UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICIN &PHARMACY

EPIDEMIOLOGY, RISK FACTORS AND 6 MONTHS OUTCOME OF PATIENTS WITH END STAGE RENAL DISEASE AT CHUK, CHUB AND RMH BETWEEN OCTOBER 2017-OCTOBER 2018

INVESTIGATOR: Dr Adeline MUGENI

SUPERVISORS: Dr Grace IGIRANEZA

Dr Leway KAILANI

A review submitted to The College of Medicine and Health Sciences, School of Medicine and Pharmacy in partial fulfillment of the requirements for the award of a Masters of Medicine in Internal Medicine, University of Rwanda.

Kigali, June 2019

DECLARATION

I, Adeline Mugeni, do hereby declare and certify that the work presented in this dissertation entitled "Epidemiology, risk factors and 6 months outcome of patients with end stage renal disease at CHUK, CHUB and RMH between October 2017-october 2018" is entirely my own and original work and it has never been presented or submitted in whole or in part to any other institution or university. This study contains my own work and where assistance was sought it was acknowledged specifically.

It is submitted to the College of Medicine and Health Sciences in partial fulfillment of the academic requirements for the award of Masters of Medicine in Internal Medicine, University of Rwanda

Dr Adeline MUGENI

Signature ..... Date 19/5/2019

Approved for submission by

SUPERVISORS:

Dr Grace IGIRANEZA

Signature ..... Date 19th May 2019

Dr Leway KAILANI

Signature ..... Date 16/5/2019

DEDICATION

To the almighty God

To my dear Parents

To my dear sisters and brothers

To my nephews and nieces

To my Supervisors

To my Patients

I dedicate this work.

ACKNOWLEDGEMENT

I owe this work to the help of many people that I would like to acknowledge.

I am grateful to the almighty God for always being with me, guiding me and strengthening me through my studies.

I am grateful to the Government of Rwanda and the Ministry of Health for the scholarship they offered me at University of Rwanda, College of Medicine and Health Sciences, School of Medicine and Pharmacy.

Special gratitude to Dr Ben KARENZI and Dr Walter JAOKO for believing in me and mentoring me in my medical career and to my senior internists for guiding me, teaching me and encouraging me through my residency.

My special gratitude to my supervisors Dr Grace IGIRANEZA and Dr Leway KAILANI for their invaluable support not only for this work but throughout my residency. Thank you for believing in me and for encouraging me to do my best.

I would like to acknowledge my colleagues Dr Gloria SHUMBUSHO and Dr Grace UWIMANA for their support in this work.

Last but not least, I would like to express my gratitude to all the study participants and their relatives for willingly accepting to participate in this study.

God bless you all.

ABSTRACT

Background

There is limited information concerning end stage renal disease in lower and middle income countries, Rwanda included. End stage renal disease has various adverse physical and social economic effects on individual patients and their families without sparing health care systems in general. The aim of our study was to determine the epidemiology, risk factors and 6 months outcomes of patients with end stage renal disease in three referral hospitals in Rwanda.

Methods

This was a prospective cohort study on patients with end stage renal disease that consulted 3 referral hospitals in Rwanda between October 2017 and October 2018. Data was collected on patients' demographics, risk factors, baseline kidney functions, mode of insurance and ability to afford RRT. Patients were followed up to assess survival after 6 months in relation to known risk factors and access to renal replacement therapy.

Results

Among 88 participants, 55.7 % were male and the median age was 45. Community based health insurance was used by 84.1 % of participants. Hypertension was the most common co- morbidity in 80.6% of participants followed by diabetes in 34.1% and 21.6% were exposed to traditional drugs .Only 16.9% of participants were able to afford renal replacement therapy (RRT) in form of hemodialysis and 58.3 % of them discontinued before the end of 6 months due to death and financial reasons. By the end of follow up period, 47% of participants had died and 19.3% were lost to follow up. There was no statistically significant association between the different co-morbidities /risk factors and the 6 months outcome.

Conclusion

End stage renal disease was found to occur in relatively young and active patients with hypertension as the most common co-morbidity. Most of them could not afford to initiate and sustain renal replacement therapy regardless of their socio economic status. Mortality was high after 6 months of follow up.

ACRONYMS AND ABBREVIATIONS

CHUK: Centre Hospitalier Universitaire de Kigali
CHUB: Centre Hospitalier Universitaire de Butare
RMH: Rwanda Military Hospital
ESRD: End Stage Renal Disease
CKD: Chronic Kidney Disease
AKI: Acute Kidney Injury
GFR: Glomerular Filtration Rate
KDIGO: Kidney Disease Improving Global Outcome
SSA: Sub Saharan Africa
BP: Blood pressure
HIV: Human Immunodefiency Virus
HIVAN: HIV Associated Nephropathy
ART: Anti-Retroviral Therapy
HAART: Highly Active Antiretroviral Therapy
CBHI: Community Based Health Insurance
MS: Mutuel de Santé
FARG: Fonds d'assistance aux rescapés du génocide
HD: Hemodialysis
LMIC: Low and middle income countries
RRT: Renal Replacement Therapy
HBV: Hepatitis B virus
USA: United States of America
NSAIDS: Non-steroidal antinflammatory drugs
IRB: Institutional Review Board
PHI: Partners in Health
HTN: Hypertension
DM: Diabetes Mellitus

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I: INTRODUCTION

1.1Background

Infections are no longer the leading causes of disease and death worldwide as it was one century ago; non communicable diseases are now taking the lead (1). End stage renal disease is also a rising major concern (2),responsible for increasing death rates and associated with costly treatments (3).

KIDGO (Kidney Disease Improving Global Outcome) criteria for definition of CKD (Chronic Kidney Disease) are: 1."Kidney damage for more than 3 months as defined by structural or functional abnormalities of the kidney, with or without decreased glomerular filtration rate (GFR), that can lead to decreased GFR, manifest by either pathological abnormalities or markers of kidney damage; including abnormalities in the composition of the blood or urine, or abnormalities in imaging tests" (4) 2."GFR< 60ml/min/1.73 m2 for > 3months with or without kidney damage"(4). On the spectrum of CKD, ESRD or kidney failure is defined as GFR< 15(4).

Majority of patients develop ESRD as a result of diabetes which affects about 135 million people world-wide(1).Diabetes prevalence is still expected to increase globally but much more in LMIC than in high income countries by the year 2025(1). About 30% of patients with diabetes and kidney diseases end with renal failure and die of cardiovascular diseases (1).Diabetic patients should be regularly screened for micro albuminuria as it indicates the beginning of diabetic nephropathy (1).

In high income countries ,where diabetes is expected to increase by 40% by the year 2025 (1), 40% of new patients on renal replacement therapy have diabetic nephropathy(5).Elderly patients are the ones mostly affected by CKD(2) in high income countries where hypertension and diabetes mellitus are responsible for most cases of CKD(2) .While the rise of both non communicable diseases and infections are responsible for the increase of ESRD in SSA (6), hypertension, which is more common in blacks , and glomerular diseases account for most CKD cases which occur in young adults between 20-50 years of age(2).

The leading cause of CKD in SSA is hypertension (2)and in countries such as South Africa hypertension is responsible for ESRD in almost a quarter of patients on RRT (2). In Africa , diabetes is found in almost 10 million people(1) and prevalence of diabetes related kidney disease is estimated to be 6–16% in SSA, with an increasing prevalence of ESRD in some parts of SSA(1).

Late presentation of patients with advanced disease in need of renal replacement therapy is a big concern in Africa(2).A cross sectional study done on the prevalence of CKD among inpatients in a medical ward in Mbarara, Uganda showed that about 4.6% had ESRD(7).Failure of early identification of patients at risk by health care professionals and lack of awareness by patients were responsible for the delay in consultation (7). One of the proposed measures of reducing CKD complications in Africa is focusing on prevention of its progression (8).

Nephrotic syndrome is reported at the top of glomerular diseases that lead to ESRD especially in African children less than 10 years of age(2)(9)and is a frequent cause of hospital admissions in Zimbabwe; in Kwa Zulu Natal, South Africa; and Uganda(9). Kidney related complaints are reported to account for a considerable number of in hospital patients in Africa(2) where resistant glomerular diseases are common and often end in renal failure(2) (9).

Although cases of HIVAN related ESRD and the incidence of HIV have been decreasing since the beginning of HAART use in SSA (10)(2), there are still challenges of the persisting HIV epidemic, lack of sufficient data on HIVAN and of patients who consult late with advanced disease in need of renal replacement therapy (2).Among those who have not yet started HAART, CKD is estimated at 6 to 45% (10). HIVAN is no longer the leading cause of ESRD in HIV infected patients as it has been overcome by FSGS. About two decades ago, HIVAN used to be mostly found in blacks who were severely immunosuppressed and had particular pathologic manifestations ending into ESRD after a short time(10).

Viral infections such chronic hepatitis B virus (HBV) which is already known to cause liver disease has been proven to affect renal function as well. Studies prove that chronic hepatitis B can lead to glomerular disease even in the absence of cirrhosis (11) . Other effects of HBV infection are insulin resistance, worsening the harmful effects of oxidants and impaired function of renal tubular cells(11) .

Chronic helminthic infections such as schistosomiasis which are prevalent in Africa and Middle East are also associated with various manifestations of kidney disease(12).Schistosoma hematobium can lead to hydroureter,hydronephrosis and bladder ulcers and may also predispose to renal failure and urothelial cancers.(13) A study done on 17 patients with ESRD and nephrotic syndrome in the Netherlands showed various pathologic manifestations of kidney disease in association with schistosoma mansoni after excluding other potential causes. (12)

The use of herbal medicine and cultural factors have also been associated with increased risk of ESRD(14). Prior studies have reported higher predisposition to ESRD in Asians in comparison to whites and in relation with the increased use of non-western medicine by the Asians (14).Unknown products that are harmful to the kidneys may be contained in these herbal products whose use is expanding to non-Asians and whose effects may be more widespread than what is currently known (14).

The predisposition to risk factors such as diabetes and hypertension, the exposure to products that are harmful to the kidneys, the affordability of different means of treatment and the prevention of ESRD are all subject to socioeconomic status (15). A study on socioeconomic status and end stage renal disease in the USA showed that ESRD was found more in males and older patients in both whites and blacks. It was proven that the less the level of income ,the more the incidence of ESRD (15).

Most patients wait to consult till their CKD has evolved to ESRD and are found with uremic manifestations in requirement of different modalities of RRT (16). Treatment goals for ESRD vary according to the income level of different countries. The LMIC are faced with the challenge of patients who are not able to afford therapy and only try to sustain life for a short time while the higher income countries can afford prolongation and improvement of the general condition of the patients. (17) Initiation of treatment such as dialysis in Africa is dependent upon the assessment of the physician in charge of the patient, who often takes into account the degree of uremia with its different complications and creatinine clearance level ,coupled with the financial ability of the patient (18)

Access to RRT was found to be different between LMIC and higher income countries as shown by a survey collected for 122 countries where dialysis was being performed in 2004. At the time, 1783000 people were on RRT worldwide; more than 70 % were on dialysis while the remaining percentage had a functioning renal transplant. Approximately half of all dialysis patients and almost 3/4 of all patients living with a transplant were residing in western countries (19).

Only a small number of patients with ESRD in Africa can afford sustainable and quality hemodialysis (2)(5). Access is influenced by factors such as level of education, economic status and place of residence(2). This has a negative impact on the outcome of patients with ESRD who cannot afford RRT and are "sentenced to death"(20). A retrospective study done on 320 ESRD patients on maintenance hemodialysis for 7years in Nigeria revealed that over 80% funded the dialysis personally, 98% were not able to sustain it for 12 weeks with weekly average session of 0.013 and the mortality was 40% within 90 days of dialysis (6).

Anecdotally, end stage renal disease is among the common causes of admission in internal medicine in Rwanda and yet the risk factors and the outcomes of ESRD in Rwanda have not been studied. The aim of this study is to assess the epidemiology, risk factors, access to different modalities of RRT and mortality of ESRD patients in the 3 referral hospitals in Rwanda in order to facilitate planning of care and prevention.

1.2. Problem Statement and Justification of the Study

In our settings, daily clinical observations in both inpatient and outpatient clinics show an increasing number of patients with ESRD, some at a very young age and most of them not able to afford RRT. This is a devastating medical, social, and economic problem for patients and their families. There are no known data about the risk factors of end stage renal disease in these patients. Since majority of the patients cannot afford RRT, it is imperative to establish the risk factors in order to address them and prevent the progression to ESRD.

This study aims to determine the clinical profile, risk factors and outcomes of ESRD in patients presenting at the 3 referral hospitals in Rwanda and therefore raise awareness among clinicians to identify the risk factors and address them before progression. It will also help in educating patients to seek medical help before it is too late and do regular follow up for those with known risk factors.

1.3. Research Question

What are the socio demographic characteristics and risk factors of ESRD and 6 months prognosis of patients at selected referral hospitals in Rwanda?

1.4. Objectives

1.4.1. General Objective

To determine the demographic, risk factors and 6 months outcome of End Stage Renal Disease patients in the 3 referral hospitals in Rwanda between October 2017- October 2018.

1.4.2. Specific Objectives

1. To determine the risk factors of ESRD in our settings compared to already known risk factors elsewhere
2. To determine the role of diabetes and hypertension in the etiology of ESRD in Rwanda
3 To determine the proportion of patients with ESRD who are able to afford RRT
4 To determine patients outcome after 6 months of follow up with and without RRT

CHAPTER II METHODOLOGY

2.1. Study settings

The study was conducted in three referral hospitals in Rwanda, CHUK, CHUB and RMH. Majority of patients that are referred to those hospitals use community based health insurance (CBHI) also known as "Mutuel de Santé" and the rest use private insurances.

CHUK is the biggest referral hospital in the country, located in the capital city, Kigali. It has a capacity of 519 beds and offers hemodialysis services since 2014.The services are available on a daily basis for both AKI and CKD patients with 5 beds in the hemodialysis service.

RMH, also located in Kigali, has a bed capacity of 500 and the hemodialysis services are new compared to the other 2 hospitals since they started 2 years ago. It has 6 hemodialysis beds and the services are available 7 days per week and take care of AKI and CKD patients.

CHUB is located in the South of Rwanda; about 3 hours drive from Kigali. It has a bed capacity of 500 and the hemodialysis unit has 5 beds. The dialysis services are available since 2007 on a daily basis and offered to both AKI and CKD patients.

2.2. Study Design

This was a prospective cohort study on the demographic, risk factors and outcome of ESRD patients in 3 referral hospitals in Rwanda, between October 2017 to October 2018.

2.3 Study Population

The study was conducted on patients with ESRD who consulted inpatients and outpatient services of the 3 referral hospitals during the study period. ESRD was defined as a compatible clinical history with a current estimated GFR <15 ml/min/m^2PLUS any one of the following:

- A previous measure of GFR from at least 3 months prior with estimated GFR <15 ml/min/m^2
- Diagnosis of ESRD by treating physician

- Ultrasound evidence of CKD, defined as obviously small kidneys for body size together with loss of corticomedullary differentiation.

GFR was calculated according to Cockcroft-Gault formula

C_{Cr}= {((l 40–age) x weight)/ (72xS_{Cr})} x 0.85 (if female)

2.4. Inclusion Criteria

- ✓ Patients with End stage renal disease consulting CHUK, CHUB and RMH during the study period
- ✓ Signed consent
- ✓ RRT naive
- ✓ 15 years and above

2.5. Exclusion Criteria

- ✓ Refusal to sign consent
- ✓ Patients with AKI

2.6. Sample size

We assumed the proportion of CKD patients with ESRD to be 5%. (Compared to a cross sectional study conducted between February and May 2013, on patients admitted to the medical ward of Mbarara Regional Referral Hospital, Southwestern Uganda, in which out of 213 patients with CKD, 4.6 % had ESRD (7). We used Kish's approximate formula to calculate an effective sample size of 73 for a 95% Confidence level. With an estimated loss to follow up of 20%, we obtained a sample size of 88.

2.7. Description of Study Process

Demographic and clinical data was collected on patients with ESRD before starting RRT. This was obtained by means of a questionnaire which was designed by the authors, translated in Kinyarwanda, pretested and adjusted accordingly. Research assistants were selected among admitting internal medicine residents in the three referral hospitals and trained on the use of the questionnaire. The trained residents and the author participated in data collection. Data was collected on patients' age, sex, and socio economic status, mode of insurance and level of education. We also gathered data on history of co-morbidities/risk factors such as diabetes, hypertension, obstructive uropathy, HIV, chronic non-steroidal antinflammatory drugs (NSAIDS) use which was defined as daily use for at least one month and more. We asked about traditional drug use be it herbs, liquids and other forms of alternative medicines in the last 6 weeks prior to enrollment.

We went through the patients files for data on renal function tests done 3 months prior to enrollment in order to differentiate AKI from CKD and at enrollment we collected data for urea, creatinine, proteinuria, HbA1c (where applicable), measured urine output and did kidney imaging (ultrasound). The enrollment investigations were either recorded from patients files as part of their routine work up for those who were admitted or consulted as OPD or for study purposes. Renal ultrasound was done and reported by a trained radiologist during admission or outpatient consultation and included in the patients' records.

Patients were then called after a period of 6 months to assess the overall survival with and without RRT. Due to financial limitations we were not able to assess renal function tests variation over time.

2.8. Data Analysis and management

Data were collected using a well-structured and pre-tested questionnaire and were entered in excel then exported to IBM SPP statistics version 25 for analysis. Frequency statistics were presented in tables and graphs. Logistic regression was done to test the measures of associations where Odds ratios were used to compare the occurrence of outcomes in different groups and the significance level was set at $p<0.05$.

2.9. Ethical Considerations

Ethical clearance was obtained from the University of Rwanda Institutional Review Board (IRB) and the research committees of the three referral hospitals. Study participants gave written informed consent prior to study enrollment and after being informed of study procedures. They were informed about their rights to withdrawal consent at any time during the study period.

CHAPTER III RESULTS

A total number of 88 patients were enrolled in the study from October 2018 to October 2019 and each participant was followed up for 6 months.

Figure 1: Participants recruitment and flow

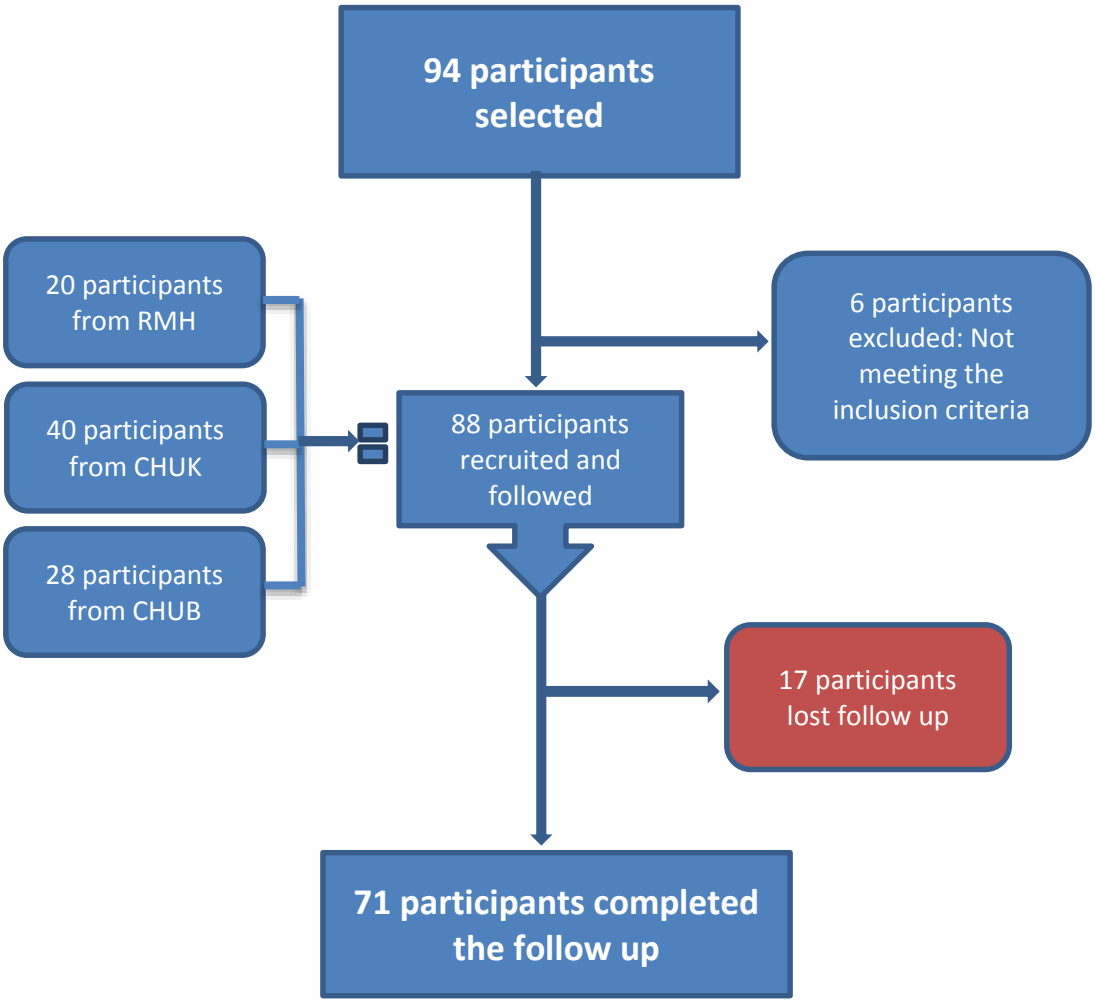


Table 1 : Baseline Characteristics.

Variables	N	%
Age (Mean ± SD, Median) in years	45.72 ± 16.9, Median=45.0 years	
Age range (years)		
<18 years	5	5.7
18-35 years	21	23.9
36-45 years	20	22.7
46-65 years	29	33.0
>65 years	13	14.8
Gender		
Male	49	55.7
Female	39	44.3
Residence/Province		
Kigali	30	34.1
South	34	38.6
East	14	15.9
North	6	6.8
West	4	4.5
Health insurance		
CBHI	74	84.1
FARG	4	4.5
Other (RSSB, MMI, ...)	7	8.0
None	3	3.4
Ubudehe Category		
Category 1	23	26.1
Category 2	22	25.0
Category 3	41	46.6
No category (Refugees)	2	2.3
Education		
None	20	22.7
Vocational	3	3.4
Primary	49	55.7
Secondary	13	14.8
University	3	3.4
Financial responsibilities		
Bread winner	38	43.2
Dependent	36	40.9
Shared	14	15.9
Number of meals per day		
Once/day	14	15.9
Twice/day	31	35.2
3 times/day	43	48.9

*Ubudehe is a Rwandan categorization of communities that ranks the households on a scale of 1 to 6 according to their perceived poverty and vulnerability status, with a score of 1 being the most vulnerable and 6 the least (21).

Majority of participants were in middle age, between 46 and 65 years but there was also a considerable number of relatively young patients between 36 and 45 years of age. There were more males than females at 55.7% and 44.3% respectively. The majority of participants were recruited from the Southern Province and Kigali. More than 80% of participants used CBHI, less than 10% were on private insurance while a small percentage (3.4%) had no insurance.

Almost half of participants were in social economic category Ubudehe 3 and there were almost equal numbers of participants in category 1 and 2. A small proportion of participants (2.3%) were refugees therefore not classified in the national ubudehe category.

Half of participants had primary school education, followed by those with no formal education at 22.7%. The 3rd category belonged to those with secondary education while the last was made of equal numbers of those with vocational training and university education at 3.4%. Majority of participants were the primary wage earners for their families.

Table 2: Risk factors and co-morbidities

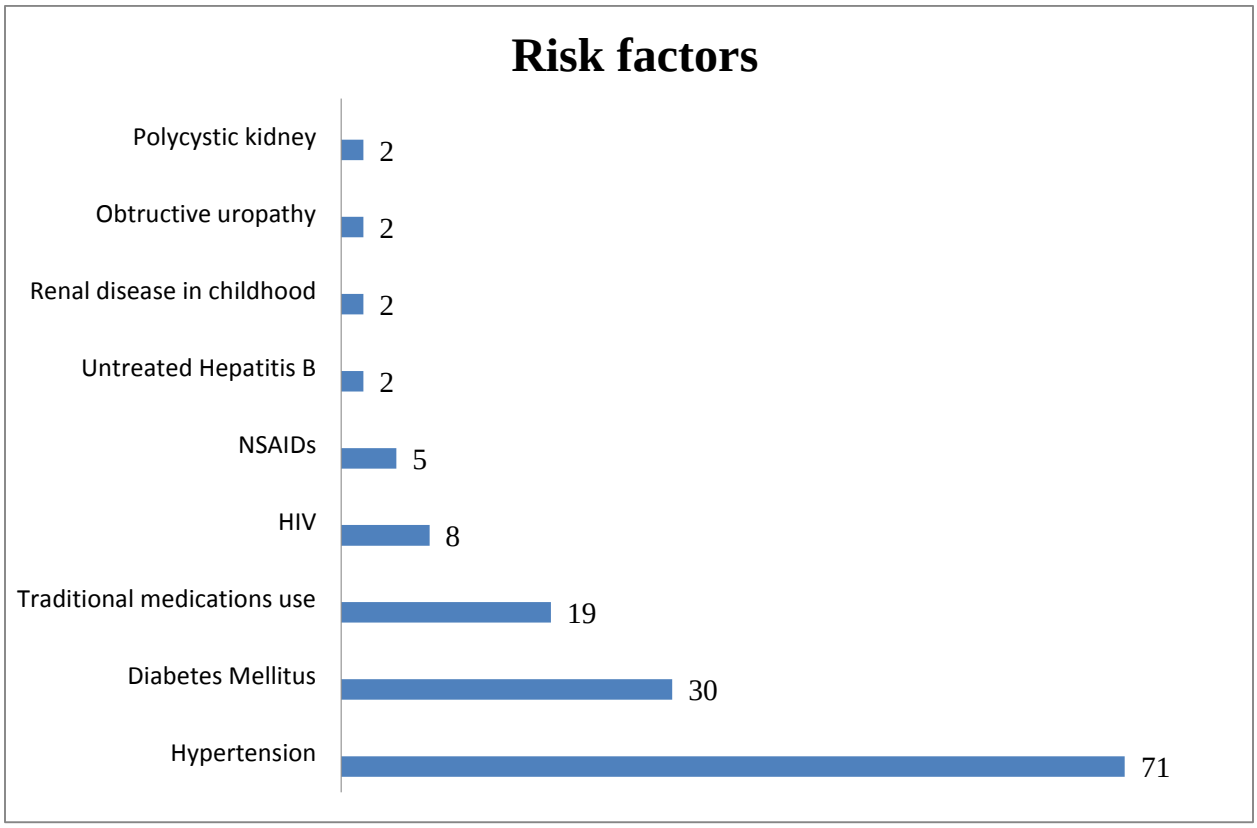
Variables	N	%
Awareness of Kidney disease		
Newly diagnosed	19	22.7
Known with ESRD	69	78.4
Co-morbidities/ Risk factors		
Diabetes mellitus	**30**	**34.1**
Duration of DM (n=30)		
<1 year	1	3.3
1-5 years	6	20.0
>5 years	23	76.7
Hypertension	**71**	**80.6**
Duration of HTN (n=71)		
<1 year	25	35.2
1-5 years	24	33.8
>5 years	16	22.5
Newly diagnosed*	6	8.5
Combined DM and HTN	**26**	**29.5**
Adherence on treatment of HTN (n=71)		
Regular	41	57.7
Inconsistent	24	33.8
Newly diagnosed	6	8.5
HIV (n=8)		
Isolated HIV	3	37.5
HIV & HTN	3	37.5
HIV associated with HTN & DM	2	25.0
Use of TDF	3	37.5
Untreated Hepatitis B	2	2.3
Renal disease in childhood	2	2.3
Other risk factors/exposures		
History of traditional drugs use**	19	21.6
Chronic NSAIDs***	5	5.7
Obstructive uropathy	6	6.8
Polycystic kidney	2	2.3

*Hypertension was said to be newly diagnosed when patients became aware of it during the time of current admission and enrollment in the study.

**History of traditional drugs use in 6 weeks prior to enrollment.

*** Chronic NSAIDS use was defined as daily use for 30 days or more

Figure 2 : Risk factors and co-morbidities



Hypertension was the most common co- morbidity in more than half of participants, followed by Diabetes while 29.5 % had both hypertension and diabetes.

Use of traditional drugs was reported in 21.6% and only a small percentage had chronic NSAIDS exposure while 8% were HIV positive.

Polycystic kidney disease, history of renal disease in childhood, obstructive uropathy and untreated Hepatitis B were each reported in 2% of participants.

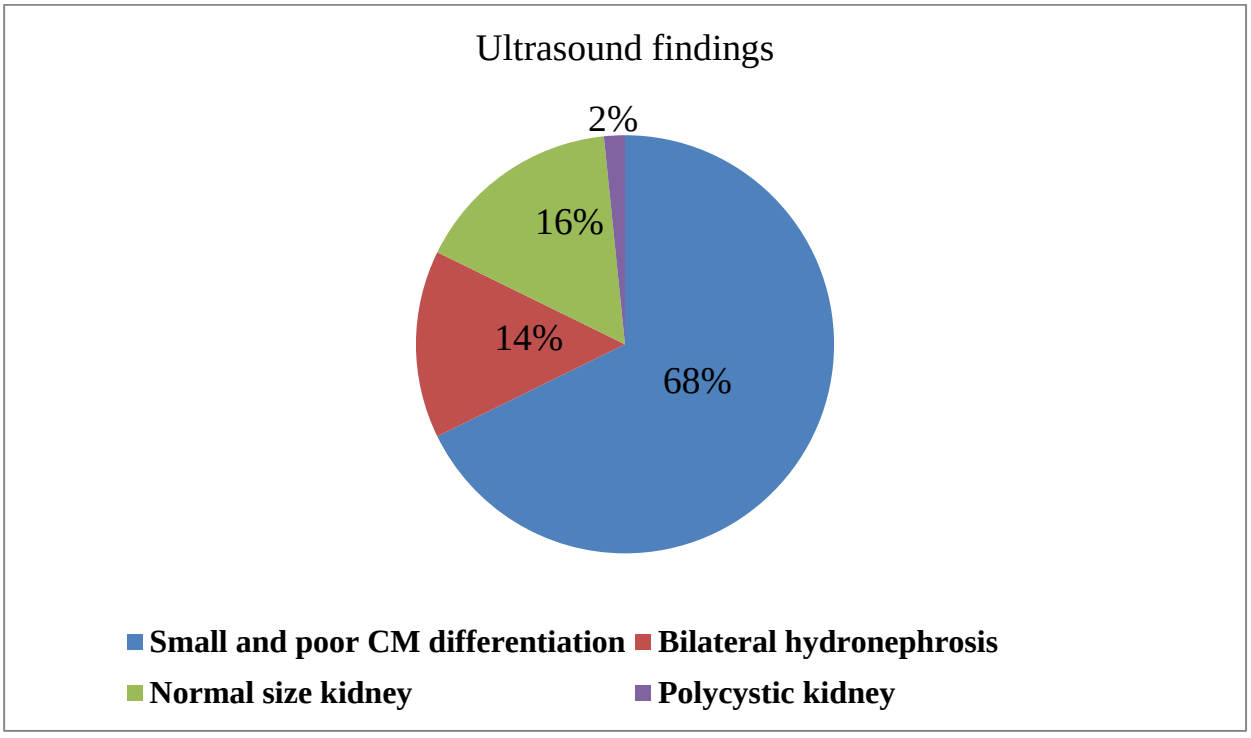
78.4% were aware of having kidney disease.

Table 3: Baseline kidney function

Measure	Median	IQR
Urea in mg/dl	48.3	110
Creatinine in mg/dl	7.2	5.6
GFR ml/min/m2	6.9	5.5

The median GFR was 6.9ml/min with an IQR of 5.5

Figure 3: Kidney imaging findings (Ultrasound)



*Normal size kidney was defined as > 10cm long (22).

The most common ultrasound finding was small kidneys with poor corticomedullary differentiation and only 2% of patient had features of polycystic kidney disease.

Table 4: 6 months outcome among the study population

Outcome	RRT	No RRT	Total	P value
Alive	8 (66%)	22 (37.2%)	30 (42.3%)	0.06
Died	4 (33.3%)	37 (62.7%)	41 (57.7%)	

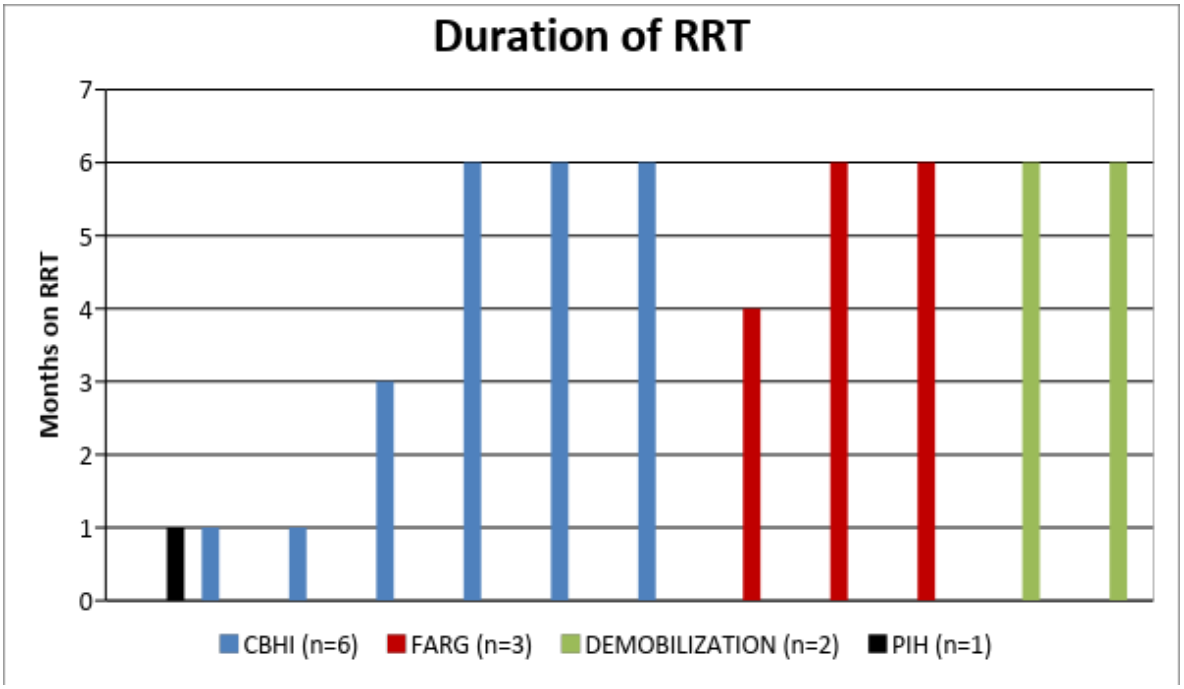
At the end of follow up19.3% of participants were lost to follow up and 41 patients (57.7 %) had died. However the risk of death among those who had RRT and those who did not was not statistically significant.

Table 5: Association between known risk factors and outcomes

Risk factors	Categories	Outcome at 6 months of follow up		OR (95%CI)	P value
		Alive	Died		
Diabetes mellitus	Yes	7 (33.3%)	14 (66.7%)	1.7 (0.5-4.9)	0.335
	No	22 (45.8%)	26 (54.2%)		
Hypertension	Yes	23 (43.4%)	30 (56.6%)	0.78 (-.24-2.46)	0.675
	No	6 (37.5%)	10 (62.5%)		
HIV	Yes	3 (42.9%)	4 (57.1%)	0.96 (0.2-4.6)	0.963
	No	26 (41.9%)	36 (58.%)		
Traditional drugs	Yes	3 (20.0%)	12 (80.0%)	3.7 (0.9-14.6)	0.061
	No	26 (48.1%)	28 (51.9%)		
Age	<18 years	1 (25.0%)	3 (75.0%)	3.3 (0.3-39.3)	0.331
	18-35 years	9 (52.9%)	8 (47.1%)		
	36-45 years	7 (43.8%)	9 (56.3%)	1.4 (0.3-5.7)	0.598
	46-65 years	9 (39.1%)	14 (60.9%)	1.7 (0.5-6.2)	0.387
	>65 years	3 (33.3%)	6 (66.7%)	2.2 (0.4-12.1)	0.344
Dialysis (RRT)	Yes	8 (66.7%)	4 (33.3%)		
	No	21 (36.8%)	36 (63.2%)	3.4 (0.9-12.7)	0.066

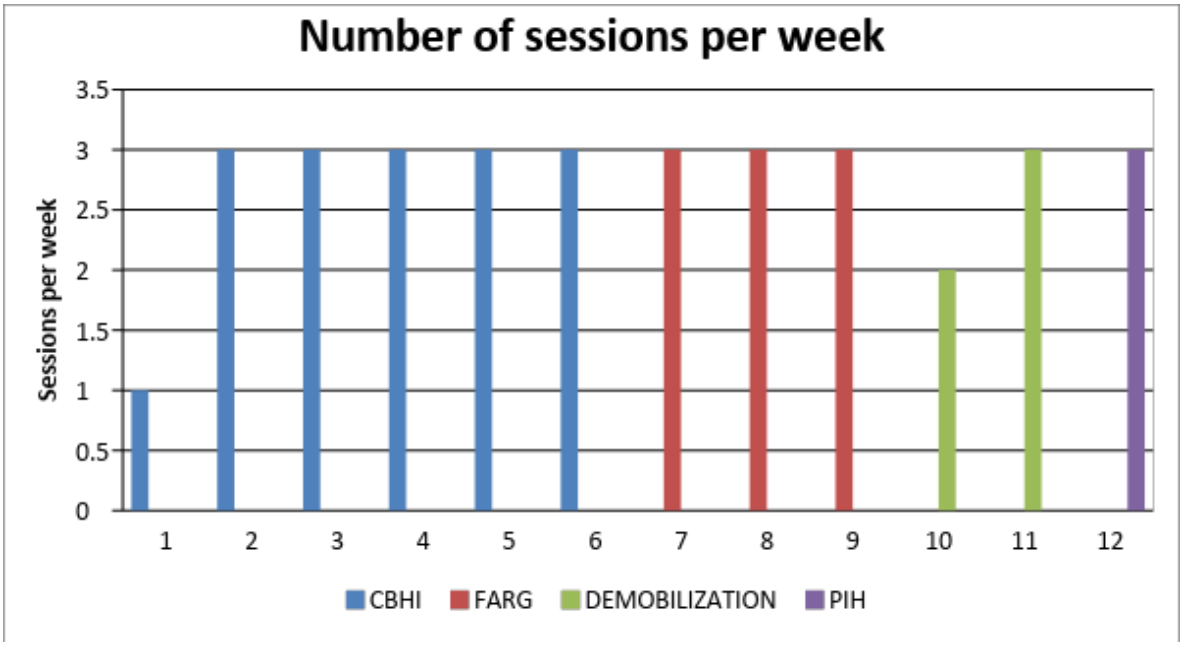
There was no statistically significant association between the various risk factors/co-morbidities and the 6 months outcome.

Figure 4: Hemodialysis duration and mode of payment



The minimum duration of RRT (HD in this case) was 1 month and the maximum 6 months. At the end of 6 months of follow up, only 7 patients were still on maintenance hemodialysis, three were under CBHI (and therefore paying out of pocket since CBHI does not cover maintenance HD), two were under FARG insurance and two under demobilization insurance.

Figure 6: Number of Hemodialysis session per week



Ten out of twelve participants had 3 sessions of HD per week, 5 were under CBHI (and therefore paid out of pocket since it does not cover chronic HD), and 3 were covered by FARG and one by Partners in health (PHI).

One patient on CBHI only managed to do one session per week and one patient on demobilization insurance managed 2 sessions per week.

CHAPTER IV DISCUSSION

This study aiming at determining the epidemiology, risk factors and outcome of end stage renal disease was conducted in 3 referral public hospitals in Rwanda and involved 88 participants. It documented majority of participants to be relatively young as 35% of participants were between 20-40 and 31.8% between 41-60 with a mean of 45.72 ± 16.9. Similar results were obtained in a study on AKI done in one tertiary hospital in Rwanda in which the median age of participants was 38 years (IQR 28–57 years)(23). This may be due to the fact that the Rwandan population is relatively young with a mean age of 22.7 as per the 2012 4th Rwandan Population and Housing Census (24). In other studies done on ESRD patients in LMIC countries, participants were also found to be relatively young or middle aged such as a retrospective study done on ESRD patients in one center in Nigeria, in which the mean age of participants was 46+/- 17.6 years (6)This is in contrast with patients in developed countries who are middle aged or elderly (2).

Not only were majority of participants young or middle aged but 43% of them were the wage earners for their families. This shows the socio economic burden of ESRD as these patients can no longer meet their families' financial needs and are also unable to meet their own heath care needs such as RRT.

In our study hypertension was the most common risk factor/co- morbidity in 80.6% of participants while diabetes was found in 34.1% of participants and both diseases in 29.5%.This is similar to other studies where diabetes, hypertension, and chronic kidney disease are identified as the most common risk factors of end-stage kidney failure worldwide(1). Hypertension and glomerular diseases are responsible of most CKD and ESRD cases in SSA while diabetes is the most common culprit in high income countries (9).

The number of participants with hypertension was higher in our study compared to other African studies. For example, in a ten year study of 368 patients on the etiology of chronic renal failure in Nigeria, 61% had hypertension and 11% diabetes mellitus(9).An Egyptian study on the prevalence of ESRD reported hypertensive nephrosclerosis as the cause in 21.4% of participants and diabetic nephropathy in 14.9%(25)and in South Africa, hypertension was reported to affect

about 25% and was the cause of ESRD in 21% of patients on RRT(2). The reason for a higher number of participants with hypertension in our study is probably due to the fact that it's not a direct cause/ effect relationship, therefore ,for some hypertension may be the cause and for others a result of ESRD.

Traditional drug use was reported in 21.6% of participants and it was associated with increased risk of death though not statistically significant [OR: 3.71 95% CI (0.9-14.6) p= 0.061]. The study did not go as far as establishing the nature and composition of these products and their potential nephrotoxicity. Most of these patients reported a visit to traditional healers and consumption of various traditional drugs before consulting health facilities. Higher exposure to traditional medicines ,in up to 57.0% of participants , was reported in a study done in Kericho County Kenya (26) and in which the absence of established protocols and knowledge on side effects were found to be the main challenges of these products (26).Potential nephrotoxic effects of herbal remedies were also reported in a comparative study between Asian and black ESRD patients in Northern California in which over 45% of Asians affirmed at least 1 visit to a practitioner of traditional Chinese medicine within the previous 12 months (14).Further studies are needed in our setting to explore the effects of various traditional drugs on kidney function since a considerable number of patients try them first and only consult health facilities when they do not seem to work.

Only 9.1% of participants were HIV positive, all were on ART and 37.5% of them were exposed to tenofovir; kidney injury may have resulted from the virus itself or from the medication. About 37.5% of the HIV positive patients did not have any other major risk factor such as hypertension and diabetes, so for them ESRD could be assumed to be related to HIV. Rwanda is on the way to achieve the UNAIDS targets through the 90/90/90 program. Statistics of June 2106 for example showed high access to antiretroviral therapy among people living with HIV at 78% with sustained viral suppression at 86% after 1year and 91.5% after 2years and a half , and 93% were still under follow up after one year of starting treatment (27).

It can be expected that with better control of HIV, the number of HIV patients with complications including HIVAN is low as it is already known that since the time when HAART became more widely available, HIVAN is reported to be on decline as a cause of CKD and ESRD(10).However HIV positive patients can have other glomerular diseases such as FSGS.

A retrospective analysis of HIV-infected patients undergoing a renal biopsy in France showed that the prevalence of HIVAN has been overcome by FSGS in the era of HAART use. HIVAN however was still linked to black race, severe immune suppression and renal failure (10).

Glomerular disease, especially nephrotic syndrome in childhood is reported to be one of the most common causes of ESRD in Africa(2). In our study, only 2.3% reported history of kidney disease in childhood but we could not precise the exact nature of the disease since we did not do kidney biopsy. It is however worth noting again that majority of our participants were relatively young so a follow up study with renal biopsy would be of major impact to determine, the epidemiology of glomerular diseases in Rwanda and the role of glomerular diseases as a cause of ESRD in this cohort.

Level of education was associated with lack of awareness of kidney disease, 45% of those without formal education was not aware of having ESRD as compared with 23% of those with secondary school education. The association was statistically significant with a P value of 0.030. This may reflect on health care seeking behavior with lack of regular checkup even though it is part of the package offered by the CBHI which was used by majority of participants. In addition patients may have spent time seeking alternative means of treatment such as traditional herbs.

Patient awareness and involvement in their care is a crucial part of the management plan especially in our setting where it has been proven that only a minority of patients are able to afford RRT. It is therefore important for health care providers to be aware of patients at high risk of CKD and initiate timely interventions and referral to a specialist before progression to ESRD. A prospective study done on ESRD patients in Korea found that , early referral of CKD patients to a nephrologist, before the stage of needing dialysis leads to reduced mortality (28).

As much as 83% of participants could not afford any form of RRT (HD in this case) regardless of their socioeconomic status, as determined by the “Ubudehe” Category and their mode of insurance including private insurances.

There was no significance difference between the three "ubudehe" categories regarding affordability of RRT as only19.4% of those in category three. 16.7% in category 2 and 15.8% in category 1 were exposed to HD. Only 12 patients (13.6 % of all participants) were able to do hemodialysis, 6 of them were on CBHI (and paid HD out of pocket since CBHI does not cover chronic HD). Five of these 6 managed to do 3 sessions of HD per week while one was doing only1 session per week. Three participants used FARG insurance and all of them were doing 3sessions per week. Two participants were sponsored by the Demobilization commission, one managed to do only 2 sessions per week while the other did three. Partners in Health sponsored 1 patient who did HD 3times/week. By the end of 6 months follow up, 42.8% had stopped HD due to financial reasons while 57.2% had died. The maximum duration of sustained HD was 6 months with a minimum of 1 and a mean of 4.3months.

Failure to afford sustainable hemodialysis was also found in a retrospective study of 320 ESRD patients in one center in Nigeria, in which, over 80% funded dialysis treatments by their own means. The duration of maintenance hemodialysis before loss to the program ranged from 1 to 37 weeks, with a mean duration of 5.2±7.6 weeks. More than 90% of the patients could not continue dialysis for more than 3 months. Only three patients (0.9%) could sustain dialysis for over 26 weeks before they were lost to follow-up(6).

On top of the high cost of RRT, two out of the three dialysis centers are situated in the capital city Kigali, which leads to more expenses for patients and sometimes logistic constraints. This shows the enormous socio economic burden of ESRD with limited availability of RRT in our setting as in most SSA countries (2) .

Our study found that after 6months of follow up, 47, 7% of participants died, 32.9% were still alive and 19.3% were lost to follow up. Patients without RRT, those at age extremities and those that used traditional drugs were more likely to die but none of the associations was statistically significant. The observed mortality rate may have been lower than accurate in our study due to the limited number of study participants as well as the considerable number of patients who were lost to follow up and in whom the outcome could not be determined.

Among study participants, 66, 7% of those over 65 years were dead by the end of 6 months. A prospective cohort study done on 125 elderly patients with ESRD aged between 70-86 years in one renal unit in England showed 71% one year survival rate overall; 80%, 69%, and 54% in patients 70–74 years, 75–79 years, and 80 years and older, respectively (p=0·008)(29).The patients in the above mentioned study are different from our participants in terms of access to RRT but other studies have shown little benefit of dialysis in elderly patients with ESRD who are often suffering from many other diseases(30).

Study strength

To our awareness, this is the first study conducted in Rwanda on the profile, risk factors and outcomes of patients with ESRD. It can serve as a pilot study for more detailed studies in the future.

The other strength of our study is that it was multicentered, conducted in 3 out of 4 hemodialysis centers in Rwanda.

Study Limitations

There were a number of limitations associated with our study.

Given that it was conducted in referral hospitals, it may not have provided a completely true picture of the general population; most patients with ESRD may die of complications before reaching the referral hospitals.

Furthermore one private referral hospital that provides nephrology services was not included in the study therefore we may have missed another category of patients with more means to afford RRT and presumably better outcomes.

The follow up time was short, limited at 6 months in order to meet academic requirements.

Follow up was done by telephone call and thus a considerable number of participants were lost because we could not reach them.

CHAPTER V: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Our study on patients with ESRD in 3 referral hospitals in Rwanda found the patients to be relatively young and middle aged. Hypertension was the most common co-morbidity/risk factor followed by diabetes mellitus. Majority of patients could not afford RRT regardless of their socio economic status and mode of insurance .Among those who did; more than 50% had to stop due death and almost 50 % due to financial reasons.

There was no statistically significant association between various co-morbidities /risk factors and outcome (survival) at the end of 6months follow up.

5.2 Recommendations

In the management of ESRD in our setting, more emphasis should be put on prevention given the high cost of RRT and the socio economic implications of ESRD diagnosis.

Health care workers should be on the lookout for risk factors and therefore do proper screening, diagnosis and follow up of patients with known risk factors and of those with early stage CKD before they progress to ESRD.

Timely referral to a specialist/nephrologist should also be facilitated before patients reach the stage at which they need RRT since majority of them cannot afford it.

Patient education on the risk factors, presentation of kidney disease and the harmfulness of nephrotoxic products should also be carried out by health care providers.

The various modes of insurance used by the participants especially the community based health insurance, which is used by majority of the population, should cover hemodialysis

References

1. Atkins RC. The epidemiology of chronic kidney disease. Kidney Int. 2005;67:S14–S18.

2. Naicker S. End-stage renal disease in Sub-Saharan Africa. kidney Int. 2013;3:161–3.

3. Schena FP. Epidemiology of end-stage renal disease: International comparisons of renal replacement therapy. Kidney Int [Internet]. 2000;57:S39–45. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0085253815470395

4. . S.Levey A. KDIGO Position Statement On The Definition and Classification Of Chronic Kidney Disease. Kidney Int. 2005;67:2089–2100.

5. County H, Division R, Nephrologie S De, Division R, Division N, Do H, et al. The risk of developing end-stage renal disease in patients with type 2 diabetes and nephropathy : The RENAAL Study. Kidney Int 63(2003):1499–507.

6. Alasia DD, Emem-Chioma P, Wokoma FS. A single-center 7-year experience with end-stage renal disease care in Nigeria - A surrogate for the poor state of ESRD care in Nigeria and other sub-Saharan African countries: Advocacy for a global fund for ESRD care program in Sub-Saharan African countr. Int J Nephrol. 2012;2012.

7. NA Kalima, BK Gabriel, R Muhindo AM. Chronic kidney disease in patients admitted to the medical ward of Mbarara Regional Referral Hospital in southwestern Uganda : Prevalence and associated factors. Int J Med Biomed Res. 2015;4(2):107–16.

8. Wachukwu CM, Emem-Chioma PC, Wokoma FS, Oko-Jaja RI. Prevalence of risk factors for chronic kidney disease among adults in a university community in Southern Nigeria. Pan Afr Med J. 2015;21:1–5.

9. Naicker S. End-stage renal disease in sub-Saharan and South Africa. Kidney Int [Internet]. 2003;63:S119–22. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0085253815491975

10. Lescure FX, Flateau C, Pacanowski J, Brocheriou I, Rondeau E, Girard PM, et al. HIV-associated kidney glomerular diseases: Changes with time and HAART. Nephrol Dial Transplant. 2012;27(6):2349–55.

11. Chen Y-C, Su Y-C, Li C-Y, Wu C-P, Lee M-S. A nationwide cohort study suggests chronic hepatitis B virus infection increases the risk of end-stage renal disease among patients in Taiwan. Kidney Int [Internet]. 2015;87(5):1030–8. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0085253815300910

12. Sobh MA, Moustafa FE, Housseini FEL, Basta MT, Deelder AM, Ghoniem MA. Schistosomal specific nephropathy leading to end — stage renal failure. Kidney Int. 1987;31:1006–11.

13. Smith JH, Christie JD. The pathobiology of schistosoma haematobium infection in humans. Hum Pathol. 1986;17(4):333–45.

14. Hall YN, Hsu CY, Iribarren C, Darbinian J, McCulloch CE, Go AS. The conundrum of increased burden of end-stage renal disease in Asians. Kidney Int. 2005;68(5):2310–6.

15. Young EW, Mauger E a, Jiang KH, Port FK, Wolfe R a. Socioeconomic status and end-stage renal disease in the United States. Kidney Int [Internet]. 1994;45(3):907–11. Available from: http://dx.doi.org/10.1038/ki.1994.120

16. Agarwal R. Defining end-stage renal disease in clinical trials: A framework for adjudication. Nephrol Dial Transplant. 2016;31(6):864–7.

17. Kher V. End-stage renal disease in developing countries. Kidney Int [Internet]. 2002;62(1):350–62. Available from: http://dx.doi.org/10.1046/j.1523-1755.2002.00426.x

18. Li L. End-stage renal disease in China. Kidney Int [Internet]. 1996;49(1):287–301. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0085253815593290

19. Grassmann A, Gioberge S, Moeller S, Brown G. ESRD patients in 2004: Global overview of patient numbers, treatment modalities and associated trends. Nephrol Dial Transplant. 2005;20(12):2587–93.

20. Moosa MR, Kidd M. The dangers of rationing dialysis treatment: The dilemma facing a developing country. Kidney Int [Internet]. 2006;70(6):1107–14. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0085253815520814

21. National Institute of Statistics of Rwanda (NISR) [Rwanda], Ministry of Health (MOH) [Rwanda], and ICF International. 2015. Rwanda Demographic and Health Survey 2014-15. Rockville, Maryland, USA: NISR, MOH, and ICF International.

22. Moghazi S. Correlation of renal histopathology with sonographic findings. Kidney Int. 2005;67:1515–20.

23. Igiraneza G, Ndayishimiye B, Nkeshimana M, Dusabejambo V, Ogbuagu O. Clinical Profile and Outcome of Patients with Acute Kidney Injury Requiring Hemodialysis : Two Years ' Experience at a Tertiary Hospital in Rwanda. Hindawi BioMed Res Int. 2018;2018.

24. National Institute of Statistics of Rwanda (NISR), Integrated Business Enterprise Survey Report 2014 (IBES 2014), May 2016

25. El-arbagy AR, Yassin YS, Boshra BN. Study of prevalence of end-stage renal disease in Assiut governorate , upper Egypt. Menoufia Med J. 2016;29:222–7.

26. Cherono RJ. The Prevalence and Risk Factors for Chronic Kidney Diseases in Kericho County , Kenya.Int J N 2017;4(2):90–105.

27. Nsanzimana S, Remera E, Ribakare M, Burns T, Dludlu S, Mills EJ, et al. Phased implementation of spaced clinic visits for stable HIV-positive patients in Rwanda to support Treat All. J Int AIDS Soc. 2017;20(June 2016):21–7.

28. Kim DH, Kim M, Kim H, Kim Y, Kang S, Yang W, et al. Early Referral to a Nephrologist Improved Patient Survival: Prospective Cohort Study for End-Stage Renal Disease in Korea. PLoS One. 2013;8(1):1–10.

29. Lamping DL, Constantinovici N, Roderick P, Normand C, Henderson L, Harris S, et al. Clinical outcomes , quality of life , and costs in the North Thames Dialysis Study of elderly people on dialysis : a prospective cohort study. Lancet. 2000;356:1543–50.

30. Chandna SM, Silva-gane M Da, Marshall C, Warwicker P, Greenwood RN, Farrington K. Survival of elderly patients with stage 5 CKD : comparison of conservative management and renal replacement therapy. Nephrol Dial Transplant. 2011;(November 2010):1608–14.

ANNEXES

1. **Data collection tool**

2. **IRB approval**

Questionnaire for the risk factors of End Stage Renal Disease

1. Identification	
Study Number	
Names	
Hospital ID	
Date of enrollment	
Mobile phone number/ Contacts	1 2 3
2.Social Demographics	
Date of birth	
Gender	□ Male □ Female
Marital status	□ Single □ Married □ Separated/ Divorced □ Widow
Weight in Kgs	
Residence	District Sector Cell Umudugudu
Medical Insurance	□ Mutuel de Sante □ Other □ No insurance
Ubudehe category	□ 1 □ 2 □ 3 □ 4
Financial Responsibilities	□ Primary bread winner □Shared financial responsibilities □ Dependent

Number of meals per day	□1 □2 □3
Education	□ No formal education □ Vocational (imyuga) □ Primary □ Secondary □ University
3. Medical History and risk factors	
1. Aware of having kidney disease	□yes □ No
If yes , since when	□< 1 year □1- 5 years □> 5 years
2.Known with Diabetes	□Yes □ NO
Years since diagnosis (Diabetes)	□< 1 year □1- 5 years □> 5 years
DM treatment modalities	□Oral hypoglycemic □ Insulin □Combined oral and insulin
Follow up in health facility	□Monthly/ Regularly □Occasionally
3.Hypertension	□yes □ No
Years since diagnosis of Hypertension	□< 1 year □ 1- 5 years □ > 5 years Found at the same time of ESRD diagnosis
Hypertension treatment	□ Taking regularly □Takes only when BP high □ Took then stopped □Stopped then resumed

	□ Stopped
4.HIV	□ Positive CD4 □ Negative
If positive, Years since diagnosis	□< 1 year □ 1- 5 years □ > 5 years
ARV	□ Has not started □ Taking regularly □ Started then stopped □ Stopped and resumed
ARV Regimen	□ 1st Line TDF based other □ 2 nd Line TDF based other □ 3 rd Line
6.Hepatitis	□ yes □ No
Treatment if Hepatitis B positive	□ yes TDF Other □ No
7 . Hepatitis C	□ yes □ No
Treatment if hepatitis C	□ Has not started □ Currently on treatment □ Finished treatment
8. History of polycystic kidney disease	□ Yes □ No
9. History of obstructive Uropathy	□ Yes

	□ No
10. History of renal disease in the past/ childhood	□ Yes □ No
11.. Smoking	□ Yes □ No
12. Chronic NSAIDS use (eg : for back pain, rheumatism…daily for more than 30 days)	□ Yes Which drug ? For how many months? How many pills per day? □ No
13. Traditional Drug use	□ yes Herbs? Liquids? How many liters per day For how long? □ No
14. Any Hospital admission in the last 6 months	□ Yes □ No
4. Work up and investigations	
3 months prior to Enrollment	
1. Urine output estimation	□ Reduced □ No change
2. Renal function tests	□ Urea value □ Creatinine Value □ GFR value □ Not available
3. Proteinuria	□ Level □ Not available
4. Hb A1C (if applicable)	□ level in % □ Not available □ Not applicable
5. Kidney Imaging in favor of chronic renal disease	□ Available (kidney size and echo pattern) □ Not available
At enrollment	
1. Urine output in cc	

2. Renal function tests	□ urea(mg/dl or umol/l): □ Creatinine(mg/d l or umol/l): □ GFR:
3. Proteinuria level	
4. HbA1C in % (if applicable)	
5. Kidney imaging (describe findings)	
5 Treatment Modalities and follow up at 6 months	
Date of 6 months follow up	
Date of enrollment	
On Renal replacement therapy	□ HD □ PD
How often(number of days per week)	
How long on RRT (in months)	
Renal Transplant	□ Done □ in plan □ No plan
Not on Dialysis, reason	□ Financial □ Other (specify)
Alive at 6 months	□ yes □ No
Urine output at 6 months in CC	

Ibisobanuro kubushakashatsi

Nitwa Dr Mugeni Adeline, nkaba ndi gukora ubushakashatsi ku ndwara y'impyiko yo mu rwego rwa nyuma. Wasabwe kwitabira ubu bushakashatsi kuko wagaragaweho ubwo burwayi. Ubu bushakashatsi bugamije kureba impanvu zitera ubu burwayi no gukirikirana ubufite mu gihe cy' amezi atandatu .

Aya masezerano abaha ibisobanuro kuri ubu bushakashatsi. Numara kumva ibijyanye n'ubu bushakashatsi kandi ukemera kubwitabira turagusaba gushyira amazina n' umukono kuri aya masezerano.

Intego y'ubu bushakashatsi.

Indwara y' impyiko ni indwara iterwa n' impanvu nyinshi zitandukanye , iyo ndwara igenda ikura mu byiciro bitandukanye kugeza ku kiciro cyanyuma gisaba ko uyirwaye abona ubuvuzi bufasha impyiko kuyungurura amaraso cyangwa agahabwa indi mpyiko.

Kugeza ubu mu Rwanda nta bushakashatsi burakorwa bugaragaza igitera iyi ndwara no kumenya niba impanvu zizwi ziyitera ahandi ari nazo ziyitera hano mu Rwanda.

Ubu bushakashatsi bugamije gushaka impanvu zitera ubu burwayi bw' impyiko yo ku rwego rwa nyuma mu Rwanda tugereranije n' impanvu zizwi ziyitera no gukuirikirana abarwayi bamaze kugaragaraho ubu burwayi mu gihe cy' amezi atandatu**.**

Hazarebwa uko ubuzima bwabo buzaba bwifashe yaba abashoboye kubona ubuvuzi bufasha impyiko (diyalize, guhabwa indi mpyiko) cyangwa abatarabishoboye.

Ibizava muri ubu bushakashatsi bizadufasha kumenya impanvu zitera ubu burwayi bukomeye bw' impyiko kugirango dushobore kubirwanya no gufasha abantu kubyirinda

Uko ubushakashatsi buzagenda

Niba wemeye kuba muri ubu bushakashatsi, uzasabwa gushyira umukono kuri iyi nyandiko. Nyuma y'umukono, uzabazwa ibibazo kandi ukazakorerwa ibizamini by'igenzura kugirango turebe uko impyiko zawe zikora, turebe izindi ndwara waba ufite kandi ko wujuje ibisabwa ngo

winjire mu bushakashatsi.

Tuzasigarana umwirondoro wawe hanyuma dukomeze kugukurikirana. Nyuma y' amezi atandatu winjiye mu bushakashatsi , tuzongera tuguhamagare tukubaze ibindi bibazo hanyuma tugukorere ibizamini kugirango tumenye uko ubuzima bwawe buhagaze.

Ingaruka zishoboka

Kubera amaraso azafatwa muri ubu bushakashatsi , uzaba aburimo ashobora kubabazwa n' urushinge ruzakoreshwa . Gusa ni ububare bw' akanya gato kandi buhita bishira atagombye guhabwa umuti.

<u>Inyungu z'ubu bushakashatsi</u>

Nta nyungu y' amafaranga uwemeye kujya muri ubu bushakashatsi azabona. Ubumenyi tuzakura muri ubu bushakashatsi buzadufasha gufata ingamba zo kwirinda ibitera indwara y' impyiko yo mu kiciro cya nyuma no kwigisha abantu kubyirinda. Ikindi kumenya uko ubuzima bw' abafite ubwo burwayi buba bwifashe nyuma y' amezi atandatu bizadufasha mu kubakurikirana .

Uburengazira bw'uwitabiriye ubushakashatsi.

Ntabwo ukwiye guhatirwa kwemera kwitabira ubu bushakashatsi. Ibibazo byose waba ufite bikwiye gusubizwa neza kuburyo wumva unyuzwe. Niba wumva udashaka kuba muri ubu bushakashatsi ufite uburenganzira bwo kuba wahindura icyemezo cyawe igihe icyo ari cyo cyose ubu bushakashatsi buzaba bukorwa kandi nta ngaruka bizakugiraho.

Niba umaze kumva ibijyanye n'ubu bushakashatsi kandi ukemera kubwitabira , turagusaba gushyira amazina n' umukono kuri aya masezerano.

KU BIBAZO BYOSE BIJYANYE N' UBUSHAKASHATSI HAMAGARA

Dr MUGENI ADELINE KURI 0788581966/0738581966.

UHAGARARIYE IKIGO GISHINZWE UBUSHAKASHATSI 0788490522

UMWUNGIRIJE 0783340040

Inyandiko y' amasezerano yo kwitabira ubushakashatsi kubushake.

Nyuma yo gusobanuirirwa ibijyanye n'ubushakashatsi , ingaruka zishobora kubaho n' uburenganzira nfite, niyemeje nta gahato kwitabira ubu bushakashatsi.

<u>Uwemeye Kwitabira ubushakashatsi</u>

Amazina yombi:

Italiki y' amavuko:

Umukono: Italiki:

<u>Uhagarariye ubushakashatsi wayoboye igikorwa</u>

Amazina yombi:

Umukono: Italiki:

Information sheet

My names are Dr Mugeni Adeline; I am doing a research on End Stage Renal Disease. You have been requested to participate in this research because you have been diagnosed with that condition. The aim of this research is to find out the risk factors of end stage renal disease and to find out patients' outcome after one year of follow up.
This consent form will give you the information on this research after which, if you agree to participate, you will be requested to sign it in order to confirm your voluntary participation.

The purpose of this research

There are many causes of kidney disease that disease progresses through different stages up to End stage which requires renal replacement therapy.
There is no available data in Rwanda regarding the causes or risk factors of End Stage Renal disease and no study has been done to establish whether the known risk factors of ESRD elsewhere are the same here in Rwanda.
The aim of this research is to establish the risk factors of End Stage Renal disease in Rwanda and to follow up selected patients with ESRD for one year in order to determine their outcome whether they have received renal replacement therapy or not.
The results of this study will help us in prevention of ESRD by addressing the specific risk factors in our settings.

Procedure

After confirming your participation by signing this consent form, you will be asked some questions and some investigations will be done in order to establish the function of your kidneys, , to find out any disease you may be having and confirm your eligibility.
We will then keep your contacts and follow you up at 6 months and after one year of enrollment. At each visit we will again ask you some questions and do some investigations in order to evaluate your health status and the function of your kidneys.

Possible risks

There may be some pain related to the needle which will be used to draw blood but the pain is usually mild and self-limiting and does not require any medications.

Benefits

The information we will get from this research will enable us to prevent end stage renal disease by targeting the specific risk factors in our settings.
Knowing your health status after one year will enable us to do better follow up of patients with end stage renal disease.

Participant's rights

You should not be forced to participate in this research. Any concerns you may be having should be addressed to your satisfaction. If you no longer want to participate in this research, you have the right to withdraw your consent at any time and there will be no consequences.
If you are now fully informed about this research and that you willingly agree to participate, we now kindly request you to sign this consent.

FOR ANY RESEARCH RELATED CONCERNS CALL
Dr ADELINE MUGENI ON 0788581966/0738581966
CHAIRPERSON OF THE INSTITUTIONAL REVIEW BOARD ON 0788490522
VICE CHAIRPERSON ON 0783340040

Consent

After receiving information on the study, the possible risks, benefits and my rights, I voluntarily agree to participate in the study.

Participant

Names:

Date of Birth:

Signature: Date

Person in charge of informed consent discussion:

Names:

Signature:

Date:

UNIVERSITY OF RWANDA **COLLEGE OF MEDICINE AND HEALTH SCIENCES**

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 11th /12/2017

Dr MUGENI Adeline
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 423 /CMHS IRB/2017

Your Project Title ***"Epidemiology And Risk Factors Of End Stage Renal Disease At CHUK , CHUB And RMH Between October 2017 To October 2018"*** has been evaluated by CMHS Institutional Review Board.

		Involved in the decision		
			No (Reason)	
Name of Members	**Institute**	Yes	**Absent**	**Withdrawn from the proceeding**
Prof Kato J. Njunwa	UR-CMHS		X	
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS		X	
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 30th November 2017, **Approval has been granted to your study.**

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/

Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 11th December 2017

Expiration date: The 11th December 2018

For Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:
- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

EMAIL: researchcenter@ur.ac.rw P.O. Box: 3286, Kigali, Rwanda WEBSITE: http://cmhs.ur.ac.rw/