BURDEN OF RESTLESS LEG SYNDROME IN PATIENTS WITH END STAGE RENAL DISEASE UNDERGOING MAINTENANCE HEMODIALYSIS

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A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE, UNIVERSITY OF NAIROBI

DECLARATION

This dissertation is my original work and has been presented as a prerequisite for a master's degree of Medicine in Internal Medicine to the department of Clinical Medicine and Therapeutics, University of Nairobi, Kenya. This dissertation has not been presented for any degree to any other university.

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I dedicate this work to my family.

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I wish to express my sincere gratitude to the following for their contribution towards the success of this dissertation.

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

BMI	Body Mass Index
CKD	Chronic Kidney Disease
EPO	Erythropoietin
ESA	Erythropoietin Stimulating Agents
ESRD	End Stage Renal Disease
GFR	Glomerular Filtration Rate
HIV	Human immunodeficiency virus
IRLSSG	International Restless Legs Syndrome Study Group
KNH	Kenyatta National Hospital
PKC	Parkland's kidney center
PLMS	Periodic Limb Movements of Sleep
QoL	Quality of Life
RLS	Restless Leg Syndrome
SHD	Short Hemodialysis Therapy
SPECT	Single Photon Emission Computed Tomography
WHOQOL BREF	World Health Organization quality of life questionnaire
UON	University of Nairobi

ABSTRACT

Background

Restless leg syndrome (RLS) is an underestimated neurological condition in hemodialysis patients. Restless leg syndrome has a negative effect on the quality of sleep and life in these patients. In Kenya, chronic kidney disease is increasing due to non-communicable diseases such as hypertension and diabetes, and many patients are getting into hemodialysis treatment program. There is no published data on Restless Leg Syndrome in Kenyan Patients.

Objectives

To determine the prevalence of restless leg syndrome in patients with end stage renal disease patients undergoing hemodialysis, evaluate the severity of restless leg syndrome and determine the quality of sleep and life.

Methods

This was a multicenter cross-sectional study done at the renal units in Kenyatta National Hospital, Mbagathi District Hospital, Nairobi Hospital and the Parkland's Kidney Center. The study participants were adults undergoing maintenance hemodialysis. Two hundred and seventy patients were undergoing maintenance hemodialysis at the four centers during the time of study. Consecutive sampling was used to recruit patients. 22 study subjects were excluded – 2 pregnant, 10 were on gabapentin and 10 declined consent. Eight (8) patients had dialyzed for less than three months, consequently 240 patients were recruited. After obtaining a written informed consent, demographic features; comorbidities, underlying cause of ESRD and dialysis history were collected using a study proforma. Diagnosis of Restless Leg Syndrome was established by administering International Restless Leg Syndrome Study Group 2012 questionnaire and severity of Restless Leg Syndrome was determined by administering the IRLSSG Severity Rating Scale; score of 31-40 was very severe, 21-30 was severe, 11-20 was moderate and 1-10 had mild Restless Leg Syndrome. Daytime sleepiness was determined by administering The Epworth Sleepiness Scale; a score of more than ten indicated a poor quality of sleep. Quality of life was determined by administering the 36 item short form health survey; a score of less than 50% indicated a poor quality of life. Data was analyzed in SPSS version 21.0.

Results

Two hundred and forty patients were recruited. The prevalence of Restless Leg Syndrome was 35.8% (95%confidence interval, [CI] 29.8 to 42.3). The mean age was 53.3 (SD 17.1) years. Ninety percent (n=78) patients had moderate to severe form of the disease. Forty two percent (n=101) of study subjects had poor quality of sleep. There was a strong association of Restless Leg Syndrome and poor quality of sleep (odds ratio, 15.5; 95% confidence interval [CI], 8.0 to 29.9; P< 0.001). Fifty one percent (n=123) of study subjects had a poor quality of life. Study subjects with Restless Leg Syndrome had a poor quality of life as compared to those without the syndrome (Odds ratio, 6.8; 95% Confidence Interval [CI], 3.7 to 12.6; P<0.001).

Conclusion

Restless Leg Syndrome is a common neurological condition among hemodialysis patients. It should be routinely looked for as it leads to a poor quality of sleep and life.

1.0 CHAPTER ONE: INTRODUCTION

Restless Leg Syndrome (RLS) is a neurological condition that has both sensory and motor components(1). It is often described as an urge to move the legs usually accompanied with unpleasant sensations such as crippling and crawling(2).The symptoms usually occur at night during inactivity(2). This leads to poor sleep cycle leading to poor standard of life(3). Restless Leg Syndrome is classified into primary and secondary(2). Primary Restless Leg Syndrome is a polygenetic condition and attributed by polymorphisms in the MEIS 1 and BTBD9gene. Secondary causes of Restless Leg Syndrome include diabetes, multiple sclerosis, Parkinson's disease, pregnancy, end stage renal disease, rheumatoid arthritis and iron deficiency(4,5).

The prevalence of Restless Leg Syndrome is 2-20 percent in the general population(6,7). Studies in the past in India, Turkey, Iran, Pakistan and Saudi Arabia have shown 6%–71% prevalence in hemodialysis patients.(5,8–11). Only one study of this kind has been carried out in Nigeria where a 5.9% prevalence was found. There are no studies of this kind in Kenya. These large variations could be due to genetic variations and ethnic variations across different countries. Another reason for the variation is different study tools and methods used for the diagnosis of Restless Leg Syndrome. A clinical diagnostic criterion for Restless Leg Syndrome has been established by the International Restless Leg Syndrome Study Group (IRLSSG) and was updated recently. The five essential criteria of the disorder are:

i. A need to shake or shift the lower limbs, with concurrent disagreeable and distressing sensations in the legs.
ii. The need to stir or shake and disagreeable perceptions start or worsen during periods of rest or inactivity, such as lying or sitting.
iii. The need to shake or disagreeable perceptions are partially or totally relieved by movement, such as walking or running, for at least as long as the activity continues.
iv. The need to shake or disagreeable perceptions are worse in the evening or night than during the day or only occur in the evening or night.
v. Other medical illness and disease are excluded that can cause the same movement in the lower limbs at night such as muscle pain, habitual foot tapping, leg cramps that are positional and leg edema(12).

Restless Leg Syndrome leads to a poor quality of life in patients undergoing maintenance hemodialysis. There is an increased burden of Restless Leg Syndrome in hemodialysis patients. Prompt diagnosis and treatment of the condition improves the standard of life of these patients.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Background Information on Restless Leg Syndrome

Restless Leg Syndrome (RLS) is a sleep disorder that occurs frequently and is often misdiagnosed(13). Out of eighty percent of patients with Restless Leg Syndrome only twenty five percent are correctly diagnosed and thirteen percent receive treatment(14). The syndrome is either idiopathic or secondary condition of other diseases such as rheumatoid arthritis, diabetes, Multiple Sclerosis, Parkinson's disease and renal problems (patients under dialysis in particular)(2,4,5). The major causes of Restless Leg Syndrome are unknown; however, iron deficiency anemia, hypercalcemia and secondary hyperparathyroidism lead to changes in neurotransmission leading to the symptoms(4).

In the general population prevalence of Restless Leg Syndrome is 2% to 20%(6,7) and studies in Pakistan, Iran, Brazil, Italy and Canada have shown that it is increased among hemodialysis patient's up to six to seventy one percent(10,15–18). Restless Leg Syndrome can be a problematic disorder(19). Patients with Restless Leg Syndrome tend to have depression, anxiety disorders and substandard sleep quality(20,21). Due to the fragmented sleep this affects their daily activities such as working and driving(20,21). Restless Leg Syndrome among hemodialysis patients affects the standard of life and the patient's adaptation to dialysis. It also increases cardiovascular risk, which in turn increases the mortality and morbidity of these patients(22).

2.2 Epidemiology of Restless Leg Syndrome in patients on hemodialysis

Twenty dialysis centers were enrolled in Triveneto area, Italy in the year 2004 to determine the prevalence of Restless Leg Syndrome in end-stage renal disease. Gigli et al, found a 21.5% prevalence of Restless Leg Syndrome among hemodialysis patients(17).

Deferio et al carried out a retrospective study using the United States Renal Records. This study determined a 0.1% prevalence of Restless Leg Syndrome in hemodialysis patients. A low prevalence was attributed due to incomplete data from the patient records, inaccurate reporting in patient files and absence of continuous validation(23).

One hundred and seventy six Brazilian patients undergoing hemodialysis in Santa Teresa hospital were evaluated for Restless Leg Syndrome. This study found a 14.8% prevalence of

Restless Leg Syndrome(16). Later in 2010, a study done by Araujo et al. found eighty out of four hundred hemodialysis patients had Restless Leg Syndrome, establishing a 21.5% prevalence(13). In Sergipe, Brazil two hundred and forty one patients on hemodialysis were recruited, the prevalence of Restless leg Syndrome was 17.4% (24).

In Canada, Walker et al found a 57.4% prevalence of Restless Leg Syndrome in a single hemodialysis unit. Fifty four patients were evaluated for various sleep disorders and Restless Leg Syndrome was a common sleep disorder among patients undergoing hemodialysis(18).

In a single dialysis unit in Turkey, seventy six patients on maintenance hemodialysis were recruited in 2009. Using the IRLSSG criteria questionnaire a 14.5% prevalence of Restless Leg Syndrome was found(8).

A descriptive analytic study in hospital of Yazd, Central Iran evaluated one hundred and forty hemodialysis patients and found a 71.2% prevalence of Restless Leg Syndrome. 30% had mild Restless Leg Syndrome, 44.8% had moderate Restless Leg Syndrome and 41.5 % had severe Restless Leg Syndrome(15).

In Pakistan a cross-sectional study in four hospitals- two government and two private sector in 2013 recruited 390 patients on hemodialysis. The prevalence of Restless Leg Syndrome in hemodialysis patients was 23.6% where 64.1% of them had mild to moderate Restless Leg Syndrome and only 10.9% had very severe Restless Leg Syndrome(10).

Bhowmik et al. found a very low prevalence rate of Restless Leg Syndrome of 6.6% among patients undergoing maintenance hemodialysis. This was attributed to racial and ethnic differences, Asians had less variants within intronic regions of MEIS 1 and BTBD9 as compared to the population in West(5).

In three major hospitals in Jeddah, Saudi Arabia, a cross-sectional descriptive study was conducted. Three hundred and fifty five patients undergoing maintenance hemodialysis were evaluated for Restless Leg Syndrome and a 19.4% prevalence was found(11).

Le Manna et al. did a study in Italy at the S Orsola university hospital where he evaluated 100 hemodialytic patients. A 31% prevalence of Restless Leg Syndrome was established(22).

A Nigerian study in University of Benin Teaching hospital on 101patients on hemodialysis found a 5.94% prevalence of Restless Leg Syndrome. This low prevalence was attributed to

ethnic and genetic variations within the African population. The genetic variation was attributed to no variants present in the MEIS 1 and BTBD9 genes. Variants in the MEIS 1

and BTBD 9 genes lead to increased risk of developing Restless Leg Syndrome in patients undergoing hemodialysis(25).

Author	Sample Size	Method	Prevalence	Country
Gigli et al.(17)	601	IRLSSG-2003 questionnaire	21.5%	Italy
Deferio et al.(23)	2,138,876	IRLSSG-2012 questionnaire	0.1%	United states of America
Goffredo et al.(16)	176	IRLSSG-1995 questionnaire	14.8%	Brazil
Araujo et al.(13)	400	IRLSSG-2003 questionnaire	21.5%	Brazil
Walker et al.(18)	54	Single question for RLS	57.4%	Canada
Soyoral et al.(8)	76	IRLSSG-2003 questionnaire	14.5%	Turkey
Bhowmik et al.(5)	121	IRLSSG-1995 questionnaire	6.6%	India
Wali et al.(11)	355	IRLSSG-2003 questionnaire	19.4%	Saudi Arabia
Mahmood et al.(10)	390	IRLSSG-2003 questionnaire	23.6%	Pakistan
Eftekhari et al.(15)	140	IRLSSG-2012 questionnaire	71.2%	Iran
Onwuch ekwa et al.(25)	101	IRLSSG-2003 questionnaire	5.9%	Nigeria
La Manna et al.(22)	100	IRLSSG-2003 questionnaire	31%	Italy

Table 1 Prevalence of Restless Leg Syndrome among hemodialysis patients

2.3 Clinical Demographic Characteristics of Patients with and Without Restless Leg Syndrome in End Stage Renal Disease

The occurrence of Restless Leg Syndrome among hemodialysis patients was common in developed countries than in developing countries. This was explained by genetic and ethnic variations. In developed countries there were additional polymorphisms present in the MEIS1 and BTBD9 genes leading to an increased risk of Restless leg Syndrome(5,26).

Restless Leg Syndrome affected the older population more than the younger population due to the neurodegenerative changes(27). Although studies in India and United Kingdom showed there was no difference between the age and Restless Leg Syndrome(5,28). Restless Leg Syndrome occurred more in the younger population in Brazil(13,29). In Nigeria Restless Leg Syndrome was more in the elderly which was attributed to disruption of dopamine transmission of pain impulses (25).

Females are twice more affected by restless leg Syndrome than males. Estrogen increases the risk of Restless Leg Syndrome(29). Restless Leg Syndrome is more prevalent in pregnancy, elevated levels of estrogen during pregnancy increased the risk of Restless Leg Syndrome(13,29). Studies in Iran and India stated there was no association between gender and Restless Leg Syndrome(5,15). In Italy there was no gender difference between patients with and without Restless Leg Syndrome(17).

Restless Leg Syndrome occurred more in smokers than non-smokers(16,30). In Iran, Masshad out of two hundred and sixty patients, nine were smokers and 83.3% of the smokers had Restless Leg Syndrome(30). In the Pakistan and Tehran studies there were no associations between smoking and Restless Leg Syndrome(10,31).

Obese hemodialysis patients have an increased frequency of Restless leg Syndrome(11). An increase in per unit body mass index increased the risk of Restless Leg Syndrome by five percent(11). Patients with Restless Leg Syndrome tended to have higher body mass index as compared to the individuals without the syndrome(21,30). There was no association of obesity and Restless Leg Syndrome in Benin, Nigeria(25).

The correlation between length of dialysis and dialysis adequacy with Restless Leg Syndrome is debatable(32). The length of dialysis correlates with an increased risk of developing

Restless Leg Syndrome. A longer dialysis duration tended to be a predisposing factor for developing Restless Leg Syndrome(17,21,30). There are other studies in Iran, Brazil which showed there was no association between the duration of dialysis and dialysis dose with restless Leg Syndrome(16,30).

There is conflicting data regarding the association between Restless Leg Syndrome and anemia(32). Restless leg Syndrome occurs secondary to iron deficiency anemia(33).

2.4 Instruments for the Diagnosis of Restless Leg Syndrome, Assessing the Severity of Restless Leg Syndrome, Assessing the Daytime Sleepiness and Quality of Life in Patients Undergoing Hemodialysis

2.4.1 Single question for RLS

This is a validated screening tool for Restless Leg Syndrome. It was validated in Italy by Ferri et al(34). It has a hundred percent sensitivity and ninety six percent specificity. This method of diagnosis of Restless Leg Syndrome has not been used commonly; it has been utilized in one clinic setting in Italy and not for the general population. The strength of this diagnostic modality is that it has hundred present sensitivity and is fast for establishing the diagnosis.

The limitation for this diagnostic method is that it does not exclude other diseases that could mimic the syndrome. Therefore this method of diagnosis is not recommended(35).

2.4.2 Restless Leg Syndrome diagnostic Index

This consists of ten items, five of these are the essential diagnostic criteria and five others are the supportive criteria. It has been validated. It has 93% sensitivity and 98.9% specificity. It has both objective and subjective criteria improving the accuracy of diagnosis of Restless Leg Syndrome. It is recommended for use in the diagnosis in Restless Leg Syndrome by a telephone interview(35).

2.4.3 Cambridge Hopkins Restless Leg questionnaire

This is self-administered questionnaire. It has been validated to be used in clinical and general population. It consists of thirteen questions and also excludes other conditions that mimic restless Leg syndrome. It has 94% specificity and 87.2% sensitivity.

The questionnaire has good clinimetric properties and an accurate diagnosis(35).

2.4.4 The International Restless Leg Syndrome Study Group 2012 criteria questionnaire

This questionnaire was validated in 2012. It consists of six questions and excludes the disorders that mimic Restless Leg Syndrome. It has 95% sensitivity and 90% specificity. It has been used for the general and clinical population. It has been validated internationally. It is useful in making a correct diagnosis. The International Restless leg Syndrome Study Group 2003 criteria consisted of four questions and did not exclude other conditions. It had a low sensitivity of 80%(12).

2.5 Instrument for Assessing the Severity of Restless Leg Syndrome

2.5.1 The IRLSSG Severity rating scale.

This consists of ten questions; each question is rated from 0 to 4. It is an important instrument used for evaluating the severity of Restless Leg Syndrome. This rating scale has been validated in multiple cross sectional studies in India, Italy, Germany, Iran, Nigeria and Brazil. It has excellent internal constancy. A limitation of this questionnaire is that it does not account for patient input. The onset of symptoms or the site of the Restless Leg Syndrome is not included in this scale(36).

2.5.2 The John Hopkin's Restless Legs severity scale

This is a single question that probes the time of initiation of symptoms. The symptoms are rated from 0 to 3 where 0= no symptoms, 1 are bedtime symptoms, 2 are symptoms that occur in the evening and bedtime that start after 6.00 PM, 3 are symptoms that occur during the day and night before 6.00PM. It is easy to administer this questionnaire and takes ten minutes to finish answering it. This questionnaire has not been validated therefore not used widely(36).

2.5.3 Restless leg Syndrome -6 scale

This consists of six items each rated from 0 to 10 where 0 is no symptoms and 10 is very severe symptoms. This is self-administered questionnaire. The questions complete information from the patient about the quality of sleep and account for the severity of symptoms at different times of the day. It accounts for the severity of symptoms in the last one week. This is a reliable, valid and acceptable tool for assessing the severity of Restless leg syndrome(36).

2.6 The Epworth Sleepiness Scale

This questionnaire consists of eight items done on a daily basis during the day usually filled in by the patients. It assesses the tendency to sleep during the activity. Each question probes the probability of falling asleep during that task. Each question is graded from 0 to 3 where 0 =never, 1= likely, 2= very likely, 3= highly likely. A total score of more than or equal to 10 is marked as excessive daytime sleepiness which indicates a poor quality of sleep(37).

2.7 The Short Form 36 item Health Survey

This questionnaire consists of eight sections with a total of thirty six questions used to assess the health status and quality of life of the patient's. The eight sections of the questionnaire are energy or fatigue, limitations due to their physical health, limitations due to their emotional state, the perception on general health, their physical functioning, mental health, the emotional state and body pain. Each section consists of three or four questions which are then answered by the patient. The answers are transformed to percentages where 0 -40% is the worst health and 60 -100% is the best health. This questionnaire has been validated internationally(38).

2.8 Quality of Sleep and Life in Patients with Restless Leg Syndrome Undergoing Maintenance Hemodialysis

Restless Leg Syndrome negatively impacts the quality of life in these patients(39). This is due to many factors such as sleep disturbances, increased risk of depression, impairment in cognitive function and mood disturbances(40).

A local study done by Kamau E. et al found that patients undergoing hemodialysis had a poor quality of life(41). In Nepal, Joshi et al found that patients undergoing maintenance dialysis had a poor quality of life(42). A study by Hussein et al in 2017 found that 69.6% of patients dialyzing at the renal unit of Kenyatta National Hospital had a poor quality of sleep using the Pittsburgh sleep quality index(43). In Brazil, poor sleep quality was found in 75% of patients undergoing maintenance hemodialysis also using the Pittsburgh sleep quality index(44). In Iran, 86.6% participants undergoing maintenance hemodialysis had a poor sleep quality using the Pittsburgh sleep quality index(45).

A multicenter cross-sectional study in two hospitals – University Hospital of Larisa and General Hospital of Trikala, Greece recruited seventy hemodialysis patients. Patients with Restless Leg Syndrome had a poor quality of life as compared to the patients without Restless Leg Syndrome. It also found that patients with Restless Leg Syndrome had an increased tendency to doze off during the day as compared to those without the syndrome using the Epworth Sleepiness Scale. Restless Leg Syndrome patients had significant depressive symptoms than those without the syndrome(46).

In Turkey one hundred and fifty six hemodialysis patients and thirty five controls were recruited to determine the prevalence of Restless Leg Syndrome and insomnia. The controls were of the same age and sex as the hemodialysis patients, and also had preexisting diabetes and hypertension. The prevalence of Restless Leg Syndrome was increased in the hemodialysis patients as compared to the controls 47% versus 20%. Patients with Restless Leg Syndrome had higher insomnia severity scores leading to poor sleep quality. This affected the mental and physical functioning of these patients hence leading to a poor quality of life. Patients with restless Leg Syndrome had severe depression as compared to those without the syndrome(20).

A multicenter study in Germany recruited fifty two patients on hemodialysis where 26 were Restless Leg Syndrome positive and 26 were Restless Leg Syndrome negative. The quality of sleep was assessed in both groups. Patients with Restless Leg Syndrome had a more significantly disturbed sleep pattern than the patients without Restless Leg Syndrome. Poor sleep quality was found in 37 of 52 patients and the mean subjective sleep quality was significantly lower in the Restless Leg Syndrome group. Fragmented sleep tended to occur in patients with Restless Leg Syndrome(47).

An analytical cross- sectional study assessed one hundred and twelve patients at the hemodialysis unit in Buali hospital, Iran. There was a strong association between insomnia, excessive sleeping during the day and poor subjective quality of sleep with the presence of Restless Leg Syndrome. The hemodialysis patients with Restless Leg Syndrome had a disturbed sleep patterns hence leading to poor quality of sleep as compared to the Restless Leg Syndrome negative patients(48).

Musci et al reported that insomnia commonly occurred in the patients with Restless Leg Syndrome(49).

Another multicenter study was done to find any association between Restless Leg Syndrome and quality of life in dialysis patients. This was done in the United States of America. Eight hundred and ninety four dialysis patients were assessed. The Choices for Healthy Outcomes in Caring for End Stage Renal Disease Health Experience Questionnaire was utilized. This is divided into two parts - SF- 36 and focused quality of life domains specific for dialysis patients. Patients with restless Leg syndrome had impaired sleep patterns leading to depressed mental and physical functioning. Patients with restless Leg Syndrome had a poor quality of life as compared to those without the syndrome(50).

Takaki et al conducted a study in Japan and noted that there was a strong correlation between anxiety and Restless Leg syndrome among dialysis patients. This was a multicenter study conducted at four hospitals in Japan

2.9 Management of Restless Leg Syndrome

2.9.1 Short daily hemodialysis

Short daily hemodialysis improved the symptomology of Restless Leg Syndrome. The FREEDOM cohort study showed that after twelve months of short daily hemodialysis significantly reduced the symptoms of restless Leg Syndrome from 35% to 26%. This improved the standard of living in these patients by reducing the sleep latency and improving sleep quality of these patients(51).

2.9.2 Iron supplementation

Intravenous infusion of iron dextran over a two week period improved the symptomology. Patients who had very severe restless Leg Syndrome had mild symptoms after the iron therapy. A study done by Schulte et al. who administered thousand milligrams of intravenous iron dextran and compared it with patients who received placebo. The patients were followed up at one, two and four weeks after the infusion. It was noted that the patients who received the iron dextran had marked improvement in symptomology(52).

2.9.3 Gabapentin

Gabapentin has been shown to improve the sleep cycle in patients with Restless leg Syndrome(53). It increases the sleep duration and sleep latency(54). Gabapentin is superior to levodopa in improving sleep quality and duration thereby improving the quality of life. (55).

2.9.4 Levodopa

With the use of Levodopa the severity of symptoms of Restless Leg Syndrome has shown a downward trend hence improving the sleep quality(56).

2.9.5 Pramipexole

non-ergoline dopamine agonist that has been shown to reduce the severity of Restless Leg Syndrome(57)

3.0 CHAPTER THREE: STUDY JUSTIFICATION & METHODOLGY

There is increasing burden of end-stage renal disease in Kenya and is associated with significant morbidity and mortality. Patients with end-stage renal disease undergoing maintenance hemodialysis have a higher prevalence of Restless Leg Syndrome as compared to the general population. Restless Leg Syndrome in these patients has a negative impact on the quality of sleep and life. However, early diagnosis and subsequent management leads to better sleep quality hence improving the quality of life. No Kenyan studies have looked at Restless Leg Syndrome in patients end stage renal disease undergoing maintenance hemodialysis

3.1 Research Question

What is the burden of Restless Leg Syndrome in patients with end stage renal disease undergoing hemodialysis at the Kenyatta National Hospital, Mbagathi County Hospital, Nairobi Hospital and Parkland's Kidney center?

3.2 Objectives

3.2.1 Broad Objective

To determine the prevalence of Restless Leg Syndrome in patients with end-stage renal disease undergoing maintenance hemodialysis for more than three months.

3.2.2 Specific Objectives

3.2.2.1 Primary Objectives

i. To determine the prevalence of Restless Leg Syndrome in patients with end stage renal disease undergoing maintenance hemodialysis
ii. To determine the severity of Restless Leg Syndrome in the study patients
iii. To assess quality of sleep using the Epworth sleepiness scale in patients with end stage renal disease undergoing maintenance hemodialysis
iv. To determine the quality of life using the 36 item short form health survey in patients with end stage renal disease undergoing maintenance hemodialysis

3.2.2.2 Secondary Objectives

i. To compare the quality of sleep and quality of life in patients with and without Restless Leg Syndrome

3.3 Methodology

3.3.1 Study Design

Cross-sectional descriptive study

3.3.2 Study Setting

This study was carried out at the renal units in Kenyatta National Hospital, Mbagathi County Hospital, Nairobi Hospital and the Parkland's kidney center between 4th January 2019 and 30th April 2019. Kenyatta National Hospital is a National referral hospital located in the Capital city of Kenya, Nairobi. It also serves as the teaching hospital for University Of Nairobi medical school. There are about 110 patients with end stage renal disease dialyzing at the renal unit in Kenyatta National Hospital at the time of this study. The renal unit runs twenty four hours. Approximately 25 to 30 patients are dialyzed at the renal unit every day. The Nairobi Hospital is one of the Nation's top hospitals which has a bed capacity of four hundred beds with over 2000 staff members. In the renal unit at Nairobi Hospital there are a total of one hundred patients dialyzed in a week with a maximum of thirty patients in a day. The Parkland's Kidney center is a private outpatient dialyses center that dialyses a total of seventy patient's in a week. Mbagathi County Hospital has a dialysis unit where fifteen patients are dialyzed in a week.

3.3.3 Study Population

Ambulatory adult patients with end-stage renal disease undergoing maintenance hemodialysis at the renal unit of the four centers were recruited.

3.3.4 Cases Definition

Medical patients above the age of 18 years who have end-stage renal disease and were undergoing maintenance hemodialysis for more than three months at the four centers.

3.3.5 Inclusion Criteria

All patients who were older than 18 years with end-stage renal disease who have been on maintenance hemodialysis for more than three months at the renal unit in a national referral and teaching hospital, level four county hospital, tertiary level private hospital and a private renal unit were included.

3.3.6 Exclusion Criteria

- **i.** Pregnancy
- **ii.** Patients who were on treatment for Parkinson's disease or known to have Parkinson's disease
- **iii.** Patients who were unable to give informed consent
- **iv.** Patients who had a current deep venous thrombosis of the lower limb based on clinical history or a Doppler venous ultrasound.
- **v.** Patients currently on antidepressants or serotonin selective reuptake inhibitors

3.4 Sample Size

A total of two hundred and ninety patients are on maintenance hemodialysis at the Kenyatta National Hospital, Mbagathi County Hospital, Nairobi Hospital and The Parkland's Kidney Center.

The sample size was determined using the Fischer's formula for prevalence studies. The following formula was used:

$$N = \frac{Z^2 * p\,(1-p)}{d^2}$$

Where:

n- Sample size

Z- 1.96 (95% confidence interval)

p – The estimated prevalence of Restless Leg Syndrome in Saudi Arabia study from Wali and Alkhouli et al 2015 19.4% (11).

d – Margin of error (precision error) +/- 5%

Sample size = 240

3.5 Sampling Method

Consecutive sampling procedure was used to recruit patients to participate in this study. Patients were consecutively enrolled as they presented for their scheduled appointments for hemodialysis until the desired sample size was achieved.

3.5.1 Recruitment and Consenting Procedure

Eligible adult ambulatory patients with end-stage renal disease on chronic hemodialysis at the renal unit at Kenyatta National Hospital, Nairobi Hospital and Parkland's Kidney Center were recruited daily(Monday to Sunday) over a three month period by the principal investigator and the trained research assistants(two registered clinical officers). Patient recruitment was done during, before or after dialysis. Approximately ten patients were recruited daily (three patients from KNH, three from Nairobi Hospital three from Parkland's Kidney center and one from Mbagathi County Hospital) , until the desired sample size was attained.

The medical records and clinical history as per the file of the selected patients were analyzed to eliminate those with any exclusion criteria. The nature and the purpose of the study was thoroughly explained to the eligible participants after which a written informed consent was obtained from those who agreed to participate in the study. Patients who declined to participate were excluded.

3.6 Data Collection Procedure

3.6.1 Clinical Methods

A study proforma was used to collect data on the demographic variables including age, sex, weight, height, BMI, history of smoking, presence of other comorbidities such as type 2 diabetes and hypertension, duration of dialysis in months, duration of each hemodialysis session, and the frequency of dialysis each week.

The International Restless Leg Syndrome Study Group 2012 questionnaire was administered to all the patients to diagnose Restless Leg Syndrome. It was self-administered questionnaire.

Severity of restless leg syndrome was determined by using the International Restless Leg Syndrome Study Group rating scale and was self-administered.

The Epworth sleepiness scale score was used to assess the daytime sleepiness in all participants. The short form 36 health survey questionnaire was used to determine the quality of life. Both the questionnaires were self-administered without any assistance from the principal investigator. All the questionnaires were then collected from the study participants.

3.7 Data Collection Instruments

a) A study proforma
b) International Restless Leg Syndrome Study Group 2012 questionnaire
c) Restless Leg Syndrome severity rating scale questionnaire
d) Epworth Sleepiness Scale
e) Short Form 36 Health Survey questionnaire

3.8 Definition of Study Variables

3.8.1 Independent Variables

i. Age in years was determined from the date of birth of the patient as at time of evaluation
ii. Sex Reported as male or female
iii. Obesity World health organization classified obesity as

- ✓ Underweight - <18.5Kg/m^2
- ✓ Normal- 18.5 – 24.9Kg/m^2
- ✓ Overweight- 24.9- 29.9Kg/m^2
- ✓ Obese- >30Kg/m^2

i. Hypertension defined as anyone on treatment or with a systolic blood pressure of >140mmHg.
ii. Diabetes – Defined as any participant on treatment for diabetes and fasting blood sugar of more than 7 and 2 hours post prandial sugar more than 11.1 or as defined by clinician previously by HbA1C of more than 7%.
iii. Smoking- current smoker is someone who has smoked 100 cigarettes in his/her lifetime and who at the time of survey continues smoking either daily or some days. Never smoker is someone who has not smoked 100 cigarettes in their lifetime. Former smoker is someone who has smoked less than 100 cigarettes in his/her lifetime, but has currently stopped.

3.8.3 Dependent Variables

i. Duration of dialysis in months from the month the patient initially commenced dialysis till the month of the study date
ii. Frequency of dialysis in a week as reported by the patient in the last one month
iii. Duration of each dialysis session in hours in the last one month

3.8.4 Outcomes

i. The presence or absence of Restless Leg Syndrome
ii. The severity of restless leg syndrome in patients who were diagnosed with restless leg syndrome using the International Restless Leg Syndrome Study Group severity rating scale.
iii. The quality of sleep in hemodialysis patients. Poor sleep quality was defined as excessive daytime sleepiness with an Epworth sleepiness score of more than 10.
iv. The quality of life in hemodialysis patients. Poor quality of life was defined as a mean score of less than 50% from the short form health survey questionnaire.

3.9 Quality Assurance

Validated questionnaires were translated into Kiswahili for ease for the patient and were utilized.

The research assistant was a trained renal nurse.

3.10 Data Management and Analysis Methods

Data was entered into a study proforma with a unique code. Data from the study proforma was then entered and managed in a password protected Microsoft Access 2013 database. After cleaning and verification, data analysis was performed using SPSS version 21.0 with the help of a statistician.

Descriptive characteristics of the study population such as age, gender marital status, level of education were summarized into percentages for categorical data and means or medians for continuous variables.

The prevalence of Restless Leg syndrome was presented as a proportion with 95% confidence intervals in each center. The severity of Restless Leg Syndrome was presented as a proportion in each class (mild, moderate, severe and very severe). The excessive daytime sleepiness was expressed as a proportion of those with excessive daytime sleepiness (an Epworth sleepiness score of more than 10) in individuals with end-stage renal disease undergoing maintenance hemodialysis. The quality of life was expressed as a proportion of those with poor quality of life (an average score of less than 50%) in individuals with end-stage renal disease undergoing maintenance hemodialysis.

Comparison of quality of sleep and quality of life between those with and without the syndrome was made using proportions of the study participants to get the odds ratio at 95% confidence interval.

3.11 Ethical Consideration

The study was carried out after approval by the Department of Clinical Medicine and Therapeutics, University of Nairobi, the Kenyatta National Hospital (UON research and Ethics committee) and the Nairobi Hospital ethics committee.

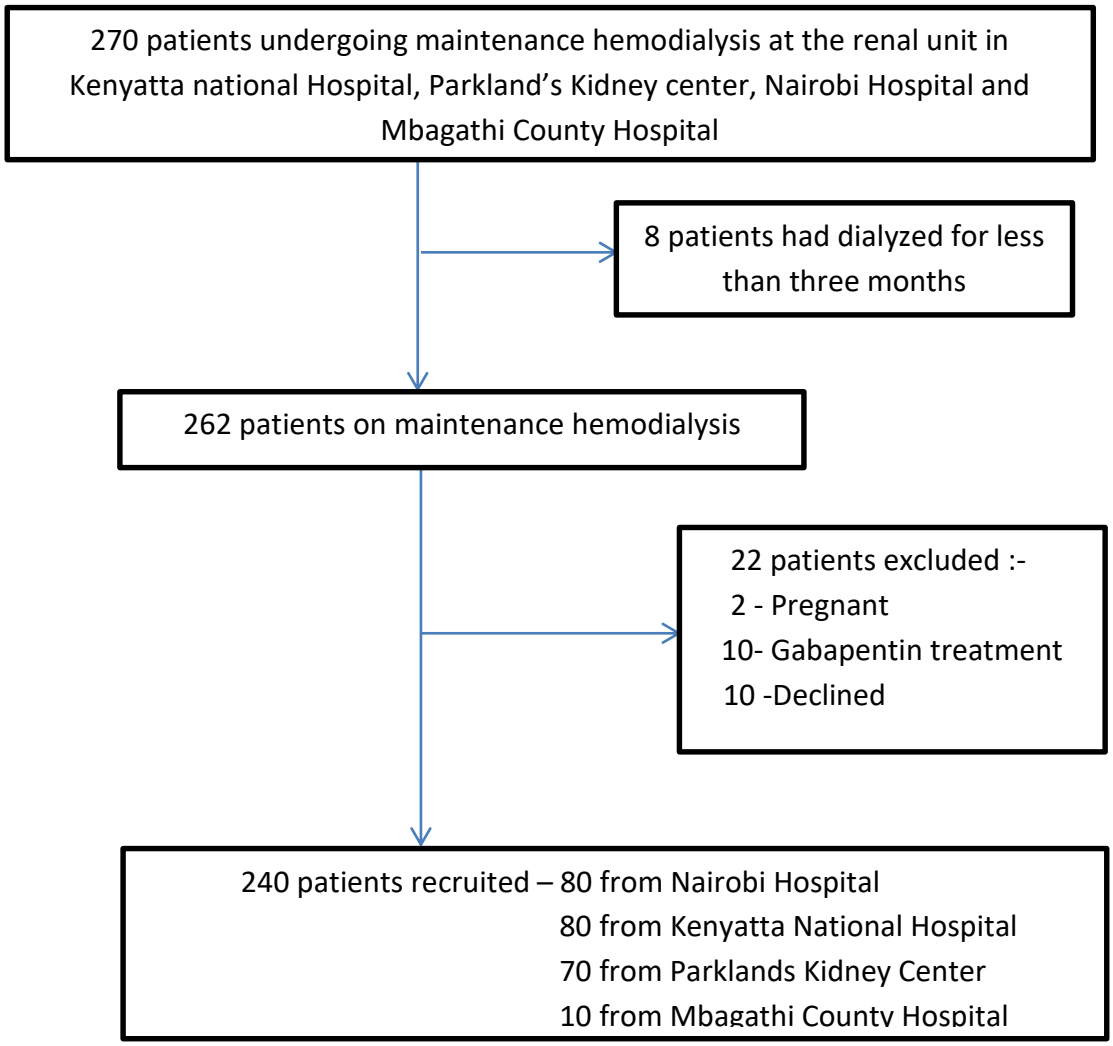
The patients were informed about the study. They were given a detailed explanation on the nature of the study and the questionnaires needed to be filled. Patients who gave informed consent were recruited into the study. No patient was coerced into participating. There was no discrimination against any patient who declined to participate. Confidentiality was strictly maintained and all data gathered was securely stored and only revealed to relevant authorities upon a need to know basis.

The renal unit doctor and senior house officer were informed about the patients who were diagnosed with Restless Leg Syndrome so that primary nephrologist can treat the condition.

4.0 CHAPTER FOUR: RESULTS

Between January and March 2019 consecutive sampling was done until the desired sample size was reached. A total of 270 participants were screened for eligibility, 8 study subjects did not meet the inclusion criteria. Out of the 262 study subjects, 22 were excluded from the study, 10 were on gabapentin for diabetic neuropathy, 2 were pregnant and 10 declined participation. A total of 240 study subjects were enrolled (80 from Kenyatta National Hospital and Nairobi Hospital each, 70 from Parkland's Kidney Center and 10 from Mbagathi County Hospital). Below is a flow chart of the recruitment, Figure 1.

Figure 1: Recruitment Flow Chart



4.1 Socio-demographic Characteristics

The mean age of the study subject's was 53.3 years (SD 17.1) with a range of 18 – 94 years. There were 153 (63.75%) males with a male to female ratio of 1.8:1. Two hundred and twenty three (92.9%) study participants had post primary education. One hundred and seventy five (72.9%) participants were married. A summary of the sociodemographic characteristics is illustrated in Table 2.

Table 1: Socio demographic characteristics of the study subjects

Variable	All Frequency (%) n=240	95% Confidence interval
Age in years		
• Mean (SD)	53.3(17.1%)	51.2-55.6
• Median(IQR)	54 (28%)	50.0-56.0
• Min - Max	18 - 94	
Age groups		
<20	2 (0.83%)	
20-29	21 (8.75%)	
30-39	33 (13.75%)	
40-49	44 (18.3%)	
50-59	57 (23.75%)	
60-69	32 (13.3%)	
≥70	51 (21.25%)	
Gender		
• Male	153 (63.7%)	57.3-69.8
• Female	87 (36.3%)	30.2-42.7
Marital status		
• Single - unmarried	40 (16.7%)	12.3-22.1
• Separated	9 (3.8%)	1.8-7.2
• Married	175 (72.9%)	66.8-78.3
• Widowed	16 (6.6%)	4.0-10.8
Education level		
• Primary	17 (7.1%)	4.3-11.3
• Secondary	108 (45%)	38.6-51.5
• Tertiary	115 (47.9%)	41.5-54.4

4.2 Clinical Characteristics

The mean weight was 67.4Kg (SD 10.7) with a range of 38 to 103Kg. The mean BMI was 27.4Kg/m^2 (SD 38). One hundred and twenty six (52.5%) had a normal body mass index, eighty one (33.7%) were overweight, eighteen (7.5%) participants were obese. Table 3 demonstrates the anthropometric measurement of all study subjects.

Among the preexisting comorbidities, 119 (49.6%) had hypertension only, 13 had diabetes only, 99 (41.25%) had coexisting diabetes and hypertension, 5 had no underlying comorbid condition, 3 had Systemic Lupus erythematous and 1 had HIV associated nephropathy. Table 4 demonstrates the comorbidities of the study subjects.

Table 2: Anthropometric measurements of patient's undergoing maintenance hemodialysis included in the study

	All Patients Frequency (%) N=240	95% Confidence interval
Weight in Kg		
• Mean (SD)	67.4 (10.7)	66.1-68.9
• Median(IQR)	68	65.0-70.0
• Min - Max	38 - 103	
Height in cm		
• Mean (SD)	167.3 (10.0)	165.8-168.4
• Median (IQR)	167.5	167.0-168.0
• Min - Max	137 - 203	
BMI categories		
• Underweight	15 (6.3%)	3.7-10.3
• Normal	126 (52.5%)	46.0-58.9
• Overweight	81 (33.7%)	27.9-40.1
• Obese	18 (7.5%)	4.6-11.8

Table 3: Co-morbidities of the study participants

Comorbidity	All frequency (%) n=240
Hypertension	119 (49.6%)
Diabetes Mellitus	13 (5.41%)
Hypertension and diabetes	99(41.25%)
HIV - associated nephropathy	1(0.42%)
Systemic lupus Erythematous	3(1.25%)
None	5 (2.1%)

4.3 Prevalence and Severity of Restless Leg Syndrome among Hemodialysis Patients

The prevalence of Restless Leg Syndrome in patients with end-stage renal disease undergoing maintenance hemodialysis was 35.8% (95%CI 29.8-42.3). The prevalence of Restless Leg Syndrome by center was Kenyatta National Hospital 42.5% (95%CI 31.7-54.1), Nairobi Hospital 36.3% (95%CI 26-47.8), Parkland's Kidney Center 30% (95%CI 19.9-42.2) and Mbagathi District Hospital 20% (95%CI 4.5- 64.4). Figure 2 below represents the overall prevalence of Restless Leg Syndrome and by each center.

Among 86 study subjects with Restless Leg Syndrome, 3(3.49%) had mild symptoms, 49 (57.0%) had moderate symptoms, 29 (33.7%) had severe and only 5(5.81%) had very severe symptoms. Figure 3 below demonstrates the severity of Restless Leg Syndrome

Figure 2: Prevalence of Restless Leg Syndrome amongst the study participants

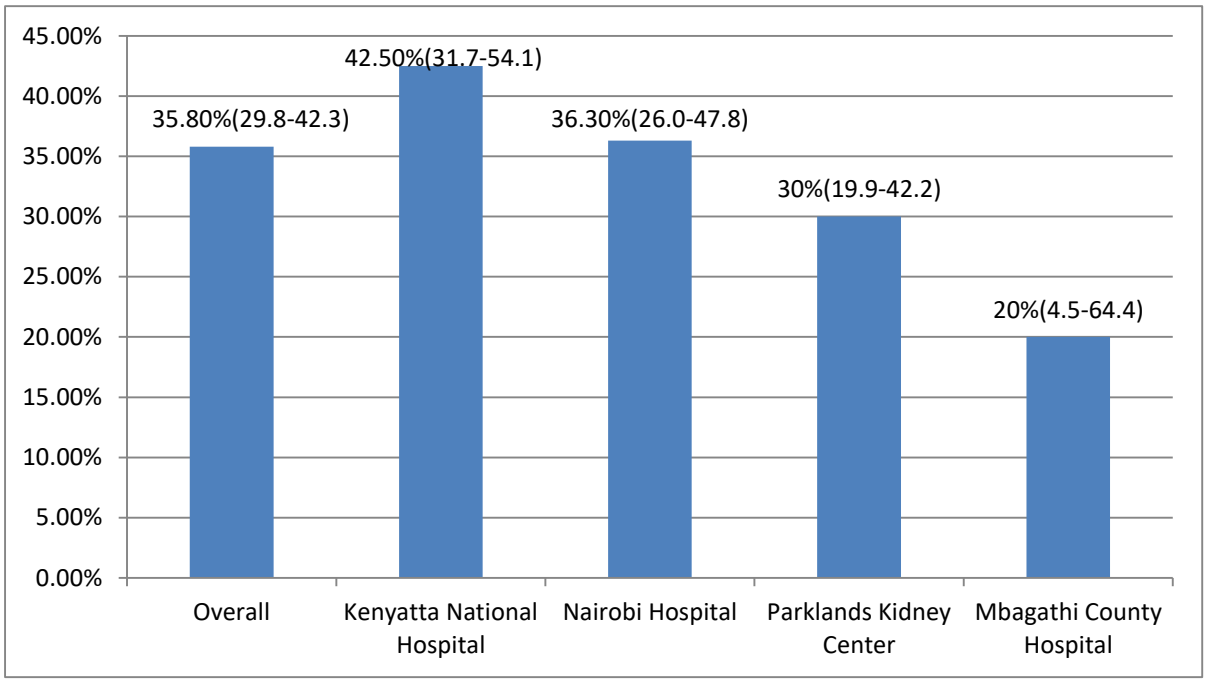
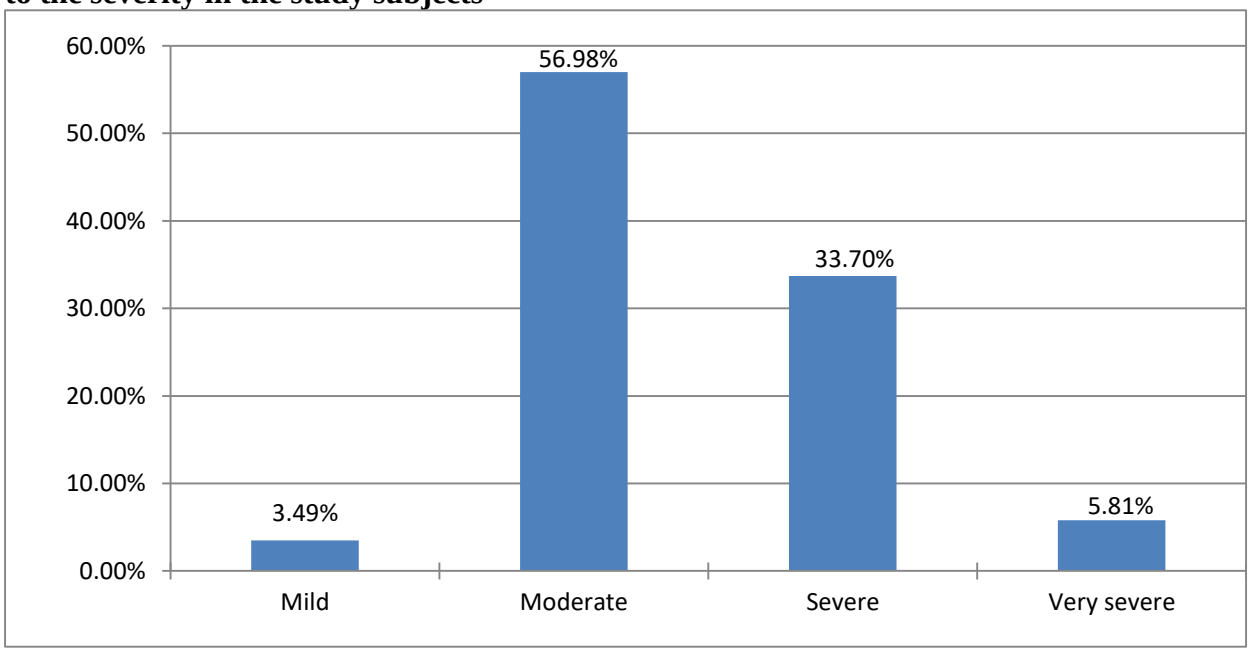


Figure 1: Percentage distribution of the Patients with Restless leg Syndrome according to the severity in the study subjects



4.4 Socio-demographic and Clinical Characteristics of Patients with Restless Leg Syndrome

There was no difference in the sociodemographic and clinical characteristics of the study subjects with and without Restless Leg Syndrome except for duration of dialysis. Those with Restless Leg Syndrome had a six months longer duration of dialysis as compared to those without the syndrome. This was statistically significant (p = 0.025). There was no association between diabetes and Restless Leg Syndrome (p=0.390). Univariate comparisons of the sociodemographic, clinical, duration of dialysis and frequency of dialysis in a week of study participants with and without RLS are illustrated in table 5 below.

Table 4: Socio-demographic and clinical characteristics of study subjects with and without Restless Leg Syndrome

Variable	All n=240 frequency (%)	Patients with RLS n=86 frequency (%)	Patients without RLS n= 154 frequency (%)	P value
Age strata				
<20	2 (0.83%)	1 (1.16%)	1 (0.65%)	0.311
20-29	21 (8.75%)	4 (4.65%)	17 (11.0%)	Ref
30-39	33 (13.75%)	15 (17.4%)	18 (11.7%)	0.068
40-49	44 (18.3%)	18 (20.9%)	26 (16.9%)	0.082
50-59	57 (23.75%)	23 (26.7%)	34 (39.5%)	0.079
60-69	32 (13.3%)	7 (8.14%)	25 (16.2%)	0.804
≥70	51 (21.25%)	18 (20.9%)	33 (21.4%)	0.174
Sex				
Male	153(63.7%)	59(68.6%)	94(61.0%)	0.242
Female	87(36.3%)	27(31.4%)	60(39.0%)	
Hypertension	119(49.6%)	46(53.3%)	73(47.4%)	0.320
Diabetes	13(5.4%)	3(3.5%)	10(6.5%)	0.390
Hypertension plus diabetes	99(41.3%)	33(38.4%)	66(42.9%)	0.545
BMI strata				
Underweight	15(6.3%)	6(7.0%)	9(5.8%)	0.720
Normal	126(52.5%)	45(52.3%)	81(52.6%)	0.908
Overweight	81(33.8%)	28(32.6%)	53(34.4%)	0.770
Obese	18(7.5%)	7(8.1%)	11(7.1%)	0.779
Median duration of Hemodialysis	24.0(28.0)	28.0 (32.0)	22.0 (24.0)	0.025

in months (IQR)				
Median weekly hemodialysis (IQR)	2.0 (1.0)	2.0 (0.0)	2.0 (1.0)	0.424
Median duration of each dialysis session (IQR)	4.0 (0.0)	4.0 (0.0)	4.0 (0.0)	0.928

4.5 Quality of Sleep among the Patients with End-Stage Renal Disease

There were 101 (42.1%) study subjects with poor quality of sleep. Out of 86 study subjects with Restless Leg Syndrome 69 (80.2%) had a poor quality of sleep. Out of 154 study participants without Restless Leg Syndrome only 32 (35.7%) had a poor quality of sleep. Study participants with Restless Leg Syndrome were fifteen times more likely to have poor quality of sleep as compared to those without the syndrome (Odds ratio, 15.5; 95% Confidence Interval [CI], 8.0 to 29.9; P<0.001). Table 6 summarizes the quality of sleep in study subjects with and without the syndrome.

Table 5: Quality of sleep in patients with and without Restless Leg Syndrome

RLS	Quality of Sleep		Odds Ratio (95% CI)	p-value
	Poor	Good		
Yes	69 (80.2%)	17 (19.8%)	15.5 (8.0-29.9)	<0.001
No	32 (35.7%)	122(79.2%)		

4.6 Quality of Life in Patients with End-Stage Renal Disease Undergoing Maintenance Hemodialysis

One hundred and twenty three study subjects with end-stage renal disease had a poor quality of life (51.2%). Among the 86 study subjects with Restless Leg Syndrome, 68 (79.1%) had a poor quality of life. Study subjects with Restless Leg Syndrome were seven times likely to have a poor quality of life as compared to those without the syndrome (Odds ratio, 6.8; 95%CI, 3.7 to12.6; p<0.001). Table 7 summarizes the quality of life in the study subjects.

Table 6: Quality of life in patients with and without Restless leg Syndrome

RLS	Quality of Life		Odds Ratio (95% CI)	p-value
	Poor	Good		
Yes	68 (79.1)	18 (20.9)	6.8 (3.7-12.6)	<0.001
No	55 (35.7)	99 (64.3)		

5.0 CHAPTER FIVE: DISCUSSION

Restless Leg Syndrome is a common neurological condition in patients with end stage renal disease(1,4). The high prevalence of Restless Leg Syndrome in end-stage renal disease is explained by the chronic inflammatory state and iron deficiency (1, 4, and 29). Another reason for the increased prevalence is inadequate dialysis. In our study the prevalence was 35.8%, which was comparable to the study done by La manna et al in Italy where the prevalence was 31% (22). The similarity in prevalence could be explained by similar clinical characteristics such as age, gender and body mass index(22). The study by La manna et al. the mean age was 65.0 years, in our study the mean age was 53.3 years. Most of the study subjects were male (63%) in the study by La Manna et al. which was similar to our study where 63.7% were male (22). Our setup had a higher prevalence as compared to other studies in Nigeria, Turkey, Saudi Arabia, Brazil and India. A study done in Nigeria by Onwuch ekwa et al found a much lower prevalence of 5.9% despite it being a similar sub-Saharan African setup, this could be explained by the younger study participants in the study as compared to our study(25). A study carried out in Turkey by Soyoral et al reported a 14.5% prevalence(8), in Saudi Arabia Wali et al found a 19.4% prevalence(11), in 2010, Araujo et al reported a 21.5% prevalence in Brazil(13). The study participants in Turkey, Saudi Arabia and Brazil had similar demographic and clinical characteristics such as age, body mass index and preexisting comorbidities (8, 11, 13).

These differences in prevalence could be explained by sociocultural variations and health seeking behavior of the study participants, different study approaches and tools. The studies in Nigeria, Turkey, Brazil and Saudi Arabia used the International Restless Leg Syndrome study Group 2003 questionnaire which has a lower sensitivity than the International Restless Leg Syndrome Study Group 2012 questionnaire (25). This could also be explained by health system challenges in our setup. Health care systems in Turkey, Saudi Arabia and Brazil are easily accessible compared to our setup hence the variation in prevalence (8, 11, 13). The variation in the socioeconomic status between the West and our setup could explain the difference in prevalence rates (8, 11, and 13). This could also explain our intercenter variation where Kenyatta National Hospital had a higher prevalence of 42.50% as compared to Parklands Kidney Center where the prevalence was 30%. This could be explained by variation in racial attributes of the study participants between the two centers. It could also be explained by younger study participants in Kenyatta National Hospital compared to the study

participants in Parkland's Kidney Center. In India the prevalence was much lower at 6.6%(5).

Our study demonstrated that majority (90.6%) of the patients had moderate to severe form of disease as compared to other studies in Western countries. In the FREEDOM study in America 59% of study participants had moderate to severe Restless Leg Syndrome(51). Stefanidis et al in Greece reported 54.5% of study subjects had moderate to severe form of the syndrome(58). The differences in proportions could be explained by variation in the health care systems and racial variation between developing and developed nations. In Western countries health care is easily accessible and provide increased frequency of dialysis in a week compared to our setup. In Pakistan Mahmood et al found that 56.5% had moderate to severe Restless Leg Syndrome(10). This was much lower compared to the results in our setup (90.6%). This could be explained by differences in study subject clinical characteristics(10). In Pakistan only 2.6% of the study participants were diabetic while in our setup 46.7% were diabetic (10). Individuals with end-stage renal disease and diabetes have an increased risk of developing Restless Leg syndrome, the increased prevalence of diabetes in our setup could have explained the high prevalence of Restless Leg Syndrome in our setup(4).

Poor quality of sleep was present in 42.1% of study subjects with end stage renal disease. However in a similar study by Hussein et al reported a higher prevalence (69.6%) of poor sleep quality in Kenyatta National Hospital(43). In Brazil and Iran, poor sleep quality was found in 75% and 90.8% of participants respectively(44,45). The difference in proportion of participants with poor sleep quality could be explained by use of different study tools to assess for quality of sleep, the Pittsburgh sleep quality index is more sensitive than the Epworth sleepiness scale questionnaire. In Brazil, Iran and Hussein et al used the Pittsburgh sleep quality index(43–45). Restless leg syndrome is also one of the neurological conditions that frequently occur at night causing uncomfortable and unpleasant sensations disturbing the sleep cycle (2, 3).

Majority of patients with Restless Leg syndrome had a poor sleep quality (80.2%). There was a positive association between poor quality of sleep and Restless Leg Syndrome. Patients with Restless Leg Syndrome were sixteen times more likely to have poor quality of sleep as compared to those without the syndrome. This was a similar observation made in Brazil, Greece and Germany(13,46,47). A study by Araujo et al in Brazil reported higher scores of

Epworth sleepiness Scale in study subjects with restless Leg Syndrome as compared to those without the syndrome 8.37 versus 6.71(13). In Greece, Giannaki et al also reported poor sleep quality and quantity in participants with Restless Leg Syndrome than those without the syndrome(46). Gade et al in Germany documented lower sleep quality in study subjects with Restless leg syndrome as compared to those without the syndrome(47).

In Turkey patients with Restless Leg Syndrome had poor sleep as compared to those without the syndrome(20). In Iran, sleep disturbances were frequently encountered in patients with Restless Leg Syndrome than in those without the syndrome(31). This explains that Restless Leg Syndrome causes fragmented and disturbed sleep patterns thereby causing poor sleep quality(47).

Approximately half of our study participants with end stage renal disease had a poor quality of life. This finding is consistent with a study by Kamau E et al. who reported a poor quality of life in participants with end stage renal disease; she documented lower mean physical composite summary and mental composite summary scores(41). In Nepal, 80% of study participants had a poor quality of life, which is higher than our study, this could be explained by different instruments, the WHOQOL BREF was utilized to determine the quality of life and sociodemographic variation(42). In this study, we found that Restless Leg Syndrome has a negative impact on quality of life of patient's with end stage renal disease. Majority of participants with Restless Leg Syndrome had a poor quality of life as compared to those without the syndrome. This was similarly found in multiple studies for example, Mucsi et al who reported that participants with Restless Leg Syndrome had lower quality of life than those without the syndrome(49). In Greece, Giannaki et al established that participants with Restless Leg Syndrome had lower health related quality of life than those without the syndrome(21). This explains that Restless Leg Syndrome had a negative impact on the quality of life on individuals with end stage renal disease.

5.1 Conclusion

In our study Restless Leg Syndrome is a common neurological condition in patients with end-stage renal disease undergoing maintenance hemodialysis. Patients with end-stage renal disease undergoing maintenance hemodialysis tend to have fragmented and poor sleep quality. The quality of life in patients undergoing maintenance hemodialysis is poor. Restless Leg syndrome affects the quality of sleep and life remarkably affecting the daily functioning of the patients. It has a negative impact on the quality of sleep and life. This has also been seen in previous studies.

5.2 Recommendation

a) Screening for Restless Leg Syndrome for early diagnosis as a standard of care among patients undergoing hemodialysis to make a diagnosis of the same

b) Early diagnosis can advocate prompt treatment therefore improving quality of sleep and improving the daytime functioning of the patients with end-stage renal disease undergoing maintenance hemodialysis.

c) All patients undergoing hemodialysis should be administered the Epworth sleepiness scale to assess the quality of sleep and the 36 item short form health survey to assess the quality of life.

d) The dialysis unit involved in the care of the patient should screen patients for sleep disorders.

e) Regular counselling and psychological support to the patients with end-stage renal disease to improve the quality of life.

f) More studies should be conducted to look at the psychosocial-economic effect of Restless Leg Syndrome. There are several hemodialysis centers now.

5.3 Study Strengths

a) This study is first of its kind to look at the burden of Restless leg Syndrome in end stage renal disease on maintenance hemodialysis.
b) It was a multicenter study.

5.4 Study Limitations

a) There was recall bias as the study participants were filling the questionnaire without assistance from the principal investigator.

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APPENDICES

Appendix I: Patient Information

Introduction

My name is Dr Jilna Raja. I am a postgraduate student of Internal Medicine at the University of Nairobi. The purpose of this statement is to inform you about a research study I am carrying out. I am doing a study on the prevalence of RLS in patients with CKD undergoing dialysis at KNH, Mbagathi county hospital, Nairobi hospital and parkland's Kidney Center. The purpose of this study is to determine how many people have RLS among CKD patients undergoing dialysis.

Procedures followed in the study

Participation in this study is voluntary should you accept to participate the following is a summary of what the study involves

1) Obtaining information such as age, sex, weight, height, BMI, history of hypertension, history of diabetes, duration of dialysis in years, frequency of dialysis per week and the duration of dialysis per session.
2) Obtaining information on the diagnosis of RLS using The IRLSSSG questionnaire, the severity of RLS and the quality of sleep.

This will take 30 minutes of your time

Risks and costs incurred

There are no risks for participating in this study. No cost will be incurred by the patient.

Your rights as a participant

Your participation in this research is voluntary and in the event that you refuse to participate in this study your treatment will not be affected. If you choose to participate and not answer certain questions you are free to do so. You are free to terminate the interview and withdraw from the study at any time. You are free to ask questions before signing the consent form.

Assurance of confidentiality

All your responses as well as your results will remain confidential. Your individual responses will be stored in a locked place under my control and will be seen by the statistician and myself, the principal investigator

Benefit to you as a participant

There will be no direct benefit to you as a participant. Your primary health physician will be informed of any findings relevant to your medical care and a copy of the IRLSSG questionnaire will be put in your file. The results obtained from this study will help improve clinical decision and patient care in this facility.

Compensation

Participants will not receive any monetary compensation for participating in this study.

Contacts

If you have any questions please do not hesitate to ask, clarifications may be sought from:

Dr. Jilna Raja
P.O BOX 250, Sarit Centre
Nairobi
Tel: 07187751213

The Secretary
KNH/UON Ethics and Review committee
Tel: 2726300 Ext: 44102

I request you to sign the attached consent form.

Appendix II: Consent Form

I have read the foregoing information or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntary to participate as a participant in this research.

Print name of Participant: ……

Signature/Left thumb print: ……

Date: ……

Investigators statement

I, principal investigator have fully informed the research participant on purpose and implications of this study.

Signed …… Date ……

Appendix: III IRLSSG Questionnaire

Essential Diagnostic Criteria (all must be met)

1. An urge to move the legs usually but not always accompanied by or felt to be caused by uncomfortable and unpleasant sensations in the legs.

2. The urge to move the legs and any accompanying unpleasant sensations begin or worsen during periods of rest or inactivity such as lying down or sitting.

3. The urge to move the legs and any accompanying unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues.

4. The urge to move the legs and any accompanying unpleasant sensations during rest or inactivity only occur or are worse in the evening or night than during the day.

5. The occurrence of the above features are not solely accounted for as symptoms primary to another medical or a behavioral condition (e.g., myalgia, venous stasis, leg edema, arthritis, leg cramps, positional discomfort, habitual foot tapping.)

    1. Have you ever had unpleasant feelings or sensations in your legs that occurred on a regular basis, and mainly while sitting or lying down?

        Yes_____ No _____

    2. Have you ever felt the need or urge to move your legs that occurred on a regular basis, and mainly while sitting or lying down?

        Yes _____ No_____

Do/did these unpleasant sensations usually start when you are/were resting (either sitting or lying down)?

Yes_____ No_____

1. If you get/got up and move/moved around, do/did these unpleasant sensations in your legs get any better with moving or walking?

   Yes_____ No_____

2. In general, are/were these unpleasant sensations in your legs or the urge to move your legs the worst in the evening, night, or after going to bed?

   Yes_____ No_____

3. How often do/did these feelings occur?

Less than one time per year	Yes _____	No _____
At least one time a year but less than one time in a month	Yes _____	No _____
2- 4 times per month	Yes _____	No _____
2- 3 times per week	Yes _____	No _____
4-5 times per week	Yes _____	No _____
6-7 times per week	Yes _____	No _____

Appendix IV: Epworth Sleepiness Scale Form

Situation	Responses	Score
Sitting and reading	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
Watching television	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
Sitting inactive in a public place for example in a theatre or a meeting	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
As a passenger in a car for an hour without a break	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
Lying down to rest in the afternoon	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
Sitting and talking to someone	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
Sitting quietly after lunch when you have had no alcohol	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	
In a car while stopped in traffic	0 –would never doze 1 – slight chance of dozing 2- moderate chance of dozing 3 – High chance of dozing	

TOTAL SCORE

Appendix V: Restless Leg Syndrome Severity Scale

1. Overall, how would you rate the RLS discomfort in your legs or arms?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

2. Overall, how would you rate the need to move around because of your RLS symptoms?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

3. Overall, how much relief of your RLS arm or leg discomfort do you get from moving around?

(4) No relief

(3) Slight relief

(2) Moderate relief

(1) Either complete or almost complete relief

(0) No RLS symptoms and therefore question does not apply

4. Overall, how severe is your sleep disturbance from your RLS symptoms?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

5. How severe is your tiredness or sleepiness from your RLS symptoms?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

6. Overall, how severe is your RLS as a whole?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

7. How often do you get RLS symptoms?

(4) Very severe (This means 6 to 7 days a week.)

(3) Severe (This means 4 to 5 days a week.)

(2) Moderate (This means 2 to 3 days a week.)

(1) Mild (This means 1 day a week or less.)

(0) None

8. When you have RLS symptoms, how severe are they on an average day?

(4) Very severe (This means 8 hours per 24 hour day or more.)

(3) Severe (This means 3 to 8 hours per 24 hour day.)

(2) Moderate (This means 1 to 3 hours per 24 hour day.)

(1) Mild (This means less than 1 hour per 24 hour day.)

(0) None

9. Overall, how severe is the impact of your RLS symptoms on your ability to carry out your daily affairs, for example carrying out a satisfactory family, home, social, school, or work life?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

10. How severe is your mood disturbance from your RLS symptoms–for example angry, depressed, sad, anxious, or irritable?

(4) Very severe

(3) Severe

(2) Moderate

(1) Mild

(0) None

Very severe=31-40 points

Severe=21-30 points

Moderate=11-20 points

Mild=1-10 points

None=0 points

Appendix VI: Short Form 36 Health Survey

Choose one option for each questionnaire item

1) In general, would you say your health is

   Excellent

   Very good

   Good

   Fair

   Poor

2) Compared to one year ago, how would you rate your health in general now?

   Much better now than one year ago

   Somewhat better now than one year ago

   About the same

   Somewhat worse now than one year ago

   Much worse now than one year ago

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

	Yes limited a lot	Yes limited a little	No, not limited at all
3) Vigorous activities such as running, lifting heavy objects, participating in strenuous sports			
4) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling			
5) Lifting or carrying groceries			

6) Climbing several flights of stairs			
7) Climbing one flight of stairs			
8) Bending, kneeling or stooping			
9) Walking more than a mile			
10) Walking several blocks			
11) Walking one block			
12) Bathing or dressing yourself			

Physical Health Problems

During the past four weeks have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

13) Cut down the amount of time you spent or other activities?	Yes	No
14) Accomplished less than you would like?	Yes	No
15) Were limited in the kind of work or other activities?	Yes	No
16) Had difficulty performing the work or other activities?	Yes	No

Emotional Health Problems

During the past four 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)

17) Cut down the amount of time you spent on work or other activities? Yes No
18) Accomplished less than you would like? Yes No
19) Didn't do work or other activities as carefully as usual? Yes No

SOCIAL ACTIVITIES

20) Emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
Not at all Slightly Moderately Severe Very severe

PAIN

21) How much bodily pain have you had during the past four weeks?
None Very mild Mild Moderate Severe Very severe

22) During the past four weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
Not at all A little bit Moderately Quite a bit extremely

ENERGY AND EMOTIONS

These questions are about how you feel and how things have been with you during the last four weeks. For each question please give the answer that comes closest to the way you have been feeling.

23) Did you feel full of pep?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

24) Have you been a very nervous person?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

25) Have you felt so down in the dumps that nothing could cheer you up?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

26) Have you felt calm and peaceful?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

27) Did you have a lot of energy?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

28) Have you felt downhearted and blue?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

29) Did you feel worn out?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

30) Have you been a happy person?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

31) Did you feel tired?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

SOCIAL ACTIVITIES

32) During the past four weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives)?

All the time

Most of the time

A good bit of the time

Some of the time

A little bit of the time

None of the time

GENERAL HEALTH

How true or false is each of the following statements for you?

33) I seem to get sick a little easier than other people

Definitely true ____

Mostly true ____

Don't know ____

Mostly false ____

Definitely false ___

34) I am as healthy as anybody I know

Definitely true

Mostly true

Don't know

Mostly false

Definitely false

35) I expect my health to get worse

Definitely true

Mostly true

Don’t know

Mostly false

Definitely false

36) My health is excellent

Definitely true

Mostly true

Don’t know

Mostly false

Definitely false

Appendix VII: Dodoso ya IRLSSG

Vigezo muhimu vya uchunguzi(zote lazima kufikiwa)

1) Haja ya kusongeza miguu kwa kawaida lakini si mar azote kuambatana au kusababishwa na hisia za wasiwasi na hisia zisizofurahisha kwa miguu
2) Haja ya kusongeza miguu na hisai zozote zisizofurahisha zinazoambatana kuanza wakati wa mapumziko au kutokua na kazi kama vile unapoketi au kulala
3) Haja ya kusongeza miguu kufuatana na hisai zisizofurahisha kimwili au kabisa kuondolewa katika ile harakati ya kutembea au kujinyoosha angalau kwa muda ambao shughuli inaendelea
4) Haja ya kusongeza miguu na kufuatanisha na hisai zisizofurahisha wakati wa mapumziko au kutokua na kazi ni mbaya Zaidi wakati wa jioni au usiku kuliko mchana
5) Matukio haya yaliyo hapo juu hayajaajibika kama dalili za msingi kwa hali nyingine ya matibabu au tabia kwa mfano (myalgia, stasis yenye sumu, kufura kwa mguu, ugonjwa wa baridi yabisi, maumivu ya misuli miguuni, usumbufu wa nafasi na mazoea ya kugonga miguu)

1) Je, umewahi kuwa na hisai zisizofurahisha au mbaya kwa miguu zinazotokea mara kwa mara hasa unapokisa unaketi au kulala?

   Ndio _____ Hapana _____

2) Je, umewahi kuhisi haja ya kusongeza miguu masa kwa mara hasa ukiwa umeketi au kulala?

   Ndio _____ Hapana_____

3) Je, hisai hizi zisizofurahisha huanza wakati unapo pumzika (aidha ukiwa umeketi au kulala)?

   Ndio_____ Hapana_____

4) Je, ukiamka au kuzunguka hizi hisai zisizofurahisha katika miguu yako hupata nafuu unapotembea au kusonga?

Ndio_____ Hapana_____

5) Kwa ujumla, hisai hizi zisizopendeza katika miguu yako au haja ya kusongeza miguu huwa mbaya Zaidi wakati wa jioni, usiku au baada ya kuenda kitandani?

Ndio _____ Hapana _____

6) Je, hisai hizi hutokea mara ngapi?

Chini ya mara moja kwa mwaka Ndio Hapana

Angalau mara moja kwa mwaka lakini chini ya wakati mmoja kwa mwezi Ndio Hapana

Mara mbili hadi nne kwa mwezi Ndio _____ Hapana _____

Mara mbili hadi tatu kwa wiki Ndio _____ Hapana _____

Mara nne hadi tano kwa wiki Ndio _____ Hapana _____

Mara sita hadi saba kwa wiki Ndio _____ Hapana _____

Appendix VIII: Epworth Sleepiness Scale in Swahili

Hali	Majibu	Alama
Kuketi na kusoma	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwezekano mkubwa wa kulala	
Kutazama televisheni	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa Kulala 3- Uwezekano mkubwa wa kulala	
Kukaa hai katika mahali pa umma kwa mfano uwanja wa michezo au mkutano	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwezekano mbubwa wa kulala	
Kuketi kwenye gari kama abiria bila mapumziko	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwenzekano mbubwa wa kulala	
Kulala chini ili kupata kupumzika mchana	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwenzekano mbubwa wa kulala	
Kuketi na kuzungumza na mtu	0- Hawazi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwenzekano mbubwa wa kulala	

Kuketi kimya baada ya chakula cha mchana wakati hujakunywa pombe	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwenzekano mbubwa wa kulala	
Kuwa kwenye gari iliyo simama kwenye trafiki	0- Hawezi kamwe kulala 1- Nafasi kidogo ya kulala 2- Uwezo wa kawaida wa kulala 3- Uwezekano mkubwa wa kulala	

Jumla ya alama

Appendix IX – Kipimo Cha Dalili Ya Kuhangaika Katika Miguu

1) Kwa ujumla, unaweza kusema usumbufu wa kuhangaika katika miguu au mikono upo katika kiwangokipi?
   (4) Kali sana
   (3) Kali
   (2) Wastani
   (1) Kidogo
   (0) Hakuna

2) Kwa ujumla,unaweza kusema haja yako ya kutembea na kuzunguka kwa sababu ya dalili ya kuhangaika katika miguu upokatika kiwango kipi?
   (4) Kali sana
   (3) Kali
   (2) Wastani
   (1) Kidoga
   (0) Hakuna

3) Kwa ujumla, unaweza kusema kwamba kwa kuzunguka au kutembea tembea, unapata urahisishaji wa usumbufu wa kuhangaika katika miguu(RLS) au mikono?
   (4) Hakuna nafuu
   (3) Kuna nafuu kidogo
   (2) kuna wastani wa nafuu
   (1) Ama au karibu kamili ya nafuu
   (0) Hakuna dalili ya kuhangaika katika miguu(RLS) hivyo basi swali halitumiki.

4) Kwa ujumla, unaweza kusema ugumu wa usingizi waka kutokana na dalili ya kuhangaika katika miguu(RLS) ni
   (4) Kali sana
   (3) Kali
   (2) Wastani
   (1) Kidogo
   (0) Hakuna

5) Je, uchovu wako au usumbufu wa kupata usingizi kutokana na dalili za kuhangaika katika miguu (RLS) uko katika kiwango kipi?
   (4) Kali sana
   (3) Kali
   (2) Wastani
   (1) Kidogo
   (0) Hakuna

6) Kwa ujumla, unaweza kusema dalili ya kuhangaika katika miguu yako uko aje?
   (4) Kali sana
   (3) Kali
   (2) Wastani
   (1) Kidogo
   (0) Hakuna

7) Je, wewe hupata dalili za kuhangaika katika miguu mara ngapi
   (4) Kali sana (hii ina maana ya siku sita hadi saba kwa wiki)
   (3) Kali (hii ina maana ya siku nne hadi tano kwa wiki)
   (2) Wastani(hii ina maana ya siku mbili hadi tatu kwa wiki)
   (1) Kiasi (hii ina maana ya siku moja kwa wiki au chini)
   (0) Hakuna

8) Je kwa siku wastani upatapo dalili za kuhangaika katika miguu, huwa kali kwa kiwangokipi?
   (4) Kali sana (hii ina maana yaa saa nane kwa siku au Zaidi)
   (3)Kali (hii ina maana ya saa tatu had inane kwa siku)
   (2) wastani (hii ina maana ya saa moja hadi tatu kwa siku)
   (1) Kiasi (Hii ina maana ya chini ya saa kwa siku)
   (0) Hakuna

9) Kwa ujumla, athari ya dalili za kuhangaika kwa miguu(RLS) juu ya uwezo wako wa kutekeleza mambo yako ya kila siku kwa mfano kufanya mambo ya kifamiliya nyumba, jamii, shule au kazi kuridhisha iko katika kiwango kipi?
   (4) Kali sana

(3) Kali

(2) Wastani

(1) Kidogo

(0) Hakuna

10) Je, dalili za kuhangaika kwa miguu huathiri aje mzunguko wako wa kihisia kwa mfano hasira huzuni wasiwasi au kukasirika?

(4) Kali sana

(3) Kali

(2) Wastani

(1) Kidogo

(0) Hakuna

Kali sana 31 – 40 points

Kali 21- 30 points

Wastani 11-20 points

Kidogo 1-10 points

Appendix X: Dodosa ya 36 Item Short Form Health Survey

Tafadhali yajibu maswali 36 yafuatayo ya utafiti wa afya kwa ukamilifu uaminifu na bila usumbufu

AFYA KWA UJUMLA

1) Kwa ujumla ungeweza kusema afya yako ni
   Bora Zaidi
   Nzuri sana
   Nzuri
   Nzuri kiasi
   Mbaya

2) Ukilinganisha na mwaka uliopita, unaweza kusemaafya yako kwa ujumla iko vipi?
   Bora Zaidi sasa kuliko mwaka uliopita
   Nzuri Zaidi sasa kuliko mwaka uliopita
   Karibu sawa na mwaka uliopita
   Mbaya kiasi sasa kuliko mwaka uliopita
   Mbaya Zaidi sasa kuliko mwaka uliopita

MAPUNGUFU YA SHUGHULI

Yafua ni shughuli ambazo unaweza kufanya kwa siku ya kawaida. Je, afya yako huathiri shughuli hizi? Kama inaa ni kwa njia ipi?

3) Shughuli kubwa kama kukimbia, kuinua vitu nzito, kushiriki katika michezo zenye nguvu?
   Ndio, imepungua sana
   Ndio, imepungua kidogo
   La haijapungua hata kidogo

4) Shughuli za wastani kama kusongeza meza, kusukuma utupu safi bowling au kucheza golf?
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

5) Kuinua au kubeba vyakula
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

6) Kupanda ngazi kadhaa
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

7) Kupanda ngazi kidogo
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

8) Kuinama, kupiga magoti au kusitisha
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

9) Kutembea zaidi ya maili moja
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

10) Kutembea vitalu kadhaa
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

11) Kutembea kitalu kimoja
   Ndio, imepungua sana
   Ndio,imepungua kidogo
   La haijapungua hata kidogo

12) Kuoga au kuvaa mwenyewe

Ndio, imepungua sana

Ndio,imepungua kidogo

La haijapungua hata kidogo

MATATIZO YA AFYA YA KIMWILI

Katika wiki nne zilizopita je umekua na shida zifuatazo na kazi yako au shughuli zako za mara kwa mara za siku kwa sababu ya afya yako ya kimwili?

13) Kupunguza muda uliotumia kwenye kazi na shughuli zingine

Ndio Hapana

14) Kukamilisha mambo chini ya vile ungependa

Ndio Hapana

15) Kupunguza aina ya kazi au shughuli zingine

Ndio Hapana

16) Kuwa na ugumu wa kufanya kazi au shughuli zingine (kwa mfano ilichukua juhudi ziada)

Ndio Hapana

MATATIZO YA AFYA YA KIHISIA

Katika wiki nne zilizopita, je, umekua na shida zifuatazo na kazi yako au shughuli zako za mara kwa mara kwa sababu ya shida kihisia (kama vile huzuni au wasiwasi)?

17) Kupunguza muda uliotumia kwenye kazi au shughuli zingine

Ndio Hapana

18) Kukamilisha kazi chini ya vile ungependa

Ndio Hapana

19) Kutofanya kazi au shughuli zingine kwa makini kama kawaida

Ndio Hapana

SHUGHULI ZA KIJAMII

20) Je shida za kihisia zimeingia katika shughuli zako za kawaida kama kijamii na familia, marafiki, majirani au vikundi?

Hapana

Kidigo

Kwa kawaida

Kwa kiasi kidogo

Kwa kiasi kikubwa

UCHUNGU

21) Je, umekua na uchungu wa kimwili wa kiwango kipi kwa wiki nne zilizopita?

Hakuna

Kidogo sana

Kidogo

Wastani

Kali

Kali sana

22) Katika wiki nne zilizopita, maumivu yaliingilia katika kazi yako ya kawaida kwa kiasi gani? (ni pamoja na kazi zote nje ya nyumba pamoja na kazi za nyumba)?

Hapana kabisa

Kidogo

Wastani

Kiasi kidogo

Kiasi kikubwa

NISHATI NA HISAI

Maswali yafuatayo ni kuhusu jinsi unavyohisi na jinsi mambo yamekwa na wewe wiki nne zilizopita. Kwa kila swali tafadhali jibu na hisia iliyo karibu na jinsi ulivyohisi au unaryohisi.

23) Je ulijiskia ukiwa na furaha Zaidi?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

24) Je, umekuwa mtu mwenye hofu?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

25) Je umejiskia ukiwa na huzuni kwamba hakuna chochote kile kilichoweza kukufurahisha?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

26) Je umejiskia mtulivu na mwenye amani?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

27) Je umekua na jitihada nyingi?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

28) Je umejiskia kuwa umevunjika moyo?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

29) Je umejiskia mzee?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

30) Je umekua mtu mwenye furaha?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

31) Je umejiskia mchovu?

Kila wakati

Mara nyingi

Muda kidogo

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

SHUGHULI ZA KIJAMII

32) Kwamuda wa wiki nne zilizopita ni kiasi gani cha muda wa afya yako ya kimwili au matatizo ya kihisia yamepatei kuingihwa na shughuli zako za kijamii(kama vile kuwatembelea marafiki, ndugu)

Kila wakati

Mara nyingi

Wakati mwingine

Muda kidogo sana wa wakati

Hakuna wakati

AFYA YA JUMLA

Jinsi ya kweli au uongo ni kila moja ya kauli zifuatazo kwako

33) Ninaonekana kuwa mgonjwa kwa urahisi Zaidi kuliko watu wengine

Hakika kweli

Zaidi ya ukweli

Sijui

Zaidi ya uongo

Hakiki uongo

34) Nina afya kama mtu yeyote ninayemjua

Hakika kweli

Zaidi ya ukweli

Sijui

Zaidi ya uongo

Hakiki uongo

35) Natarajia afya yangu kuwa mbaya Zaidi

Hakika kweli

Zaidi ya ukweli

Sijui

Zaidi ya uongo

Hakiki uongo

36) Afya yangu ni bora zaidi

Hakika kweli

Zaidi ya ukweli

Sijui

Zaidi ya uongo

Hakiki uongo

Appendix XI: Study Proforma

PARTICIPANT'S STUDY NUMBER _____

PART A Sociodemographic Characteristics

Age _____ Years

Sex M____ F_____

Marital status

a) Single ____
b) Married _____
c) Separated ____
d) Divorced ___

Level of education

a) None
b) Primary
c) Secondary
d) Tertiary

PART B ANTHROPOMETRIC MEASURES

Height (cm) _____

Weight (Kg)_____

BMI _____

PART C COMORBIDITIES

Are you hypertensive? Yes____ No____

Are you diabetic? Yes____ No____

Do you have Parkinson's disease? Yes ____ No___

PART D DRUG HISTORY

Are you currently on any medications? Yes____ No____

If yes please name them _____

PART E CIGARETTE SMOKING

Current smoker ☐

Ever smoked ☐

Never smoked ☐

PART Of CAUSES OF END STAGE RENAL DISEASE

Hypertension ☐

Diabetes ☐

Hypertension and diabetes ☐

Chronic glomerulonephritis ☐

Autoimmune disorders like SLE ☐

PART G DIALYSIS HISTORY

Duration of dialysis in months _____

Frequency of dialysis in a week _____

Duration of dialysis per session _____