Prevalence was 37%, 21%, and 20% in established market economies, India, and China respectively. In Latin America, 40·7% of men and 34·8% of women had hypertension, whereas in sub-Saharan Africa the values were 27·0% for men and 28·0% for women.[47] Prevalence is higher in urban populations than in rural populations in developing countries.[48] The worldwide hypertension prevalence, when age-specific and sex-specific adjustments are made to take into account changes in the world population, is projected to increase to 1·56 billion by 2025.[47] The actual number, however, might well exceed these projections, as suggested by a Canadian Hypertension Education Program Outcomes Research Task force study,[49] which projected increases in prevalence of

25·7% and 60·0% between 1995 and 2005, respectively, in Ontario, Canada, after adjustment for age and sex. Moreover, rates of hypertension control are dismal. Pereira and colleagues[50] showed that only 9·8% of men and 16·2% of women in developing, and 10·8% of men and 17·3% of women in developed countries had controlled hypertension. Similar trends are apparent for diabetes. The worldwide prevalence of diabetes in adults is estimated to be 6·4%, affecting 285 million people, and is expected to rise to 7·7% by 2030 (439 million cases).[51] The largest increases in prevalence are expected in developing regions (the Middle East, 163%; sub-Saharan Africa, 161%; India, 151%; Latin America, 148%; and China, 104%).[52] Although diabetes is predicted to increase in all age strata, ageing populations and a shift towards urbanisation will contribute substantially. Similarly to hypertension, the projections are probably conservative, and could be exceeded by the actual growth.[53] The prevalence of obesity worldwide is also increasing. 312 million adults worldwide were estimated to be obese at the beginning of the 21stcentury. Particularly alarming is the increase in the number of overweight and obese children. In contrast to the developed world, obesity in developing countries is rising in affluent and educated populations.[54]

Herbs

Herbal medicines are widely used by rural populations in Africa and Asia and have become popular in developed countries.[55] Nephrotoxic effects can result from consumption of potentially toxic herbs, incorrect substitution of harmless herbs with toxic herbs, contamination with toxic compounds, such as heavy metals, or interactions between herbs and conventional treatments.[56] Herbs can cause acute kidney injury, tubular dysfunction, electrolyte disturbances, hypertension, renal papillary necrosis, urolithiasis, chronic kidney disease, and urothelial cancer.[55] Herbal causes should be considered in cases of unexplained kidney disease, especially in areaswhere consumption of herbal preparations is high. Aristolochic-acid nephropathy is a progressive interstitial nephritis that leads to end-stage kidney disease and urothelial malignant disease.

It was first reported in 1993, Three clinical subtypes of aristolochic-acid nephropathy have been classified: chronic tubulointerstitial nephropathy (accounting for 93·3% of cases), acute kidney injury (4·3%), and tubular dysfunction with unchanged glomerular filtration rate (2·3%).[57] The worldwide incidence of aristolochic-acid nephropathy is probably higher than initially thought. In Asian countries, where traditional medicines are very popular and pharmaceutical medicines are frequently substituted or supplemented by botanical products that include herbs containing aristolochic acid.[58]

Infections

HIV infection is epidemic in sub-Saharan Africa. Population screening has shown kidney involvement in 5–83% of HIV-infected individuals in this region.[59-60] In the USA, HIV-associated nephropathy is seen in African Americans but not in white people. Despite a large HIV infected population, HIV-associated nephropathy is rare in Asia.[61] The differences between regions could be explained by differential prevalence of high-risk alleles in MYH9 and APOL1.[62-63] Early initiation of antiretroviral therapy reduces the burden of HIV-associated nephropathy but carries the risk of nephrotoxic effects, such as crystal-induced obstruction, tubular toxic effects, interstitial nephritis, lactic acidosis, and electrolyte disorders. Other specific infections that cause severe kidney lesions in populations worldwide include hepatitis B and C viruses.

Water

Various disorders directly or indirectly related to water can cause kidney disease. High temperatures frequently lead to water scarcity in tropical regions, which raises the risk of dehydration. Flowing water might be contaminated by heavy metals and organic compounds leached from soil, and grain in waterlogged fields can become contaminated with harmful substances.[64] Many water borne diseases (eg, schistosomiasis, leptospirosis, scrub typhus, hanta virus, and malaria) affect the kidneys. Children are particularly vulnerable to acute kidney injury because of

diarrheal diseases.[65] Enteric infections can cause haemolytic-uraemic syndrome, which eventually leads to the development of chronic kidney disease in a substantial proportion of affected individuals. In Germany an outbreak was triggered by Shigatoxin-producing Escherichia coli,[66]and in South Asia, haemolytic-uraemic syndrome is frequently seen after infection with Shigella dysenteriae.[67]

Chronic kidney disease of unknown origin

Clusters of cases of chronic kidney disease of unknown origin have been reported in some areas of Sri Lanka and India.[27] The affected individuals are mainly young male farmers. Clinical presentation resembles that of interstitial nephritis. Histology shows interstitial fibrosis, tubular atrophy, and interstitial mononuclear-cell infiltration. Contamination of water, food, or both, by heavy metals, industrial chemicals, fertilizers, and pesticides has been suspected.[68] Nevertheless, in a study funded by the Research and Prevention Committee of the International Society of Nephrology, no excess of heavy metals was found in the water in the Srikakulam district of India.

Awareness of chronic kidney disease

Despite its recognition as an important public health issue, awareness of chronic kidney disease remains low.[69-70] In a nationwide health screening programme in the USA that involved around 90000 adults at high risk of chronic kidney disease, the prevalence and awareness rates were, respectively, 29·7% and 8·6% for white respondents, 22·8% and 6·3% for African Americans, 29·2% and 6·8% for Native Americans, 20·3% and 11·1% for Hispanics, and 23·4% and 11·9% for Asians and Pacific Islanders.[71]Awareness was higher among people with advanced chronic kidney disease (overall 7·8% for stage 3 and 41·0% for stage 4) and those with diabetes, hypertension, and proteinuria.[72] Furthermore, use of nephrology care was low, with less than 6% of participants with stage 3 disease and less than 30% of those with stage 4–5 disease ever having seen a nephrologists. Low awareness has also been noted among health-

care providers. In a nationwide audit adults followed up by general practitioners in Italy,[70] only 17% had undergone serum creatinine testing, of whom 16% had glomerular filtration rates lower than 60 mL/min per 1·73 m². Among these adults, chronic kidney disease had been correctly diagnosed in only 15%. In another study 525 hypertensive patients, 23% had chronic kidney disease, but general practitioners diagnosed it correctly in only 3·9%.[73] Incorrect diagnosis results in delayed referrals to nephrologists, which leads to missed opportunities to implement strategies for slowing disease progression, cardiovascular protection, and preparation for RRT.[74] Data suggest that increased awareness does not necessarily translate to improved outcomes. The risk of progression to end-stage kidney disease and death was higher among people aware of their chronic kidney disease status at entry into the US Kidney Early Evaluation programme. Adjustment for socioeconomic and clinical variables and presence of cardiovascular disease and cancer reduced the difference, but it remained significant.[75]

Interactions with other disorders

Cardiovascular mortality is ten to 30 times higher in individuals with end-stage kidney disease than in the general population when matched for age, ethnic origin, and sex. The association between chronic kidney disease and increased risk of cardiovascular disease is observed in high-risk groups and in people in the general population with low glomerular filtration rates and albuminuria.[76-78] The increased risks associated with low estimated glomerular filtration rates and albumin uria seem to be independent of each other. Furthermore, death seems to be a far more likely outcome than progression to end stage kidney disease in all stages of chronic kidney disease, and the high death rates might reflect accelerated rates of atherosclerosis and heart failure.[79] Thus, individuals with chronic kidney disease should be viewed as being in the highest risk group for cardiovascular disease. Even among dialysis patients, decline in residual kidney function is associated with an increased risk of cardiovascular-related mortality and adverse outcomes.[80] Additionally,

cardiovascular disease itself is a well recognised risk factor for chronic kidney disease and predicts progression to endstage kidney disease.[76]

Acute kidney injury

Patients with chronic kidney disease are at an increased risk of acute kidney injury.[81] A transient increase in serum creatinine of as little as 27 µmol/L increases the risk of death.[82] Acute kidney injury might occur with the use of several medications, such as non-steroidal anti-inflammatory drugs, several antibiotics, and angiotensin converting-enzyme inhibitors, and, therefore, chronic kidney disease must be taken into account when drugs are being prescribed to enable adjustment or complete avoidance of specific drugs. Severe, long, and repeated episodes of acute kidney injury increase the risk of progression of chronic kidney disease. Despite different initial presentations and expression over time, chronic kidney disease and acute kidney injury should be viewed as parts of the same clinical syndrome related to reduced glomerular filtration rates.

Socioeconomic effects and economicimplications

The risk of chronic kidney disease is bi-directionally affected by level of economic development. Poverty increases the risk of disorders that predispose chronic kidney disease to develop or progress, and worsens outcomes in those who already have chronic kidney disease. An analysis of National Health and Nutrition Examination Survey data showed that poverty is associated with an increased risk of protein uria even after correction for age, sex, ethnic origin, education, obesity, hypertension, diabetes, decreased glomerular filtration rate, and medication use.[83] People in the lowest socio-economic quartile are at a 60% greater risk of progressive chronic kidney disease than are those who are in the highest quartile.[84] An interaction between ethnic origin and poverty has also been shown in minority and indigenous groups in many developed countries.[29] Chronic kidney disease imposes substantial economic burden on affected individuals, especially in developing countries. Their families experience

direct loss of income and changes in consumption patterns because of the spending of household finances on care and welfare costs.

About 2–3% of the health-care expenditure in developed nations is used to provide treatment for patients with end stage kidney disease even though they account for only 0·1–0·2% of the total population; in 2010 treatment costs accounted for 6·3% of the Medicare budget in the USA,[85] 4·1% of the total health-care budget in Japan in 1996, and 3·24% of national health expenditure in South Korea in 2004.[86] The economic costs associated with milder forms of chronic kidney disease are even higher. In India, the cost of a dialysis session varies from US$20 to $60, dependent on the type of facility.[87] Some Indian states have started schemes to provide free RRT to the poor, but coverage is limited.[27] Care of people with chronic kidney disease, particularly those who present for the first time with advanced disease, leads to catastrophic personal health expenditure in countries where treatment requires out-of-pocket spending. Patients frequently have to travel long distances, often with families, to receive specialized care.[87] Most patients with end-stage kidney disease have complications at presentation and need emergency admission to hospital and dialysis.[74] An analysis of the costs of treatment for 50 consecutive patients with end-stage kidney disease who underwent highly subsidised kidney transplantations in a public-sector hospital in India showed that 82% experienced financial crisis during treatment and more than half (56%) of patients lost their jobs.

Kidney Disease Quality of Life Questionnaire

The Kidney Disease Quality of Life Questionnaire (KDQOL) (and its shorter version, the KDQOL-SF) is one of the most widely-used instruments in assessing the quality of life of patients with ESRD.[88-90] Developed at RAND, the KDQOL is a composite of a previously existing instrument and newly-developed questions targeted specifically to kidney dialysis. As such, it is both a generic and a disease-specific instrument. Development of the disease-specific components was based on the results

of Hays' work with focus groups of patients with ESRD. The symptoms/problems scale assesses muscle soreness, back/chest pain, headaches, cramps, bruising, itchy skin, shortness of breath, dizziness, lack of appetite, excessive thirst, numbness of hands and feet, trouble with memory, blurred vision, nausea and clotting, or other problems associated with the vascular access site. A second segment addresses daily concerns: dietary and fluid restrictions, impact of dialysis on work or family responsibilities, travel, lifting objects, personal appearance and ability to accomplish fewer tasks than normal. A third segment addresses work-related difficulties. Additional items were taken from already-existing instruments: cognitive function items from the SIP,[91] quality of social interaction from the Functional Status Questionnaire,[92] sexual function from the MOS Sexual Function Scale,[93] sleep dysfunctionfrom the SIP Sleep subscale,[51] and a previously-existing social support scale.[94] An additional six items eliciting responses to dialysis staff encouragement were written exclusively for Hays' study. Finally, patient satisfaction was also measured using two items from The Chiropractic Questionnaire.[95] The totalinstrument contains 134 items. Due to the length of the KDQOL, a shorter version has been created.[96] The KDQOL-SF, also developed at RAND, contains the SF-36 core, as well as an additional 44 items targeted toward kidney disease and patient satisfaction, as listed above. Korevaar and colleagues have recently published the first validation study of the KDQOL-SF in a cohort of Dutch dialysis patients.[90]

HRQOL among dialysis modalities

The findings comparing dialysis with transplant patients are those comparing HRQOL among patients receiving various dialysis modalities. Studies comparing HD and PDhave yielded mixed results. Evans' 1985 study reported those receiving home HD or PD maintained a HRQOL higher than those receiving in-center HD.[97] Similarly, using multiple instruments Simmons compared a group of patients on PDwith a group on in-center HD and found the PD group had better scores in physical,

social and emotional arenas.[98] Merkus found mental health to be superior in PD patients compared with HD patients.[99] In contrast, Mittal and colleagues found physical health and function were lower in patients receiving PD compared with HD.[100] Korevaar and colleagues assessed HRQOL with the SF-36 and the EuroQoL, in pre-dialysis ESRD patients at the initiation of therapy and found significant baseline differences between those initiating HD versus PD, lending credence to the idea that there are underlying differences between patient groups prior to dialysis initiation.[101] The use of the disease-specific.[102]

HRQOL in early versus late diagnosis of ESRD

Sesso and Yoshihiro used several instruments in their study measuring HRQOL in patients with ESRD who were diagnosed early (≥6 months before dialysis initiation) versus late (≤1 month) with chronic renal failure.[103] They found a significant between-group difference in the symptoms of depression, relationships and frustration dimensions. Functional status declined compared with 1 year prior to dialysis, particularly in the late diagnosis group. Elderly patients were particularly affected by these differences. Of note, however, is that several of these differences had diminished after an average of 9 months of dialysis treatment.[103]

Relationship between dialysis adequacy &HRQOL

Hamilton used the SF-36 and the KDQ to study whether dialysis adequacy corresponded with HRQOL.[104] Although their pilot study demonstrated that improvements in dialysis adequacy paralleled improvements in HRQOL over a period of 3 months, the authors cautioned that there were too many competing explanations of the results to definitively attribute adequacy to improved HRQOL.

2. LITERATURE REVIEW

***Pereira B* et al.,[105]** aimed to evaluate the prevalence of anxiety, depression, stress, fatigue, social support, and quality of life in patients with CKD and their caregivers. A cross sectional study was conducted with 21 patients and their caregivers, from January to September 2015. The study included patients aged over 18 years, with at least 6 months on dialysis treatment, and caregivers who were family members. The participant's social, demographic, clinical, laboratory, and psychological variables were evaluated. 38.1% had symptoms that indicated anxiety and depression. The average score for practical social support was 3.15 ± 0.769 and that for emotional social support was 3.16 ± 0.79. As for fatigue, 14.3% of patients reported being 'extremely tired' and 14.3% reported that they engaged in all the activities they usually performed before the illness. Further, 57.1% presented stress, and of these, 66.7% were at the resistance stage, with predominance of psychological symptoms in 60.0%. The quality of life domain in terms of functional capacity (FC) presented a correlation with haemoglobin level ($r = 0.581$, $p = 0.006$) and non-anaemic patients presented better FC. Among caregivers, we observed symptoms that indicated anxiety and depression in 33.3% of the sample. Caregivers exhibited an average score of 2.88 ± 0.77 for practical social support and 3.0 ± 0.72 for emotional social support. Further, 14.3% reported being 'extremely tired' and 28.8% reported that they engaged in all activities that they usually performed before the patient's illness. While comparing the two groups, (patients vs. caregivers), they presented similar results for the presence of anxiety, depression, and fatigue. The mental health characteristics of patients and caregivers were similar, and within the context of dialysis for renal disease, both must undergo specific interventions.

***Senanayake SJ* et al.,[106]** conducted a community based cross-sectional study included a representative sample of 1174 registered CKD patients from all 19 Medical Officer of Health areas in the District of

Anuradhapura. Trained paramedical staff visited the households and administered an interviewer administered questionnaire to gather information. A total of 1118 CKD patients participated. Mean age was 58.3 (SD 10.8) years. Fifty nine (5.3%) patients had been hospitalized during the six months preceding data collection. The total OOP for a hospital admission for one patient was Rs. 3625 (IQR 1650-8760). Thirty eight (3.4%) patients were on dialysis. The median direct cost per patient for an episode of dialysis was Rs.595 (IQR 415-995) while the median direct cost for a dialysis patient per month was Rs.5490 (IQR 3950-10934). In the study population a total of 1095 (98.0%) had attended clinic at least once during the six months preceding the study. The OOP expenditure for a single clinic visit for one patient was Rs.434 (IQR 200-860).CKDpatients living in the Anuradhapura District spent significant amounts on accessing health care which can worsen their economic hardships. Planned interventions are warranted in order to improve their quality of life and financial situation.

***Lemos CF* et al.,**[107] evaluated the quality of life (QOL) using the generic instrument SF-36 in patients with CKD in pre-dialysis and identify the possible influence of the degree of renal function, hemoglobin level, age, gender, family income and level of education on QOL. A cross-sectional study was conducted and included 170 individuals (83 men) with a mean age of 57 ± 15 years who met the inclusion criteria and answered the SF-36. Laboratory tests and clinical and demographic data were obtained, and the glomerular filtration rate was estimated using the CKD-EPI formula. The degree of renal function did not influence QOL. Women had lower scores in functional capacity, physical aspects, pain, and mental health. Patients younger than 47 years old showed better QOL in the functional capacity; however, their QOL was worse in terms of social aspects. Subjects with an income higher than 5.1 times the minimum wage had better QOL in the functional capacity, pain, social, physical and emotional roles, and mental health. Hemoglobin levels and education did not globally influence QOL.Gender and age influenced QOL, but

family income was the most important factor affecting QOL (6 out of 8 domains investigated by SF-36) in this sample of 170 individuals with CKD in pre-dialysis. These findings suggest that many efforts should be made to reduce the effect of these factors on quality of life in patients with CKD and reinforce the need for longitudinal studies and intervention.

***Brown MA* et al.,[108]** examined the outcome of patients with renal supportive care without dialysis (RSC-NFD) and those planned for or commencing dialysis. In this prospective observational study, symptoms were measured using the Memorial Symptom Assessment Scale and the Palliative care Outcomes Scale - Symptoms (renal) inventory and QOL was measured using the Short Form-36 survey. 273 pre-dialysispatients who had usual nephrology care and 122 non-dialysis patients were enrolled in the study. A further 72 patients commenced dialysis during study period without attending either clinic. Non-dialysispatients were older than the pre-dialysis group (82 vs 67 years; P<0.001) but had similar eGFR at the first clinic visit (16 ml/min per 1.73 m(2); P=0.92). Compared with the RSC-NFD group, the death rate was lower in the pre-dialysis group who did not require dialysis. Median survival in RSC-NFD patients was 16 (interquartile range, 9, 37) months and 32% survived >12 months after eGFR fell below 10 ml/min per 1.73 m(2). For the whole group, age, serum albumin, and eGFR<15 ml/min per 1.73 m(2) were associated with poorer survival of the non-dialysis patients, 57% had stable or improved symptoms over 12 months and 58% had stable or improved QOL. Elderly patients who choose not to have dialysis as part of shared decision making survive a median of 16 months and about one-third survive 12 months past a time when dialysis might have otherwise been indicated.

***Lee SJ* et al.,[109]** intended to examine the prevalence of frailty and investigate the contribution of frailty to quality of life in pre-dialysis CKD patients in Korea. Using a cross-sectional survey design, data were

collected at an outpatient CKD clinic in a general hospital in Korea. The frailty criterion was modified from previous studies. The Short Form-36 Health Survey version 2 was used to measure physical and mental component summary scores. Data were analyzed using chi-square, t-tests, and hierarchical linear regression. Of the 168 CKD patients, 63 (37.5 %) were frail. Frail patients were significantly older and had lower physical and mental quality of life than those who were non-frail. In hierarchical regression evaluating the influence of frailty on physical and mental quality of life, the initial model was significantly improved when frailty was included. Frail patients had lower physical and mental quality of life. Frailty affected both physical and mental quality of life in pre-dialysis patients with CKD. More attention should be paid to the potential role of early detection and prevention of frailty to improve patients' quality of life.

Fassbinder **et al.,**[110] compare the physical fitness and quality of life of patients with chronic kidney disease submitted on hemodialysis (G1) and pre-dialysis treatment (G2). A cross-sectional study, 54 patients with CKD, 27 of the G1 group (58.15 ± 10.84 years), 27 of G2 group (62.04 ± 16.56 years). There were cardiovascular risk factors, anthropometric measurements, respiratory muscle strength was measured by the inspiratory pressure (MIP) and expiratory (MEP) maximum measured in the manometer, six-minute walk (TC6'), cardiopulmonary exercise test, sit and stand one minute test (TSL1') and the Short-Form Questioner (SF-36) to assess QOL.
The patients presented disease of stage between 2 and 5. It was applied the Kolmogorov-Smirnov normality test and used the t (Student) test or the U (Mann Whitney) test to compare the means of quantitative variables and the chi-square Pearson test and Fisher's exact test for qualitative variables. Pearson's or Spearman's test was used to identify correlations. No statistically significant difference was found between G1 and G2 in VO2peak (p = 0,259) in TC6' (p = 0,433) in the MIPmax (p = 0,158) and found only in the MEPmax (p = 0,024) to G1. The scores of

the SF-36 in both groups showed a worse health status as evidenced by the low score in scores for QOL. Patients with CKD had reduced functional capacity and QOL, and hemodialysis, statistically, didn't have showed negative repercussions when compared with pre-dialysis patients.

Ho SE et al.,[111] examined the quality of life amongst the end stage renal disease (ESRD) hemodialysis patients in Malaysia. A cross sectional descriptive study was conducted on 72 ESRD patients at a Dialysis Centre in Malaysia. The modified KDQOL-SF™ subscales, kidney disease-targeted scale and 36 item health survey scale questionnaires were used. The overall health rating was 66.73 ± 11.670 indicating good quality of life. There was no significant difference between quality of life for the different domains according to gender (p >0.05).A significant difference between quality of life in the domain of burden of kidney disease. Physical functioning deteriorated significantly with age (p=0.012) while social functioning was lowest in the 50-65 years age group (p=0.037). Those who had no morbidities had significantly better scores on the effects of kidney (p=0.036), burden of kidney disease (p=0.011) and physical functioning (p=0.025). Patients undergoing hemodialysis have been found to have good quality of life despite having ESRD. It is therefore of paramount importance to constantly monitoring the standard of care for these patients to enable them to live their life to the fullest.

***Abraham S* et al.,**[112] intended to revealed that patient education can play a significant role in improving the QOL in these patients. The primary objective of the study was to assess the QOL of patients on hemodialysis by using the World Health Organization Quality of Life assessment scale and also to study the impact of patient counselling in these patients. Fifty patients were selected for the study and they were randomly divided into two groups, control and test; counselling was given to the test group of patients. There was an increase in score in all the four domains (physical, psychological, environmental and social) among the test group when compared with the control group. The psychological

domain showed significant increase in score compared with others. Findings demonstrate that patient counseling plays an important role in improving the QOL by changing their psychological thinking and bringing them toward spirituality.

***Wyld M* et al.,[113]** conducted a systematic review, meta-analysis, and meta-regression of peer-reviewed published articles and of PhD dissertations published through 1 December 2010 that reported utility-based quality of life (utility) for adults with late-stage CKD. Studies reporting utilities by proxy (e.g., reported by a patient's doctor or family member) were excluded. In total, 190 studies reporting 326 utilities from over 56,000 patients were analyzed. There were 25 utilities from pre-treatment CKD patients, 226 from dialysis patients (haemodialysis, $n=163$; peritoneal dialysis, $n=44$), 66 from kidney transplant patients, and three from patients treated with non-dialytic conservative care. Using time tradeoff as a referent instrument, kidney transplant recipients had a mean utility of 0.82 (95% CI: 0.74, 0.90). The mean utility was comparable in pre-treatment CKD patients (difference = −0.02; 95% CI: −0.09, 0.04), 0.11 lower in dialysis patients (95% CI: −0.15, −0.08), and 0.2 lower in conservative care patients (95% CI: −0.38, −0.01). Patients treated with automated peritoneal dialysis had a significantly higher mean utility (0.80) than those on continuous ambulatory peritoneal dialysis (0.72; $p=0.02$). The mean utility of transplant patients increased over time, from 0.66 in the 1980s to 0.85 in the 2000s, an increase of 0.19 (95% CI: 0.11, 0.26). The main limitations of this study were that treatment assignments were not random, that only transplant had longitudinal data available, and that we calculated EuroQol Group EQ-5D scores from SF-36 and SF-12 health survey data, and therefore the algorithms may not reflect EQ-5D scores measured directly. For patients with late-stage CKD, treatment with dialysis is associated with a significant decrement in quality of life compared to treatment with kidney transplantation. These findings provide evidence-based utility estimates to inform economic evaluations

of kidney therapies, useful for policy makers and in individual treatment discussions with CKD patients.

***Cruz MC* et al.,[114]** conducted a study to compare the dimensions of quality of life in the stages of chronic kidney disease and the influence of socio demographic, clinical and laboratory data. A total of 155 chronic kidney failure patients were enrolled of which 36 were undergone hemodialysis. Quality of life was rated by the Medical Outcomes Study Short Form 36-Item (SF-36) and functional status by the Karnofsky Performance Scale. Clinical, laboratory and socio demographic variables were investigated. They found that quality of life decreased in all stages of kidney disease. A reduction in physical functions, physical role functioning and in the physical component summary was observed progressively in the different stages of kidney disease. Individuals with higher educational level who were professionally active displayed higher physical component summary values, whereas men and those with a higher income presented better mental component summary values. Older patients performed worse on the physical component summary and better on the mental component summary. Three or more comorbidities had an impact on the physical dimension. They found quality of life is decreased in renal patients in the early stages of disease. No association was detected between the stages of the disease and the quality of life. It was possible to establish socio demographic, clinical and laboratory risk factors for a worse quality of life in this population.

***Mujais SK* et al.,[115]** investigated the determinants of health-related quality of life (HRQOL) in chronic kidney disease (CKD) patients not on dialysis. A prospective study was undertaken of HRQOL in a cohort of 1186 CKD patients cared for in nephrology clinics in North America. Baseline and follow-up HRQOL were evaluated using the validated Kidney Disease Quality Of Life instrument. Baseline measures of HRQOL were reduced in CKD patients in proportion to the severity grade of CKD. Physical functioning score declined progressively with more advanced

stages of CKD and so did the score for role-physical. Female gender and the presence of diabetes and a history of cardiovascular co-morbidities were also associated with reduced HRQOL (physical composite score: male: 41.0 ± 10.2; female: 37.7 ± 10.8; *P*< 0.0001; diabetic: 37.3 ± 10.6; non-diabetic: 41.6 ± 10.2; *P*< 0.0001; history of congestive heart failure, yes: 35.4 ± 9.7; no: 40.3 ± 10.6; *P*< 0.0001; history of myocardial infarction, yes: 36.1 ± 10.0; no: 40.2 ± 10.6; *P*< 0.0001). Anemia and beta blocker usage were also associated with lower HRQOL scores. HRQOL measures declined over time in this population. The main correlates of change over time were age, albumin level and co-existent co-morbidities. The observations profound CKD has impact on HRQOL and suggests potential areas that can be targeted for therapeutic intervention.

3. NEED OF THE STUDY

The incidence and prevalence of patients with chronic kidney disease (CKD) is increasing worldwide. HEALTH-RELATED quality of life (QOL) has been defined in different ways over the years. The World Health Organization (WHO) has defined QOL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns". In fact, QOL is an important outcome that is used as a valuable parameter of health and well-being. Research findings have shown that lower scores on QOL were strongly associated with higher risk of death and hospitalization than clinical parameters such as serum albumin levels in cases of CKD patients.This is despite the factsobtained from various studies that have shown the patient with CKD had lower QOL compared to the healthy individuals. Therefore, improving CKD patients' life span as well as QOL is of utmost importance. Health-related QOL includes physical, psychological, and social domains of health, each of which includes a diversity of components. Moreover, each component can be expressed in different ways according to the subjective perception of each patient, resulting in a different assessment of QOL. Therefore, two patients with similar clinical and therapeutic conditions may assess QOL differently because the concept is the result of the interaction between the patient's life conditions and the way in which these are perceived by the patient.[88, 115-118]

4. AIM AND OBJECTIVES

Aim

The aim of the study is to assess quality of life in dialysis and non-dialysis chronic kidney disease patients.

Objectives

1. To study the demographic details of patients with Chronic Kidney Disease and Dialysis Patients.
2. To study the Prevalence of symptoms in patients with Chronic Kidney Disease and Dialysis Patients.
3. Determine the quality of life ofpatients with Chronic Kidney Disease and Dialysis Patients by using Kidney Disease Quality of Life Questionnaire–Short Form (KDQOL-SF™).

5. METHODOLOGY

Study design: Observational and prospective study.

Study population comprised of 200 patients with CRF sampled from nephrology department of a tertiary care hospital, Erode. CRF patients undergoing dialysis and not on dialysis aged 18 years and above of either sex and be able to provide informed consent to participate were included in the study. The patients who had undergone renal transplant were excluded. Participation in the study was voluntary and data was gathered from November 2016 through August 2017**.** The complete project was carried out according to the permission granted by the Institutional Human ethics committee. Written consent was obtained from participants prior to study. Demographic data recorded were age, gender, educational status, financial status and co-morbidities. KDQOL-SF™ was administered to CRF patients divided into two groups CRF on dialysis (CRF-D, n = 74) and CRF not on dialysis (CRF-ND, n = 126).

Survey Instrument

The disease – specific instrument used in this study was the Kidney Disease Quality of Life –short form (KDQOL-SF™) version 1.3, from RAND Corporation a self – report measure developed for CRF patients.[88] The KDQOL-SF™ was available in English version.

Even though KDQOL-SF™ is a self-reported questionnaire, considering the high proportion of illiterate participants, in this study questionnaires were administered by an interview to all the study participants.

The SF 36 assesses the HRQOL in eight domains (physical functioning, role limitations caused by physical problems,role limitations caused by emotional problems, pain,general health, energy/fatigue, emotional well-being,and social function).

The KDQOL-SF™ includes multi-item scales targeted at the particular health-related concerns of individuals who have kidney disease and are on dialysis.

KDQOL-SF™is a multidimensional, reliable and validated questionnaire intended for dialysis patients. It has 43 domains targeted for ESRD (43 items) and has as its generic core the 36 domain of the short form health survey (SF-36). Domains, on a 100-point scale, are generally measured with these questions, including (1) burden of kidney disease; (2) cognitive function; (3) dialysis staff encouragement; (4) effects of kidney disease; (5) patient satisfaction; (6) quality of social interaction; (7) sexual function; (8) sleep; (9) social support; (10) symptom problem; and (11) work status. Since our patient population comprised on CRF patients on dialysis and not on dialysis, two questions relating to dialysis staff encouragement and patient satisfaction that are generally part of the disease-specific component of the KDQOL-SF™ were excluded as they were not relevant to the population under evaluation as reported by *Mujais* et al*.,* 2009.[115] Question related to sexual function question was also eliminated.

Scoring algorithm was used to calculate scores ranging from 0 to100. The scores represent the percentage of total possible score achieved, with 100 representing the highest quality of life.

6. RESULTS

DEMOGRAPHIC CHARACTERISTICS OF STUDY POPULATION

Table 1. Gender wise distribution of Study population

Sl.No	Gender	CRF-ND(n=126)	CRF-D(n=74)
1	Male	71(56.3%)	44(59.4%)
2	Female	55(43.6%)	30(40.5%)

Data are reported as number (%)

Figure 1. Gender wise distribution of Study population

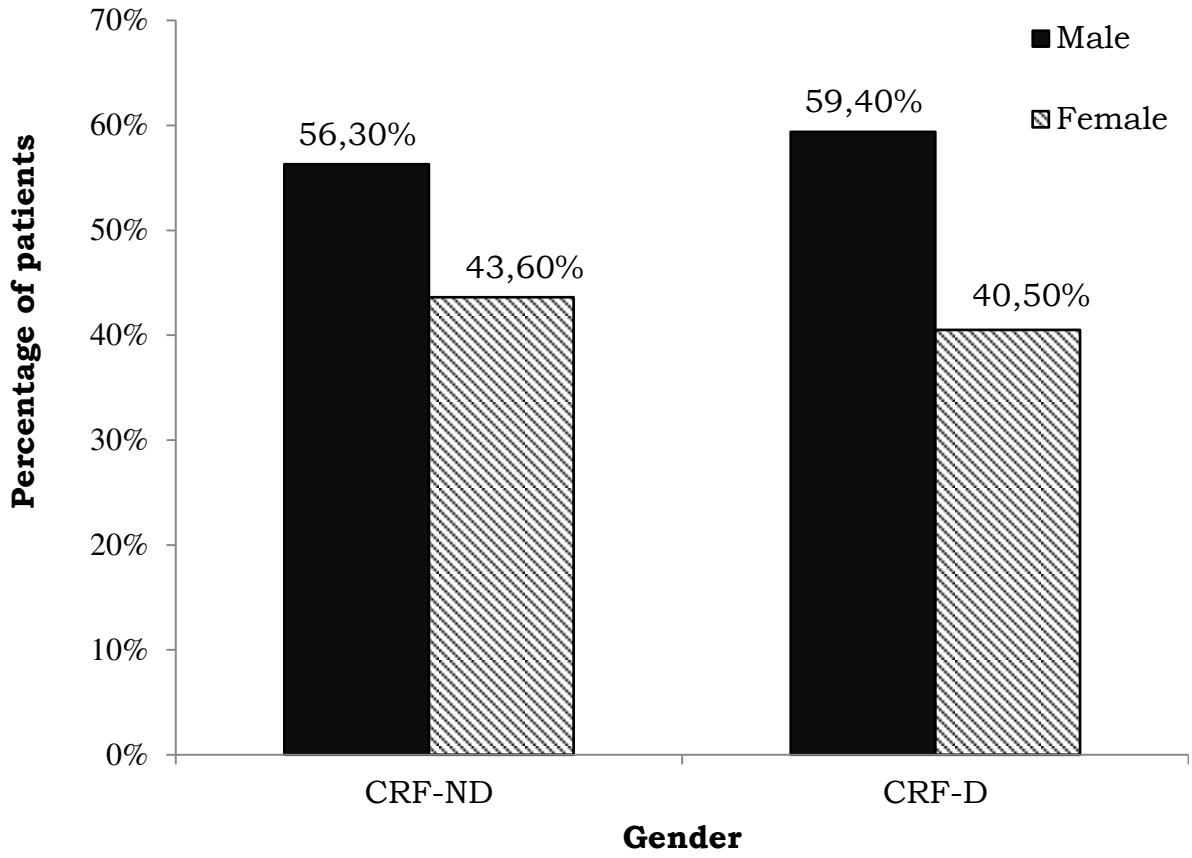


Table 2. Age wise distribution of Study population

Sl.No	Age (in years)	CRF- ND(n=126)	CRF- D(n=74)
1	<40	21(16.6%)	09(12.1%)
2	41-50	27(21.4%)	13(17.5%)
3	51-60	31(24.6%)	19(25.6%)
4	>60	47(37.3%)	33(44.5%)

Figure 2. Age wise distribution of Study population

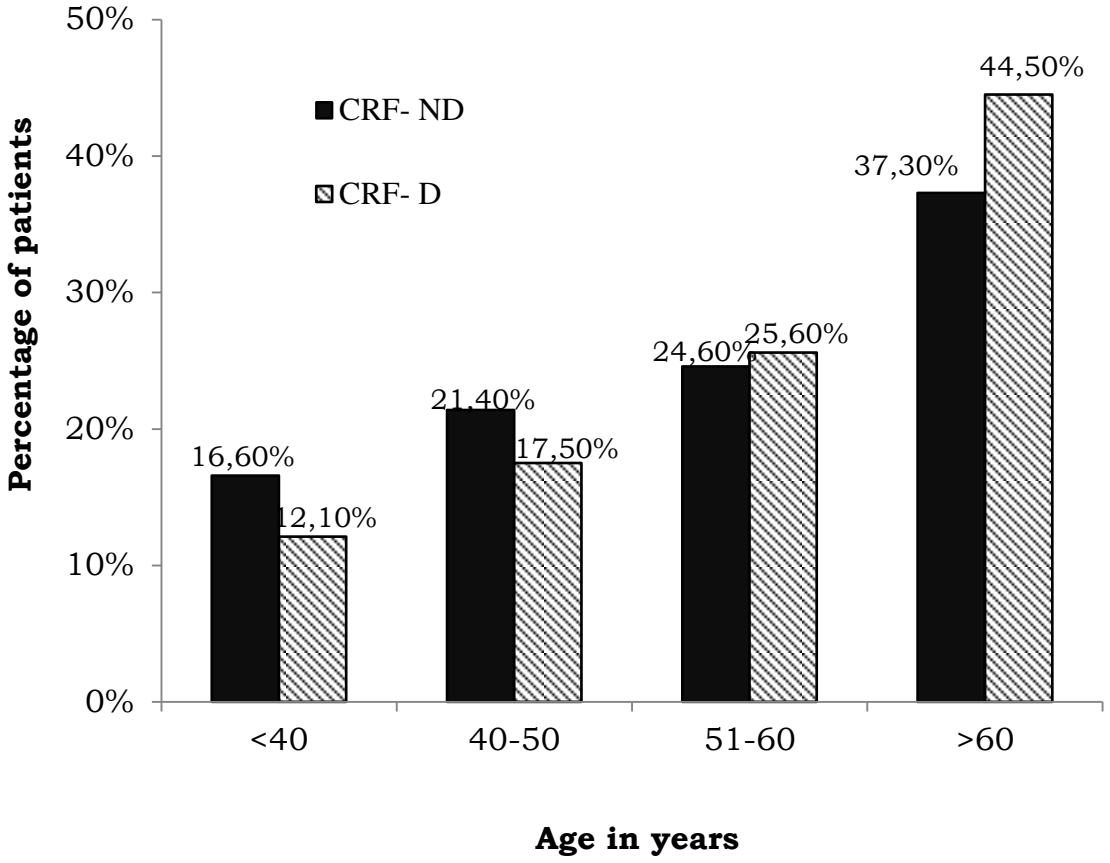


Table 3. Co-morbidities in study population

Sl.No	Co-morbidities	CRF- ND(n=126)	CRF- D(n=74)
1	Hypertension	107(84.9%)	69(93.2%)
2	Ischemic Heart Disease	63(50.0%)	47(63.5%)
3	Diabetes Mellitus	93(73.8%)	59(79.7%)
4	Anaemia	98(77.7%)	63(85.1%)
5	Others	47(37.3%)	27(36.4%)

Figure 3. Co-morbidities in study population

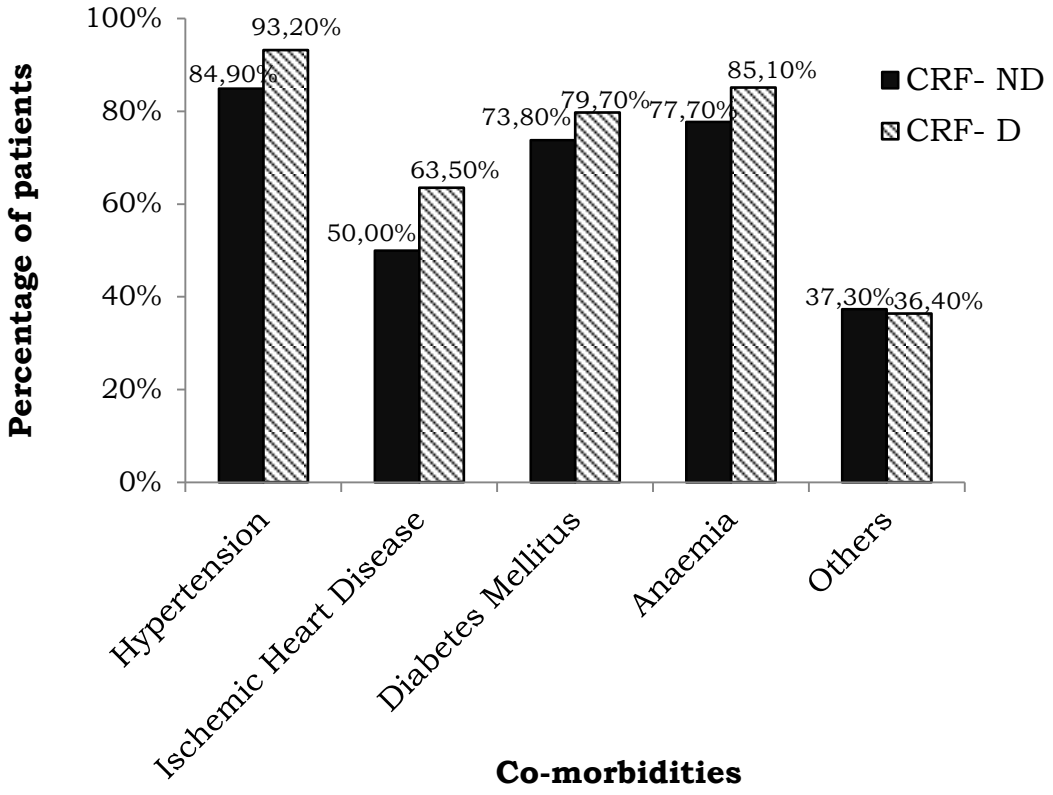


Table 4. Educational level of study population

Sl. No	Educational status	CRF- ND(n=126)	CRF- D(n=74)
1	Illiterate	53(42.0%)	31(41.8%)
2	School	45(35.7%)	25(33.7%)
3	Degree	28(22.2%)	18(24.3%)

Figure 4.Educational level of study population

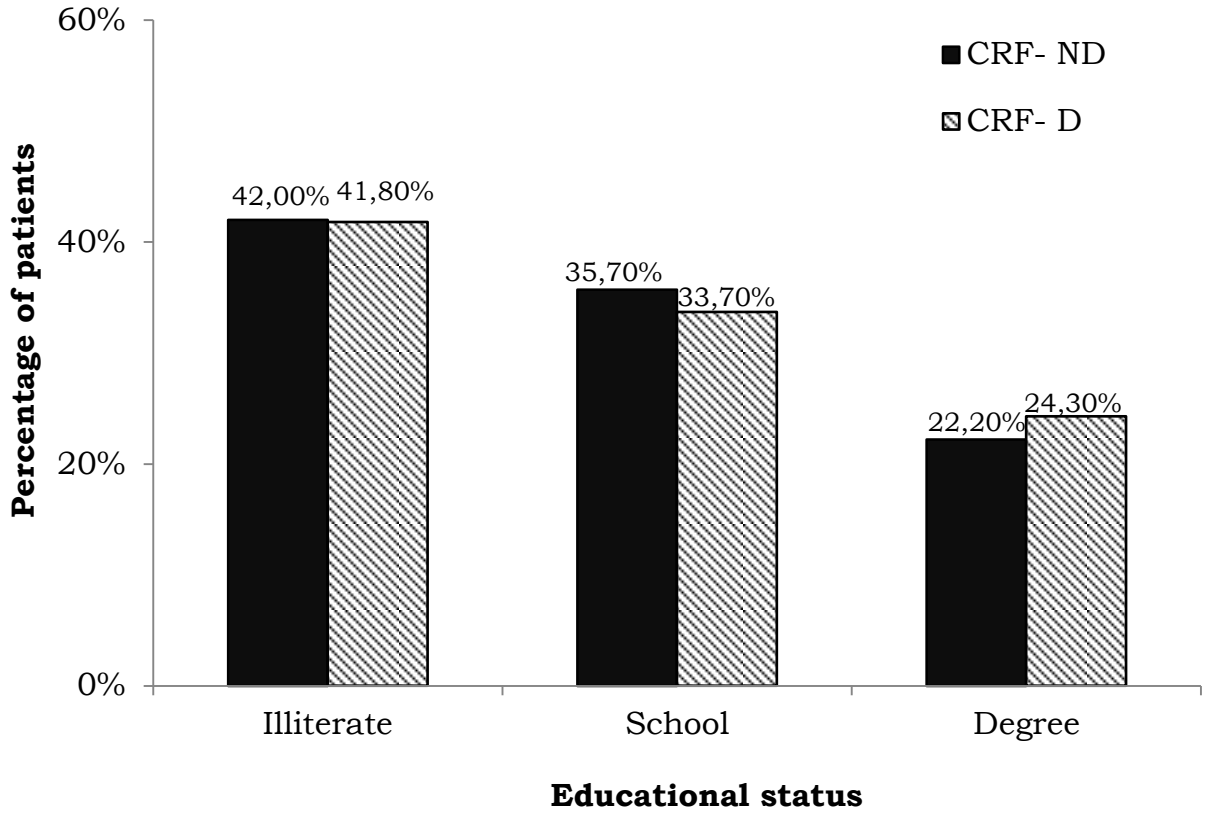


Table 5 .Individual monthly income of study population

Sl.no	Monthly per capita Income(INR)	CRF-ND(n=126)	CRF- D(n=74)
1	<5000	48(38.0%)	28(37.8%)
2	5000 – 15000	64(50.7%)	37(50.0%)
3	>15000	14(11.1%)	09(12.1%)

Figure 5.Individual monthly income of study population

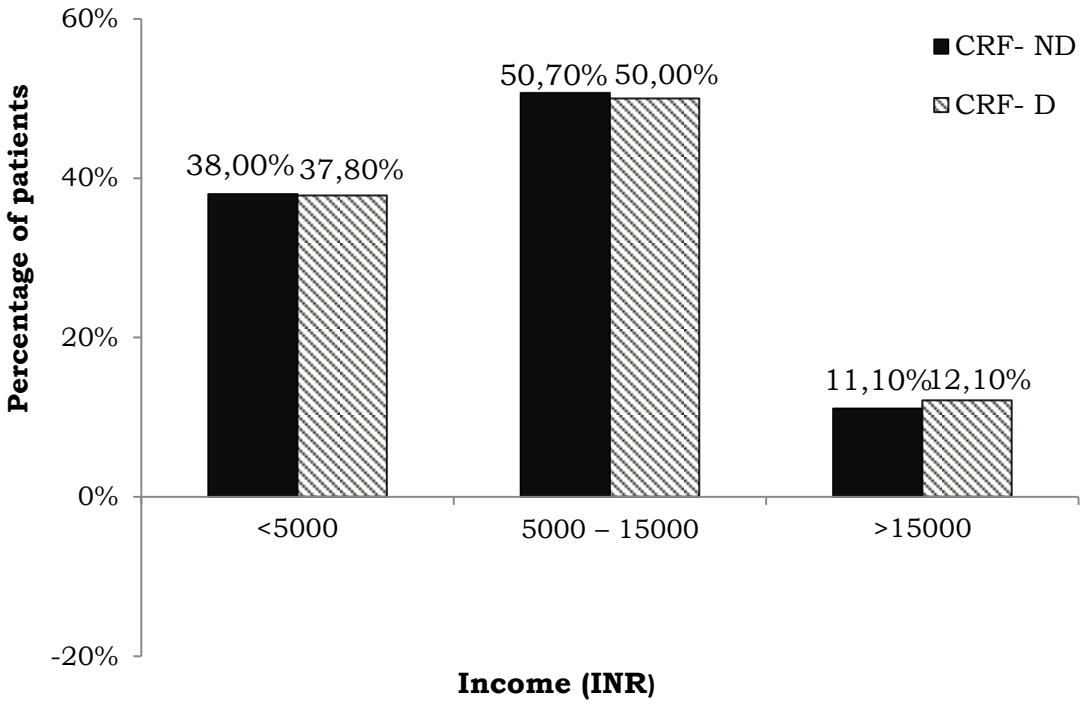


Table 6. Marital status of study population

Sl.no	Marital Status	CRF- ND(n=126)	CRF- D(n=74)
1	Married	95(75.3%)	56(75.6%)
2	Divorced	22(17.4%)	11(14.8%)
3	Single	9(7.1%)	7(9.4%)

Figure 6. Marital status of study population

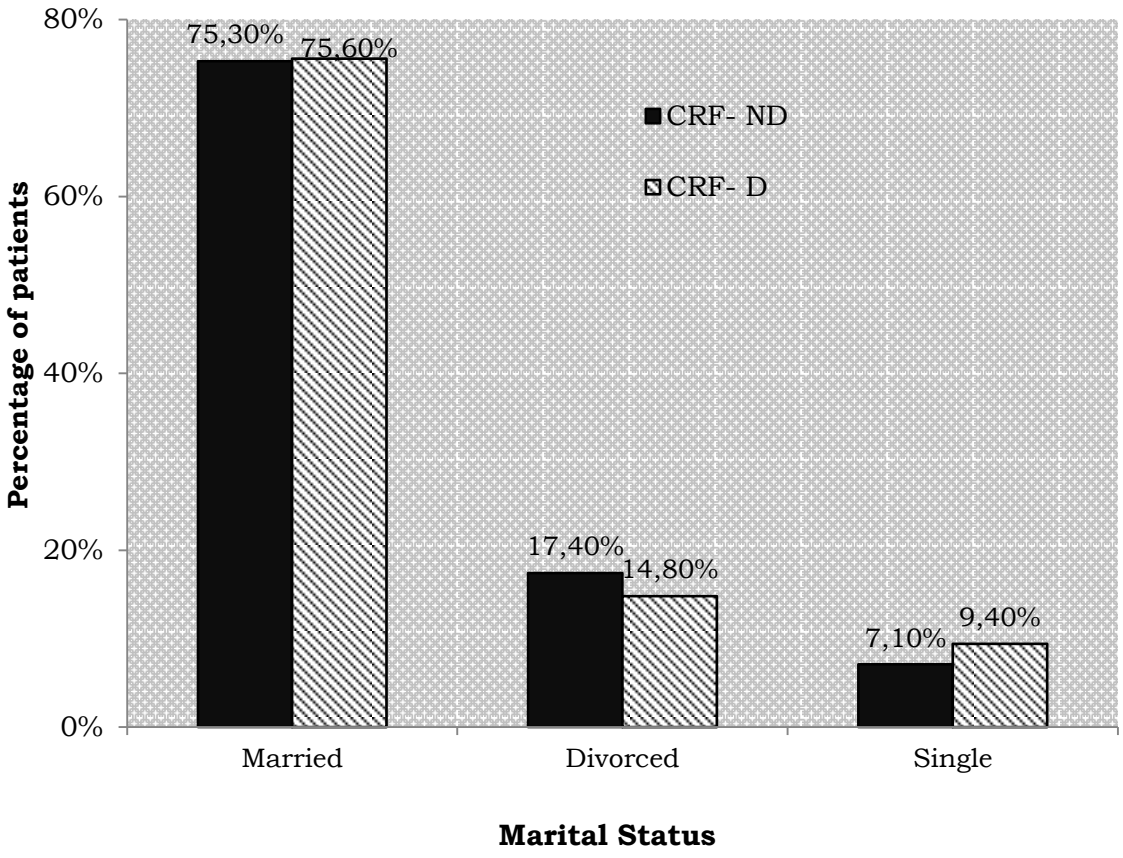


Table 7. Laboratory data of study population

Sl.no	Laboratory Data	CRF- ND (Mean ± SD)	CRF- D (Mean ± SD)	P Value
1	Hb(g/dl)*	11.7±1.2	11.2±1.8	0.01
2	Serum Urea(mg/dl)*	82.4± 32.9	127±30.3	0.03
3	Serum calcium (mg/dl)*	9.1±0.5	9.0±1.0	0.01
4	Serum albumin (mg/dl)*	3.8±0.5	3.6±0.6	0.04
5	Serum Phosphorous (mg/dl)*	4.1±0.7	4.9±0.8	0.01

*P<0.05. CKD ND: CKD –D

Figure 7. Laboratory data of study population

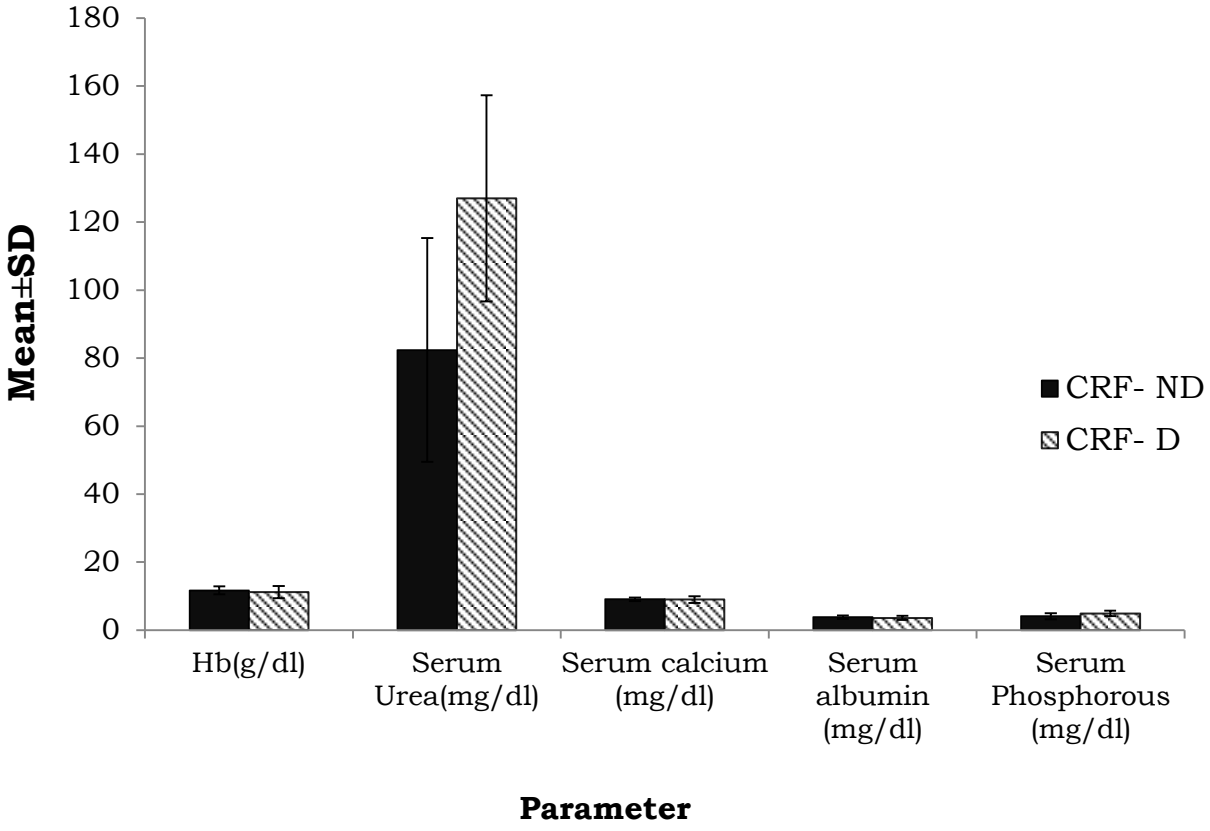


Table 8. Prevalence of symptoms in study population

Sl.no	Prevalence of symptoms	CRF-ND(n=126)	CRF- D(n=74)	P Value
1	Feeling tired and lack of energy	108(85.7%)	55(74.3%)	0.41
2	Worrying	87(69.0%)	41(55.4%)	0.82
3	Trouble in sleep	73(57.9%)	30(40.5%)	0.37
4	Itching	92(73.0%)	55(74.3%)	0.81
5	Feeling depressed*	41(32.5%)	19(25.6%)	0.03
6	Bone and joint pain	43(34.1%)	21(28.3%)	0.77
7	Muscle cramps	83(65.8%)	42(56.7%)	0.15
8	Dry mouth	79(62.6%)	37(50.0%)	0.04
9	Constipation	31(24.6%)	26(35.1%)	0.44
10	Swelling legs	29(23.0%)	11(14.8%)	0.11
11	Feeling nervous	41(32.5%)	21(28.3%)	0.25
12	Headache	47(37.3%)	22(29.7%)	0.12
13	Diarrhea	31(24.6%)	14(18.9%)	0.68
14	Decreased appetite	41(32.5%)	20(27.0%)	0.43
15	Cough	44(34.9%)	21(28.3%)	0.67
16	Nausea	43(34.1%)	22(29.7%)	0.19
17	Vomiting	41(32.5%)	24(32.4%)	0.61
18	Numbness in feet	51(40.4%)	28(37.8%)	0.18
19	Suppressed breathing*	40(31.7%)	19(25.6%)	0.01
20	Decreased interest in sex	27(21.4%)	16(21.6%)	0.27

*$P<0.05$. CKD ND: CKD –D

Figure8. Prevalence of symptoms in study population

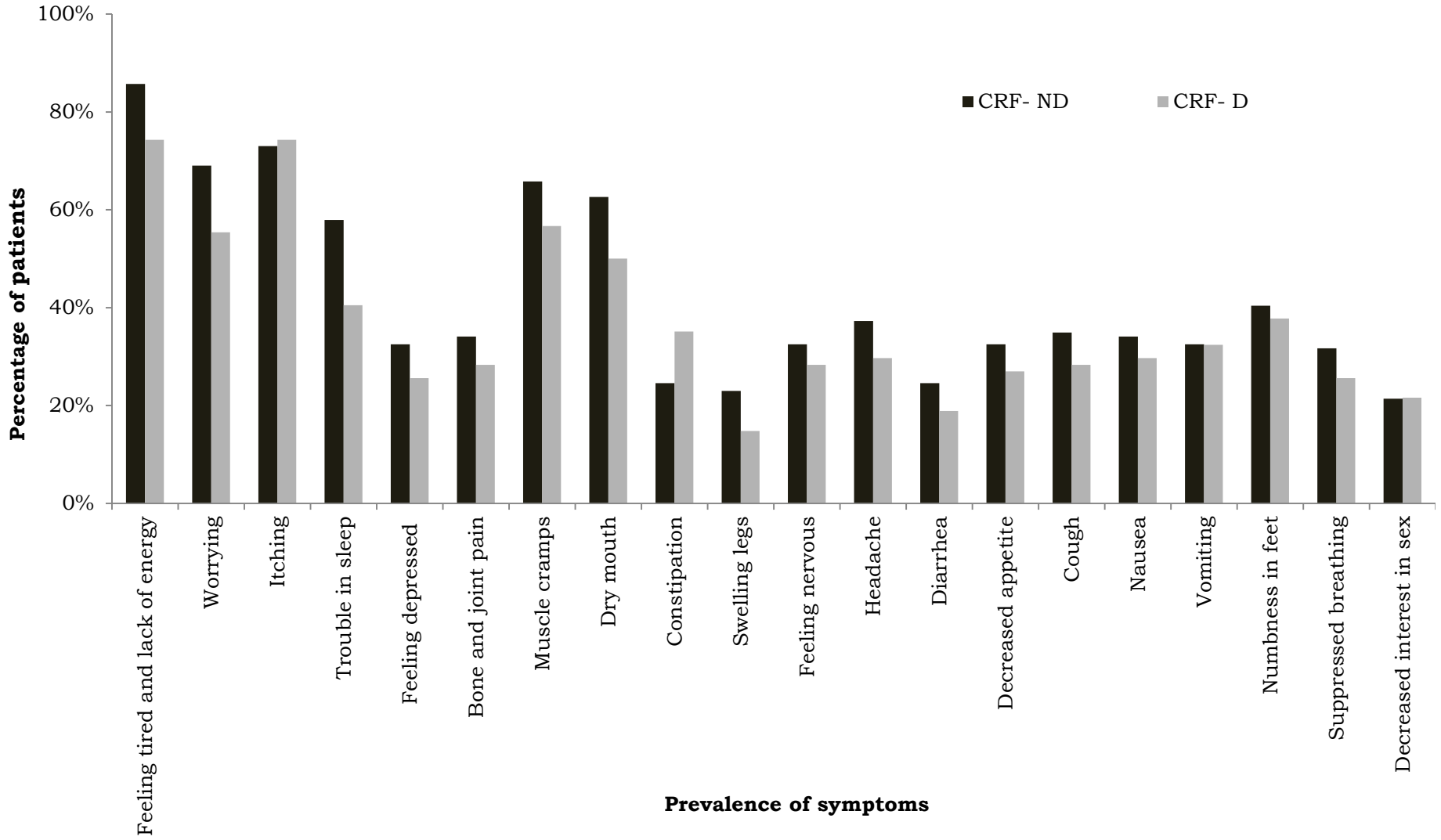


Table 9. KDQOL domain scores in study population

Sl.no	Kidney disease-specific domains	CRF- ND (Mean±SD)	CRF- D (Mean±SD)	P Value
1	Symptoms/problems	79.37±14.11	77.35±12.25	0.60
2	Effect of Kidney Disease	66.13±14.07	74.66±13.44	0.11
3	Burden of kidney disease	27.41±17.06	34.15±21.07	0.55
4	Work status	43.43±26.15	40.39±32.62	0.12
5	Cognitive	72.91±18.19	62.52±20.17	0.23
6	Quality of social interaction	77.66±20.42	75.91±19.72	0.22
7	Sleep	65.88±22.28	65.22±18.37	0.29
8	Social support	86.15±22.71	78.21±23.86	0.16

Figure 9. KDQOL domain scores in study population

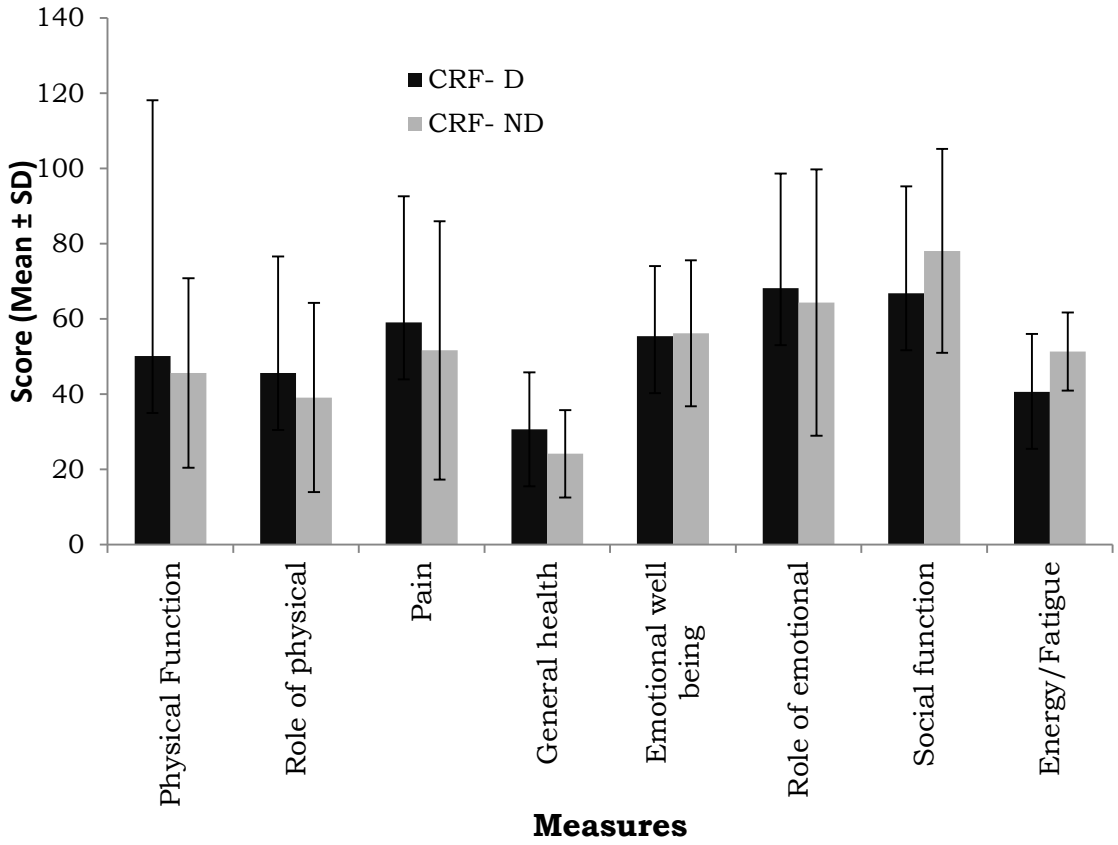
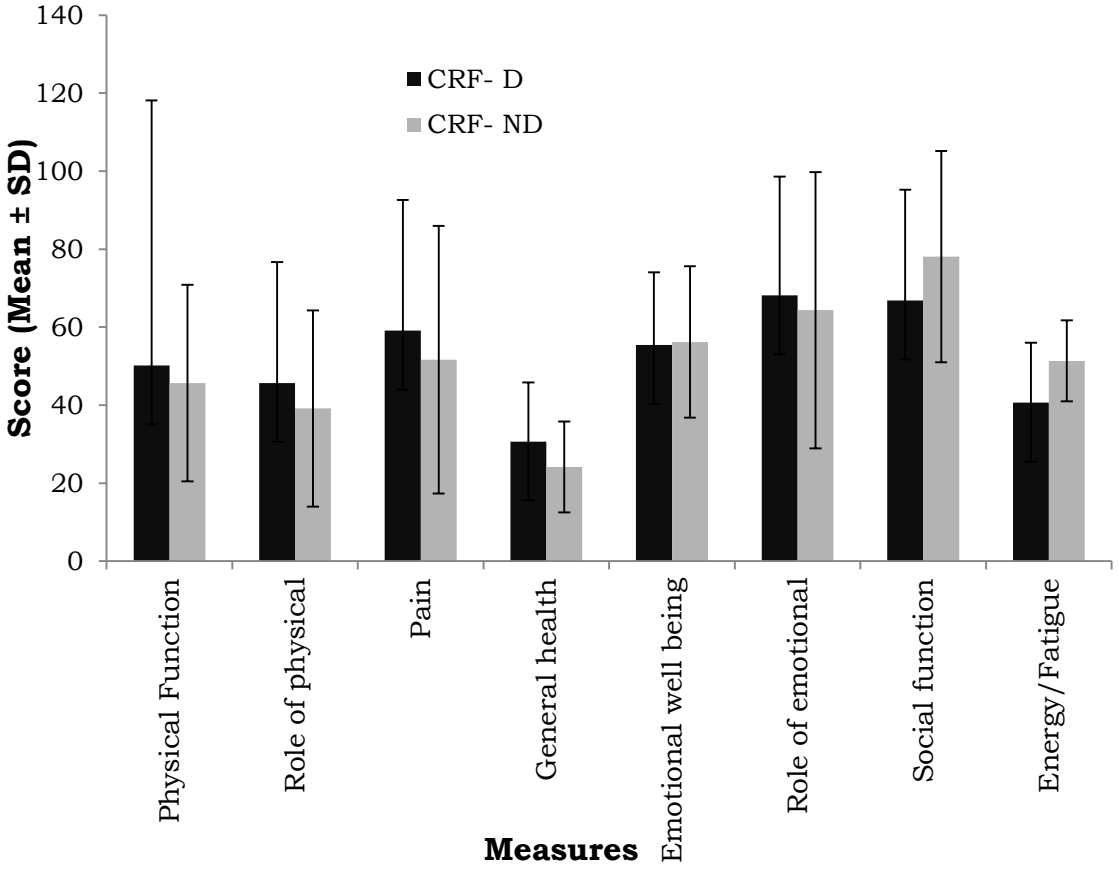


Table 10 .SF 36 items health survey scalescore in study population

Sl.No	SF 36 items health survey scales	CRF- ND (Mean± SD)	CRF- D (Mean± SD)	P Value
1	Physical Function	45.66±25.17	50.17±38.11	0.14
2	Role - physical	39.13±21.67	45.66±31.00	0.24
3	Pain	51.66±34.33	59.13±33.52	0.16
4	General health	24.17±11.65	30.66±15.14	0.11
5	Emotional well being	56.17±19.41	55.41±18.66	0.02
6	Role -emotional	64.36±35.42	68.17±30.47	0.01
7	Social function	78.11±27.09	66.86±28.38	0.02
8	Energy/Fatigue	51.36±10.39	40.66±15.33	0.15

Figure 10.SF 36 items health survey scale score in study population



7. DISCUSSION

Measuring the impact of CRF treatment on patients' quality of life is being recognized as an important outcome measure. The main aim along with treatment in patients with chronic medical conditions, such as CRF, in particular, is to reduce disease burden and suffering caused by thedisease. This means to improve the overall wellbeing of the patient and to improve the individual's quality of life. The Kidney Disease Quality of Life Questionnaire–Short Form (KDQOL-SF™) has become themost widely used QOL measures for CRF patients. In this study Quality of Life compared using KDQOL-SF™ scores among patients with dialysis and different CKD stages to study the relationship between QOL and the risks of outcomes. A total of 200CRF patients participated in the study which included 74CRF patients on dialysis (CRF-D) and 126CRF patients not on dialysis (CRF-ND).

Table no. 1, shows the gender wise distribution of Study population. Overall 59.4% were male patients greater in number than female 40.5% in CRF-D group, whereas CRF-ND comprised of 56.3% male patients and 43.6% of female.

Table no. 2, shows theage wise distribution. In this most of the CRF-D patients were in the age group of more than 60 years (44.5%) followed by 51-60 years (25.6%),41-50 years (17.5%) and less than 40 years(12.1%).CRF-ND patients were more in the age group of more than 60 years (37.3%) followed by 51-60 years (24.6%),41-50 years (21.4%)and less than 40 years(16.6%).

In both the groups, most of the participants were over 60 years.

Table no. 3, shows the co-morbidities of the study population. Hypertension, Ischemic Heart Disease, Diabetes Mellitus, and Anaemia are the co-morbid diseases commonly found with the CKD patients. In this study most of the CRF-D patients have hypertension(93.2%),

followed by anaemia (85.1%), Diabetes mellitus (79.7%), Ischemic Heart Disease (63.5%) and other diseases (36.4%).

Most of the CRF-ND patients have hypertension(84.9%), followed by anaemia (77.7%), Diabetes Mellitus (73.8%), Ischemic Heart Disease (50.0%) and other diseases (37.3%).

Table no. 4, shows the educational level of study population. 41.8%(CRF-D) and 42.0% (CRF-ND) patients were mostly Illiterates. 35.7% (CRF-ND) and 33.7% (CRF-D) of patients had education up to school level. Only 20% of the study population completed degree.

Table no. 5, shows theindividual monthly income.50% of the CRF-D andCRF-ND patients getting an income of 5000-15000 per month. Only CRF-D (12.1%) and CRF-ND (11.1%) have monthly wage of 15000.

Table no. 6, shows the marital status of study population. About 75% of the CRF-D and CRF-ND patients are married. CRF-D(9.4%) and CRF-ND (7.1%) patients are single in the study population.

Table no. 7, shows the laboratory data of study population. Heamoglobin, serum urea, serum albumin, serum phosphorous and serum calcium shows a significant difference in the CRF-D andCRF-ND patients.

Table no. 8, shows the prevalence of symptoms in study population. Feeling tired and lack of energy, worrying, Itching, feeling depressed, bone and joint pain,muscle cramps, dry mouth, constipation, swelling legs, feeling nervous, headache, diarrhea, decreased appetite, nausea, vomiting, numbness in feet, suppressed breathing, decreased interest in sex are the prevalence of symptoms associated with the study population.

The most prevalent symptoms in the dialysis groups were feeling tired and lack of energy (74.3%),itching (74.3%)Worrying (55.4%),and muscle cramps (56.7%); whereas then on-dialysis group commonly experienced feeling tired and lack of energy (85.7%), worry (69.0%), itching (73.0%) and muscle cramps (65.8%). Feeling tired and lack of energy(fatigue) was

the most prevalent symptom across all groups. In this study, nausea and decreased appetite were reported frequently.Our findings show that some symptom burden was higher in the non-dialysis group, compared to the dialysis group but most of the symptoms are did not reach statistical significance. Feeling depressed ($p<0.03$) and suppressed breathing ($p<0.01$) have significant difference in the CRF-D and CRF-ND patients. For instance, the most prevalent symptoms are not necessarily the most severe ordistressing symptoms, and that other symptoms are less important in respect of their severity but are frequently experienced.

CRF patients not on dialysis*:* As seen in Table 9 and 10, kidney disease targeted scale ranged from 40.39to 81.37 in the possible of 0-100 scores. The 36 items health scale ranged from 21.31to 54.02. In kidney disease targeted scales burden of kidney disease (27.41±17.06), cognitive function (72.91±18.19), quality of social interaction (77.66±20.42), Effects of kidney disease (66.13±14.07), work status (43.43±26.15) whereas symptom/problem list (81.37±12.22), Sleep (65.88±22.28) and social support (86.15 ± 22.71). SF36 items health survey scales indicated that physical function (45.66± 25.17), role physical (39.13±21.67), role emotional (64.36±35.42), social support (78.11 ± 27.09), emotional well-being (56.17±19.41), energy and fatigue (51.36 ± 10.39), general health (24.17 ±11.65) had a mean score below 50, but pain (51.66 ± 34.33) scored above 50.

CRF patients on dialysis: The kidney disease targeted scales ranged from 25.63 to 78.30 in the possible (0-100) scores. Kidney disease targeted scales showed that burden of kidney disease (34.15±21.07), Quality of social interaction (75.91±19.72) cognitive function (65.52±20.17), effects of kidney disease (74.66±13.44), work status (40.39±32.62) had mean score below 50 whereas symptom/problem list (77.35±12.25), sleep (65.22±18.37), social support (78.21±23.86) had mean score of above 50.The 36 items health survey scales such as physical function (50.17±38.11), role physical (45.66±31.00), role emotional (68.17±30.47), social function (68.66±28.38), emotional well-being (55.41±18.66),

energy/fatigue (40.66±15.33), general health (30.66±15.14) had a mean score below 50. On the other pain (59.13±33.52) had mean score of above 50.

Overall, there was no significant change in the KDQOL-SF™ scores among patients with CRF patients on dialysis and CRF patients not on dialysis. Comparison of mean score as shown in Table 9 and 10, between CRF-D and CRF-ND groups revealed that quality of social interaction, role emotional, emotional well-being had a significant difference ($p < 0.05$)

Apart from the physical, clinical, and functional parameters, factors such as the socio-cultural environment, economic status, emotional status, accessibility to medical care,and spiritual attitudes possibly play a significant role inan individual's perception of life and disease.[114,119-121]These parameters could not be assessed with the current toolfor HRQOL.

Some limitations of the present study are the relatively small sample size to detect significant differences betweenthe stages of CKD and the difficulties we encountered inrecruiting subjects in the initial stages of the disease. The cross-sectional design of the study only permitted us to determine associations between variables and not causal relationships. Thus, longitudinal studies that take intoaccount qualitative assessments should be conducted toseek a better understanding of the influence of the progression of CKD on QOL.

8. CONCLUSION

The proper measures of QOL in patients with renal disease are unknown. Measures include subjective and objective tools, and generic and disease-specific scales. The past several years have witnessed an explosion in the number of studies and the populations of patients with CKD in which various aspects of HRQOL have been assessed. It is clear that the many QOL measures are intertwined. A challenge remains to make these domains clinically meaningful. Use of KDQOL-SFTM as a QOL assessment tool, may be valuable in the global assistance of these patients and allow timely health care intervention in the course of the disease. Our findings show that some symptom burden was higher in the non-dialysis group, compared to the dialysis group but most of the symptoms are did not reach statistical significance. Similarly, there was no significant change in the KDQOL-SFTM scores among patients with CRF patients on dialysis and CRF patients not on dialysis. Results obtained from the use of KDQOL-SFTM in CRF patients undergoing dialysis and not on dialysis supports the reliability of the instrument in study area population. Hence, KDQOL-SFTM would help physicians in routine monitoring of patient's perception of their wellbeing as it forms an integral part to impart better patient care. A better understanding of HRQoL and its determinants would help to formulate individualized treatment strategies. There is a compelling need for further research to better define the spectrum of changes in symptom burden and physical performance among patients started on maintenance dialysis. Such research will crucially inform the discussion between clinicians and patients in the shared decision making process around the timing of dialysis initiation.

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INFORMATION FOR PATIENT

Dear participant,

I **Mr. SAIFUL ISLAM.M, [REG.No. 261540210]** student of **J.K.K.Nattraja College of Pharmacy, Kumarapalayam** currently conducting a project entitled **"Assessment of Quality Of Life in Dialysis and Non-Dialysis Chronic Kidney Disease Patients"** for the partial fulfillment for the award of Degree of **Master of Pharmacy** in **Pharmacy Practice.**

As the part of project we need to collect data from you including socio-demographic details, symptoms of disease, answers regarding your quality of life and Medications prescribed.

We will appreciate very much if you could kindly assist us to collect your medical data's. However identifiable personal data's will not be disclosed.

Thank you very much for your kind participation.

CONSENT FORM

I, _____, have read and understand the above information. I have agreed to allow my data to be collected for the project work.

_____ _____

Signature of participant Date

_____

Signature of translator

DATAENTRY

Name: Height:

Age: Weight:

Sex: BMI:

Chronic Renal Failure:

Non-Dialysis ☐ [Stage1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Stage 5 ☐]

Dialysis ☐ [Hemodialysis ☐ Peritoneal Dialysis ☐]

Marital Status:

Married ☐ Divorced ☐ Single ☐

Educational status:

Illiterate ☐ School ☐ Degree ☐

Monthly Income (Rs):

<5000 ☐ 5000 – 15000 ☐ >15000 ☐

Co-morbid diseases:

Hypertension ☐

Diabetes mellitus ☐

Ischemic Heart Disease ☐

Anaemia ☐

Others ☐

Laboratory Data:

Sl.no	Laboratory Parameter	Values
1	Hb(g/dl)	
2	Serum Urea(mg/dl)	
3	Serum calcium (mg/dl)	
4	Serum albumin (mg/dl)	
5	Serum Phosphorous (mg/dl)	

Prevalence of symptoms:

Sl.no	Prevalence of symptoms	
1	Feeling tired and lack of energy	
2	Worrying	
3	Itching	
4	Trouble in sleep	
5	Feeling depressed	
6	Bone and joint pain	
7	Muscle cramps	
8	Dry mouth	
9	Constipation	
10	Swelling legs	
11	Feeling nervous	
12	Headache	
13	Diarrhea	
14	Decreased appetite	
15	Cough	
16	Nausea	
17	Vomiting	
18	Numbness in feet	
19	Suppressed breathing	
20	Decreased interest in sex	

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?

	Yes	No
4. <u>Accomplished less</u> than you would like.....	☐ 1	☐ 2
5. Were limited in the <u>kind</u> of work or other activities.....	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. <u>Accomplished less</u> than you would like.....	☐ 1	☐ 2
7. Didn't do work or other activities as <u>carefully</u> as usual.....	☐ 1	☐ 2

8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the <u>past 4 weeks</u>…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How <u>true</u> or <u>false</u> is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time is spent dealing with my kidney disease.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the <u>past 4 weeks</u>, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
	▼	▼	▼	▼	▼
17. Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23. Faintness or dizziness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Lack of appetite?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Washed out or drained?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Numbness in hands or feet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Nausea or upset stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[a]. (Hemodialysis patient only) Problems with your access site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[b]. (Peritoneal dialysis patient only) Problems with your catheter site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease <u>bother</u> you in each of the following areas?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29. Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30. Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31. Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. Being dependent on doctors and other medical staff?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34. Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35. Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36. Your personal appearance?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5