PREVALENCE, TRENDS AND RISK FACTORS OF INFECTIONS IN POST RENAL TRANSPLANT RECIPIENTS IN KENYATTA NATIONAL HOSPITAL

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November 2020

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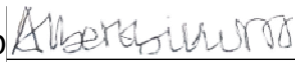
SIGNED  DATE:16/11/2020

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DECLARATION OF ORIGINALITY

SUPERVISOR APPROVAL

This is to certify that this research proposal has been submitted for review with our approval as the University supervisors.

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DEDICATION

I dedicate this work to all the renal transplant recipients attending transplant clinic at Kenyatta National Hospital

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ABBREVIATIONS AND ACRONYMS

ANOVA Analysis of variance

CI Confidence interval

CMV Cytomegalovirus

DM Diabetes mellitus

EBV Epstein Barr virus

ELSPOT Enzyme-linked immunosorbent spot

ESKD End-stage kidney disease

ESRD End-stage renal disease

HBV Hepatitis B virus

HBsAg Surface antigen for hepatitis B virus

HBV Hepatitis B virus

HBsAg Surface antigen for hepatitis B virus

HCV Hepatitis C virus

HIV/AIDS Human immunodeficiency virus/ Acquired immunodeficiency syndrome

HLA Human leucocyte antigen

HHV Human herpes virus

HSV Herpes simplex virus

IQ Interquartile range

KIDGO Kidney disease global improving outcomes

KNH Kenyatta National Hospital

KNH/UoN-ERC Kenyatta national hospital/ University of Nairobi

MoH Ministry of Health

PCR	Polymerase chain reaction
PPD	Purified protein derivative
PTLD	Post-transplant lymphoproliferative disease
OR	Odds ratio
RTRs	Renal transplant recipients
TB	Tuberculosis
UoN	University of Nairobi
USA	United States of America
UTI	Urinary tract infections
VZV	Varicella zoster virus

DEFINITION OF TERMS

Allograft Is a tissue graft from a donor of the same species as the recipient but not genetically identical

Nosocomial infections They are diseases originating in an hospital

De novo It means starting from the beginning

Paucity It is the presence of something in only small or insufficient quantities

Prevalence Is the fact or condition of being prevalent; commonness

Morbidity Is the condition of being diseased

Mortality Is the state of being subjected to death

Induction therapy It is the first in a series of therapeutic measures taken to treat a disease

Maintenance therapy It is treatment designed to help a primary treatment to succeed

Virus latency It is the ability of a pathogenic virus to lie dormant within a cell

Independent predictors Are variables that are being manipulated in an experiment to observe the effect on a dependent variable.

Comorbidities It is the presence of one or more conditions co-occurring with a primary condition

ABSTRACT

Background: Infections in post renal transplant recipients remain a major concern despite advances in medical care post procedure. They are significantly higher compared to hospitalizations arising from allograft rejection.

Broad objectives: To determine the prevalence, trends and the associated risk factors of post renal transplant infections

Methodology: A retrospective cross-sectional study was conducted. This study was carried out at the renal unit of Kenyatta National Hospital. One hundred and seven renal transplant recipients' files who had attended the clinic over the past five years were randomly selected. The patients were above 18 years of age.

Data collection and analysis: Data on socio demographics and clinical characteristics were taken from the patient files and recorded in the data collection forms. These were analyzed with STATA version 13. Descriptive statistics were presented in tables and figures. Bivariate and multivariate regression analyses were done to determine the independent predictors. The level of significance was set at $P \leq 0.05$.

Results: The mean age of study participants was 41.3 (±12.5) years. Most of the study participants came from Nairobi county (20, 18.69%) followed by its neighboring counties like Murang'a (13, 12.15%). Bacterial infection (92, 86.97%) had the highest prevalence among the study population followed by viral (10, 9.43%) and fungal infections (4, 3.77%). Most bacterial infections occurred in less than six months into the post renal transplant period (29, 50%) while viral (16, 94.12%) and fungal infections (10, 83.33%) were most prevalent in more than 18 months. Female sex and diabetes mellitus were independent predictors of infections in renal transplant recipients.

Conclusion: Infections in renal transplant recipients are still a major concern following the procedure in KNH. All patients with infections were treated. Most bacterial infections were experienced during the few first months of the post transplantation period. Most viral and fungal infections emerged in late stages of post renal transplant. Diabetes and female sex were identified as independent predictors of infections in renal transplant recipients post procedure.

Recommendations: We recommend regular screening for infections in renal transplant recipients post procedure. Besides, culture and sensitivity should be done among those identified with infections.

CHAPTER ONE: INTRODUCTION

1.1 Background

Renal transplantation is the treatment of choice for patients with End-Stage Renal Disease (ESRD) (1). Initially, the most common complications among renal transplant recipients (RTRs) were infections, cardiovascular and carcinogenesis (2). During the time of transplantation infections as a complication develops in up to 70% of the recipients with 11% to 40% resulting in fatal outcomes (2). In the last decade of the 20th century, infections in post-renal recipients declined drastically. Improved surgical procedures, a better understanding of immunosuppressive therapy used in the post-transplant period, vaccinations and screening of graft donors were attributed to these declines (3). Despite the above preventive measures, infections are still the second leading cause of morbidity and mortality in post-renal transplant recipients. These infections also play a major role in allograft rejection and survival (4).

Some of the important risk factors that are associated with post renal transplant infection include the degree of human leukocyte antigen (HLA) mismatch, early renal function, early rejection episode, donor kidney source and the general state of immunosuppression (5). Mostly post-renal transplantation infections occur immediately following the transplantation procedure with approximately 70% of the infections resulting from bacterial, fungal and viral cases occurring within the first 3 months (6). Six months after transplantation about 75% of patients usually have almost perfect allograft function and thus require a low dose of immunosuppression therapy for maintenance (7). In these patients, the incidence of infection is almost similar to that of the normal population. About 15% of the patients have moderate graft function and experience a high risk of viral infections. On the other hand, the remaining 10% have poor allograft function and hence develop frequent episodes of acute and chronic rejection. This increases the risk of developing opportunistic infections.

Post renal transplant infections are thought to follow a particular trend which is subject to the choice of immunosuppressive agents and the duration of antimicrobial prophylactic agents (3). Nosocomial infections are the most likely early infections after the transplantation procedure. This is due to nosocomial acquired pathogens, surgical issues, and donor-derived infections. Opportunistic infections mostly occur during the subsequent five months of transplant reflecting

the greater impact of immunosuppressive therapy. Infections which come later may be secondary to opportunistic pathogens (3).

Post renal transplant infections can be attributed to three sources i.e. de novo infections that arise from organisms colonizing RTR or from the nosocomial origin, reactivation of latent infections presents in RTR or in donor allograft, or contamination which may occur during preservation of the graft (3). De novo infections include UTI, line sepsis, wound infections and pneumonia (8). These types of infections are commonly seen in RTR in the first month. The organisms involved in de novo infections do so by colonizing the RTR's mucous membranes. Some are acquired from the hospital environment and these are often resistant to antimicrobials. Reactivation type of infections usually replicates upon long term immune suppression (9). Examples of these latent viruses are CMV, tuberculosis, and histoplasmosis (10). Infections that are transmitted from donor to RTR may be latent chronic or active asymptomatic. Donor-transmitted infections are usually rare and hard to prove (11).

All infectious pathogens have the potential of causing complications in RTR. However, the ones that are most identified are Enterobacteriaceae causing urinary tract infections, pneumonia due to Pneumocystis jirovecii, Candida species causing invasive fungal infection, herpes viruses, hepatitis viruses and parasites (7). Despite post-renal transplantation being issues in RTRs, there are multifaceted approaches that have been discovered which try to minimize them as much as possible. These include an effective screening of the transplant candidate and potential donor, vaccination, prophylaxis by effective antimicrobial, environmental control and diligent in diagnosis (12). The challenge that complicates the management of these infections is that many infections do not show typical signs. As a result, it might take longer to detect and manage these infections appropriately. Furthermore, treatment regimen which the RTRs are on may cause drug-drug interactions with the immunosuppression regimen the patient is on (6). The current study aimed at determining the prevalence, trends and risk factors of post renal transplant infections in KNH. Also, the study aimed to establish the drugs used in the pre- and post-transplant period by RTRs.

1.2 Problem statement

Post renal infections rank highly among the most common complications in RTR patients. There is a paucity of local data on the prevalence, risk factors, and trends of infections in RTR. Masinde *et al* (2015) carried a study that is closely related to this one even though that work was on the prevalence of cervical cytological abnormalities and human papillomavirus (13). Infections, trends of those infections and the risk factors that facilitate RTR patients to contract the infections were not investigated. Another recent study related to this research was conducted by Barasa *et al* (2016). This study was on cytomegalovirus infections among RTR attending the Kenyatta National Hospital outpatient clinic. This study didn't take a broad look at infections and their trends too (14). The current study was to try to fill the knowledge gaps in the previous studies on post-renal transplant infections, risk factors, and their trends. The findings were to help clinicians and pharmacists to provide appropriate care to RTRs.

1.3 Justification

Post renal transplant infections have been a major issue in many clinical setups. In KNH the infections more especially bacterial infections have been a major concern among renal transplant recipients. The rate of those infections is approximated at 95% with cytomegalovirus infection rated as the most common opportunistic infection (15). These infections are seen to be following a particular pattern in the post-transplant period. For instance, nosocomial infections will come earlier in the post-transplant period since the patient is transplanted in the hospital and these infections are acquired in hospitals. In about six months past the transplantation procedure, opportunistic diseases usually attack the RTRs. this is because of the immunosuppressive therapy the RTRs are on (2). The therapy suppresses their immunity making them vulnerable to opportunistic infections.

Post renal transplant infections rank second as the cause of death in RTRs. Approximately the rate of death of RTRs with infections is approximated to be 40 per 100 patient-years (3). Many attempts including pre-transplant screening of donors and recipients, vaccination, and prophylaxis and management of these infections among others have been devised as ways of trying to combat the post-renal transplant infections (16). Since post-renal transplant infections are problems in most RTRs, this study, therefore, aims to increase graft survival and reduce infection-related morbidity and mortality. It will also aim to help the health care team in providing appropriate therapy to the

RTRs. Besides, the current research through the ministry of health aims at making an impact on the policy and development of treatment and infection prevention guidelines among RTRs.

1.4 The Significance of the Study

This study is to help identify the prevalence of infections that emerge in RTR, the trends, and the risk factors in KNH. By doing so it will help health care providers and other stakeholders to enhance the quality of management they provide to RTR who have these infections in case a lapse is established. The current study set out to establish ways that would minimize the emergence of post renal transplant infections. It aims to achieve this through identifying the risk factors that poses a threat to RTRs hence creating awareness. It will also ascertain the common pattern followed by post-renal transplant infections hence helping the clinicians to prevent the infections before they invade the RTRs.

1.5 Research Questions

1. What is the prevalence of post renal transplant infections in RTRs in KNH?
2. What are the trends of post renal infections in RTRs in KNH?
3. What are the risk factors for the emergence of infections in RTRs in KNH?
4. What are the drug regimens used in prophylaxis and management of post renal transplant infections in KNH?

1.6 Limitations

Being a retrospective cross-sectional study, there were limitations to generalizability and application to actual practice due to challenges like the snapshot timing was not adequate of being a representative of the actual occurrence and hence it was a challenge in analyzing the behavior. Moreover, KNH is yet to go fully digitalized in terms of their data storage. Some data was not available hence brought challenges in data collection.

1.7 Delimitations

This study will be important in proving or disapproving certain assumptions made here like infections in post-renal transplant period usually take a common trend, the common risk factors and the regimen mostly used in KNH for prophylaxis and management of post renal transplant infections. Moreover, the research methodology will be quick and cheap since it will be a retrospective cross-sectional study.

1.7 Objectives

1.7.1 Broad objective

To determine the prevalence, trends and risk factors of infections those emerge in post-renal transplant recipients

1.7.2 Specific objectives

I. To ascertain the prevalence of infections in post-renal transplant patients.

II. To establish the risk factors associated with infections in renal transplant recipients

III. To ascertain the trends of infections in post-renal transplant recipients over the last 5 years

IV. To identify the antimicrobial regimens used in prophylaxis and management of post renal transplant infections in RTRs in KNH

1.8 Conceptual Framework

The main outcome variable was the prevalence of post renal transplant infections among the RTRs. Predictive variables impact heavily on post-renal transplant infections in RTRs. These factors are known as independent variables and they include risk factors such as diabetes mellitus, liver disease, and glomerulonephritis among others. Also, some other intervening factors if present exacerbate the prevalence of post-renal transplantation infections. Examples of these factors are surgical technique applied during transplantation, long term use of immunosuppressive drugs in post renal transplantation, screening methods used in donors before the actual transplantation, infections that exist in a donor among others. Some factors contribute to prophylaxis or towards eradicating the prevalence of post renal infections. These factors include vaccinations against various infections, pre- and post-renal transplant antimicrobial prophylaxis, post-renal transplant infections management by various antimicrobials. Below is a conceptual framework on how all these factors are interconnected.

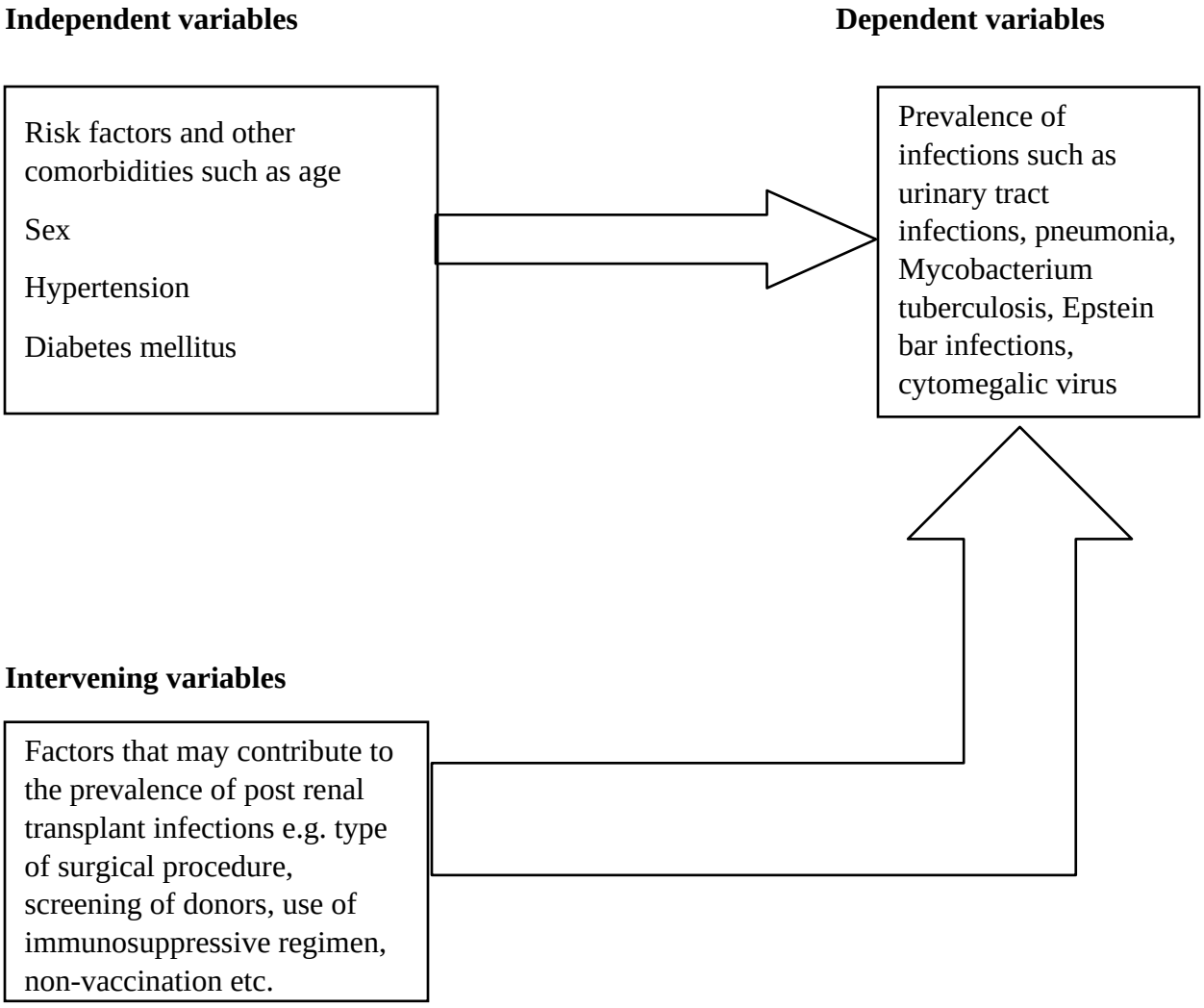

Figure 1 Conceptual framework

The independent variables in our study are the factors that necessarily need not be present for various infections to occur and examples include age, sex, comorbidities like DM, type of surgical procedure involved, non-screening of donors, etc. Dependent variables in our study will be different types of infections prevalent in RTRs. These may be bacterial, fungal, or viral. Comorbidities like diabetes mellitus, hypertension coupled with long term use of immunosuppressant therapy to suppress one's immunity. This will make opportunistic infections to invade an RTR aggressively.

CHAPTER 2: LITERATURE REVIEW

2.1 Overview

After renal transplantation, patients face various challenges one of them being infections. Infections are the second most common cause of death in RTRs (16). Infections pose an even greater risk in terms of graft rejection and increase the likelihood of mortality. These challenges usually come as a result of using immunosuppressant therapy prescribed immediately after the transplantation procedure. Immunosuppressant therapy is recommended to prevent the body's immune mechanisms from acting against the newly transplanted tissue. This regimen makes the immune system less effective against the newly transplanted solid organ (17). The goal is to avoid organ rejection.

Long term suppression of the immune system results in other infections attacking an individual. To overcome these scenarios, transplant recipients are normally put on prophylactic medication against common opportunistic infection e.g. cytomegalovirus pneumonia, Pneumocystis jirovecii and other (18). However, other infections such as those of the urinary tract, EBV, BK can lead to post-renal complications (6). Diagnosis of post renal infections may be a challenge since their signs and symptoms are usually confounded. However, infections are roughly speculated when RTRs experience fever, chills, flushing, cloudy urine, pain on urination, swelling/ redness on the incision area. Post-transplant infections can be worsened if there are other existing comorbidities such as diabetes mellitus, lung disease, and polycystic kidneys among others.

Among the infections experienced by RTRs, bacterial infections are the leading cause of death (5). They are followed closely by viral and fungal infections. In the first month following transplantation, nosocomial infections and surgical complications emerge as the most common cause of death (26). Although latent infections can activate late after six months following kidney transplantation, they usually do so in a period of up to 6 months. The late activation is due to the intense usage of the immunosuppressant regimen.

2.2 Types of infection that may occur in post-transplant recipients

2.2.1 Urinary tract infections

Urinary tract infection (UTI) includes asymptomatic bacteriuria, cystitis, and pyelonephritis. Urinary tract infections more especially the recurrent one is the commonest type of infections that occur in most post renal transplant recipients. It occurs in approximately more than 75% of kidney transplant recipients (19). Factors that play a significant role in a high incidence of urinary tract

infection in post-renal transplant recipients include female sex, diabetes mellitus, underlying urinary tract complications, urethral stenting and urinary catheterization (20). Urinary tract infections not only lower the quality of life of a patient but also lead to graft loss. *Escherichia coli* and *Enterococcus faecium* are the most common causative organisms UTI in RTRs (21).

2.2.2 Colds and influenza

Also known as the swine flu and it's caused by the H1N1 influenza virus. It is common in many other patients with infections. The prevalence of swine flu among the RTRs is yet to be known. However, the world health organization (WHO) estimates the rate of swine flu attack among renal transplant recipients to be approximately 20 to 30 percent (25). In post renal transplants patients, the flu occurs in a recurrent nature or may take longer to recover after the attack (26). The flu usually manifests in other parts of the body but mostly in the upper respiratory system. Cough, running nose and fever usually accompanies the swine flu as upper respiratory system manifestations. This may progress to lower respiratory tract and the lungs causing pneumonia. The flu can also manifest in the non-respiratory system which normally affects the renal system.

2.2.3 Mycobacterium tuberculosis.

Tuberculosis is acquired through inhalation of tuberculosis- bacilli into the lungs. Reactivation of the prior infection causes TB in renal transplant recipients. The prevalence of TB infections in many developing countries like Kenya, Tunisia and the rest are endemic and is approximated to be a hundred thousand inhabitants 2700 cases per (23) The incidence of tuberculosis in North America, Europe and India is approximately 0.5-1%, 0.7-5%, and 5-15%. The time between transplantation and the tuberculosis onset is significantly longer as compared to other organ transplantations (24). Mycobacterium tuberculosis presents itself clinically differently as compared to the normal healthy population. In immune-compromised patients, extrapulmonary tuberculosis is predominant compared to the pulmonary form (25). Factors exacerbating TB in healthy individuals and immunocompromised patients include country of origin, history of untreated TB, cigarette smoking diabetes mellitus, chronic kidney disease, lupus, and human immunodeficiency virus. Besides, social risk factors such as homelessness, alcoholism, and a known TB contact also contribute (26). Due to diverse pulmonary and extrapulmonary conditions that resemble tuberculosis, diagnosis is often tricky. Furthermore, frequent adverse events from first-line anti- tuberculosis drugs and massive interactions with graft rejection drugs complicate the situation further. The difference in the clinical presentation of tuberculosis in the renal

transplant patient as compared to the general population is that symptoms are more unusual and varied hence delaying diagnosis resulting in poor outcomes. Diffuse pulmonary infiltrates are seen in the chest x-ray of post renal transplant recipients with tuberculosis while cavity lesions are seen in the general population, therefore, distinguishing the two. Evidence supporting management and support of renal transplant patients who contract TB is lacking, therefore, making expert opinion and information from immunocompetent and immunocompromised people to be the only option (27)

2.2.4 Pneumonia or Pneumocystis jirovecii

Initially, *P. jirovecii* was known to cause pulmonary infections or pneumonia. *P. jirovecii* is a yeast-like fungus that exists in the environment but it does not express itself not unless the immune system is depressed. P. jirovecii is known to cause infection or pneumonia during the first 3-6 months but due to appropriate prophylaxis, this has greatly reduced (28).

The presentation of pneumonia includes fever, cough, shortness of breath and hypoxia (29). Diagnosis is based on the identification of the organism in the sputum, Bronchoalveolar lavage or bronchial biopsy. High doses of sulfamethoxazole or intravenous pentamidine are recommended for treatment. Atovaquone or a combination of clindamycin and pyrimethamine can be used for prophylaxis (30). Moreover, vaccination against P. jirovecii given once is recommended for renal transplant patients.

2.2.5 Cytomegalovirus

It's the most common opportunistic infection in kidney transplant recipients. CMV affects approximately 59% of the RTRs. Approximately 19% of the infected recipients usually have an asymptomatic type of CMV (31) Risk factors for this cytomegalovirus (CMV) include donors who already have the virus before the transplant and use of induction therapy in an effort of trying to oppose the immunity which the body mounts in an effort of opposing the new graft (36). CMV infections occur mainly in 1 month to 3 months after transplantation. Its diagnosed by PP65 antigenemia and polymerase chain reaction (37). Clinical manifestations of CMV virus include fever, malaise, leukopenia, thrombocytopenia and elevated liver enzymes (38). The above signs normally appear 3-4 weeks with the peak being experienced as from 6-16th week. After 6 months the clinical signs reduce significantly. In addition, pain on the upper digestive tract and diarrhea which may be bloodstained maybe experienced (14). Respiratory symptoms if experienced

indicate a more severe state of disease and hence necessitating hospital admission. Potential approaches for preventing CMV virus infection are by prophylaxis and pre-emptive treatment which involves diagnosis by pp65 or polymerase chain reaction (PCR). If the tests are positive antivirals are begun. Valganciclovir is the antiviral of choice due to good oral bioavailability. The disadvantage of pre-emptive therapy includes regular monitoring using sensitive diagnostic techniques and good patient adherence (16)

2.2.6 Epstein bar virus

Less common viral infection in comparison to the CMV virus (39). Currently, there is still a paucity of information on the prevalence of Epstein bar virus (EBV) among RTRs (37). It causes some fewer common diseases among them being the lymphoproliferative disease. The incidence of PTLD is on the rise since the use of new immunosuppressive came in place (41). It's the second most prevalent malignant disease in post-renal transplant recipient adult population and the most in pediatrics. The incidence of PTLD in RTRs is approximately 0.9% and its 20 times common in RTRs compared to the healthy population (39). Difficulties in lab surveillance and diagnosis make EBV therapeutic intervention challenging. EBV has an etiological role in infectious mononucleosis which is a benign disorder which is a disorder prevalent in adolescents.

In HIV/AIDS, T cells are highly suppressed and therefore EBV B cell infected may expand unchecked which can result in malignant lymph proliferation (43). In immunocompetent individuals this virus is in latent state however transplant may allow activation, proliferation, and spread of the virus.

Currently, the available guidelines suggest testing of high-risk recipients of EBV for a year after transplantation (43). Reduction of immunosuppression is regularly used for the treatment of EBV infected PTLD but in addition, other measures that come in handy are surgery, monoclonal antibody therapy, chemotherapy, and radiation. Rituximab is the commonly used monoclonal antibody and is utilized whenever therapy beyond immunosuppression is required (44)

2.2.7 Bk viral infection

With the development of effective immunosuppression agents and reduction of loss of graft, viral infections are on the rise. Among them is the BK virus which is the most common post-transplant virus affecting approximately 15% of post-transplant recipients in their first year (45). BK virus was first isolated in 1971(46). Among other risk factors for BK virus infection, extreme

immunosuppression remains the most common one. Other risk factors include male gender, old age recipients, prior rejection episodes, and the degree of human leukocyte antigen mismatch, BK serostatus, and urethral stent placement.

The detection of BKVN virus can be as early as the first year of transplantation. Patients usually experience asymptomatic viremia and /or nephritis and can only be detected on experiencing renal insufficiency. The pathogenesis of the BK virus remains a mystery i.e. not yet fully discovered. The diagnosis of BK depends mainly on the detection of the virus or its effect in urine, blood and renal tissue. In preventing allograft loss regular screening, early detection, prompt diagnosis, and preventive therapy have all played a role in achieving better outcomes. Some drugs like mycophenolate mofetil and tacrolimus in the past have been suspected to cause the occurrence of this infection although this infection can also be seen in cyclosporine and sirolimus. In the past, about 30-60% of patients who developed BK resulted in graft loss (47).

Regular screening for BK of post renal transplant recipients to an extent proves to be effective in avoiding allograft loss in patients with BK viruria and viremia. Some laboratories have come up with insights into the immune response and may prove vital in the future therapy of BK viral infection. A candid example of this is ELSPOT (45). ELISPOT is an assay method by various laboratories used to measure immune response at cellular levels. These are normally done by directing the response against BKV T antigens in patients in possession of BKVN at diagnosis point and at times of full recovery.

2.2.8 Hepatitis C infection

Hepatitis C is one of the most common chronic viral infections. It plays an important role in the morbidity and mortality of renal transplant recipients. In people with ESKD, the prevalence of HCV infection is very high and this influences both dialysis patients and kidney transplant patients (48). Nowadays clearance of the virus is achieved in some cases due to the decrease in the progression rate of liver disease and its complication, credit to advancement in HCV infection therapy. Since kidney transplantation is the most preferred choice of therapy for people with ESKD, it prompts clinical assessment for HCV infection in this setup. Mortality due to liver cirrhosis and hepatocellular carcinoma may be associated with HCV viral infection. Graft survival in kidney transplant recipients may be predicted by the severity of liver disease. Liver biopsy is

the gold standard test in such patients mainly used to assess liver fibrosis. Among the HCV infected patient's mortality rates are usually high as compared to HCV negative patients.

If HCV is present in the donor, pretreatment is important in decreasing the risk for progression of liver-associated complications, stabilize renal function in patients with HCV related glomerulopathy and prevent the development of HCV related renal disease in post-transplantation (49). The risk of precipitating acute rejection makes it not recommendable in post- transplant treatment. However, in most advanced liver fibrosis antivirals may be given to hinder the progression of the disease. Combination therapy of interferon and ribavirin is the most appropriate therapy of choice though not applicable to all. The example is in a dialysis patient where ribavirin is contraindicated in case there is renal failure. It this situation interferon is used as a monotherapy. ESKD and HCV positive patient's kidney transplantation is the most suitable recommended treatment. In HCV decompensated cirrhosis kidney transplantation should be done along with liver transplantation (50)

2.2.9 Hepatitis B virus infection

Although hepatitis B virus infection being on the decline, it’s still a concern due to its high morbidity and mortality in the long term. In the recent past, HBV infections have declined due to the better understanding of HBV virology and their natural course in combination with a highly sensitive HBV DNA assay. Besides, the discovery of very effective antiviral drugs with the different mechanisms of action has played a role too (50). Transmission possibility by organ transplantation can be predicted by the serological status of both the donor and the recipient. Transplantation of an organ from a positive HBV donor to HBV negative patient carries significant risk. Use of immunosuppression drugs enables viral replications hence accelerated liver injury and hepatocellular failure (51)

2.3 Measures of preventing and minimizing post-transplant infection

2.3.1 Recipient and donor pre-transplant screening

Prescreening the potential donor and the recipient before transplantation is essential to know whether there are pre-existing conditions in either party which may lead to infections or graft loss (52). The infections which are normally screened are the latent infections (15). Latent infections can reactivate in immunocompromised recipients. These latent infections include CMV, HSV, BK hepatitis B and C, HIV 1 and HIV 2. In addition, donors and RTRs should be given a purified protein derivative (PPD) skin test to determine whether they are infected with TB

or not. For living donors, obtain a detailed physical assessment and medical history. Rapid serological tests are recommended for deceased donors. The more the information is available about donors, the better the preventive measures that will be put in place.

2.3.2 Vaccination

The American Society for transplantation guidelines for clinical practice and KIDGO came up with a suitable schedule for RTRs vaccination. The American Society for Transplantation recommends that renal transplant recipients should maintain up-to-date vaccination status. This is made possible when the recipient receives the vaccines four weeks before transplantation and commencement of the immunosuppressant regimen (53). The four-week grace period allows these patients to receive live vaccines which enable them to develop the strongest immunity possible. The minimum recommended vaccines before transplantation include varicella, influenza, hepatitis B and pneumococcus (54). Further administration of routine vaccine boosters against diseases like measles, mumps, and rubella; diphtheria, tetanus, and pertussis; poliovirus is of great benefit. Children who are on the transplant list should continue receiving their regular vaccination as much as possible.

2.3.3 Pre- and post-renal transplant infection prophylaxis

Routine antimicrobial prophylaxis for RTRs is the best practice in reducing patient risk to infection from commonly observed organisms. Available guidelines recommend prophylaxis with antivirals and antifungals starting at or immediately after the transplantation procedure (35). The major concern though is, the antivirals given won't eradicate the latent virus already available in the transplanted tissue or in the recipient before transplantation.

The most commonly prescribed antivirals are ganciclovir and Valganciclovir. Both of them are used in the prevention of new-onset CMV and reducing infection from HSV, VZV, human herpesvirus (HHV-6), HHV-7 and EBV (17). In the unfortunate event that a patient develops CMV during the first year of transplant, the health care personnel should reduce the doses of the immunosuppressive drugs to the lowest recommended while still taking care not to lose the allograft.

2.3.4 Minimizing environmental risk factors

In the first year of transplant, one should be vigilant enough in reducing the risks of infections from the environment and invasive devices. This includes maximum wound care in the prevention of infections through the surgical site. The patient can shower after 48 hours of post-transplant if

no complications experienced during the surgical procedure (55). In addition, patients should be advised appropriately about wound care before they are discharged. Moreover, invasive devices if not well taken care of may introduce nosocomial organisms like Staphylococcus and Candida hence their use in RTRs should be minimized and in the same time ensuring essential therapy is achieved (8).

There is also a need to enlighten the caregivers and RTRs on issues which on modification can reduce or eliminate contraction of infections (56). These issues include obesity, smoking, nutrition status, poor blood glucose management. Smoking does not only interfere with the cardiovascular system but also with wound healing. Smoking delays wound healing by depriving it adequate blood perfusion (55). If possible, one should cease smoking 4 weeks before the transplantation procedure (52).

Advice patients to maintain a well-balanced diet on daily basis. Also, overweight RTRs should try and reduce their body mass index to internationally recommended values. This can be achieved by modifying their diet and doing constant and routine exercise. Diabetic RTRs should maintain their blood glucose levels within the required range.

2.4 Trends of post renal infections

Post renal transplant infections usually follow a particular trend. There are majorly two types of post renal transplant infections in RTRs. These are donor-derived and recipient-derived. These infections can further be subdivided into nosocomial or hospital-acquired infections, opportunistic infections, and community-acquired infections (2).

Nosocomial infections normally occur in less than 1 month of post renal transplant (55). Nosocomial infections are usually caused by the antimicrobial-resistant type of organisms. Examples of nosocomial infections are methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), Clostridium defficile colitis, Aspergillus, Pseudomonas, lymphocytic choriomeningitis (LMCV), hepatitis c(HCV) and rhabdovirus (3).

Opportunistic infections normally occur in a period of 1 to 6 months after the transplantation procedure. They include CMV, Clostridium defficile colitis, HCV, adeno infection, influenza, Cryptococcus neoformans, mycobacterium TB infections, pneumocystis, HSV, VZV, EBV, HBV, infections with listeria, Nocardia, toxoplasmosis, Strongyloidiasis, leishmania a T cruzi (56).

Community-acquired infections usually occur in a period exceeding 6 months after the transplantation procedure. They include pneumonia, UTI with Aspergillus or atypical molds or mucous species, infections with Rhodococcus species, infections with Nocardia species, HBV, HSV, PTLD, SARS, HCV and progressive multifocal leukoencephalopathy (PML).

2.5 Regimen used in the post-transplant period

Medication in the post-transplant period is given majorly for suppression of RTRs immunity to prevent graft rejection of the transplanted organ and for prophylaxis of post-transplant infections (56). In the post-transplant period, one takes three types among them anti-rejection medications, anti-infectives, and miscellaneous medications. There are two types of anti-rejection drugs. These include induction agents and maintenance drugs. Induction agents include polyclonal antibodies like muromonab, alemtuzumab among others (57). Maintenance therapy comprises four groups of medications which include corticosteroids, calcineurin inhibitors, m-tor inhibitors and antiproliferative agents (58). Corticosteroid therapy includes prednisolone among others, m-tor inhibitors include sirolimus among others, calcineurin inhibitors include tacrolimus among others while antiproliferative agents include mycophenolate mofetil among others. In a typical setting like KNH the RTR taking combination of various drugs. An RTR can take a combination of tacrolimus which is in a concentration of 0.5 mg, 1 mg, and 5mg. this is taken twice daily. Besides, an RTR will take mycophenolate 250mg twice daily. They will also take co-trimoxazole 960 mg once daily for prophylaxis against bacterial infections, Valganciclovir 450 mg given 1 tablet 3 times a week for prophylaxis against viral infections, prednisolone 5mg taken 4 tablets daily as immunosuppression maintenance therapy and ranitidine 150 mg given for prevention of the stomach (59). Some patients get proton pump inhibitors such as omeprazole, pantoprazole, lansoprazole instead of ranitidine.

2.6 Gaps in the literature

The major gaps in the literature are the paucity of studies locally. Similar studies have been carried elsewhere like in the United States of America (3) and other countries like India. These, therefore, created a need to carry out the research locally on prevalence, trends and risk factors of infections in post-renal transplant recipients.

Masinde et al (2015) carried out research related to this area even though the study didn't quite look at the prevalence, trends and risk factors in post-renal transplant infections (13). Instead, it concentrated on cytological abnormalities and human papillomavirus infection among renal

transplant recipients. Barasa et al (2016) too carried out on almost similar study (14) although he looked on only one type of infection CMV in RTRs.

Due to paucity of studies in KNH on all the infections, therefore, it creates a need to carry out one. The current study will try and fill the gap left by all other studies by looking at the prevalence of post renal transplant infections, the trends followed by those infections in KNH and the antimicrobial use by the RTRs in KNH. The study will also find out the potential risk factors which exacerbate those infections.

CHAPTER 3: METHODOLOGY

3.1 Study Design

This study was retrospective cross-sectional in design. The design was best suited for this study because it captures descriptive and analytic information about population phenomena at a specific point in time. Moreover, this type of study does not consume a lot of time. In the current study, we were looking at post-renal transplant infections which normally occur at various stages of the post-transplant period. The study was done for patients who attended the clinic in the past five years. This is because some infections more especially nosocomial infections may occur between first and six months of the post-transplant period while others may manifest later like even after a year or two. Cross-sectional captured the information of the current study without consuming more time.

3.2 Study Area

The study was conducted at the Kenyatta National Hospital which is the biggest and oldest referral hospital in Kenya located approximately 3.5km on the west of the Nairobi central business district. Patients who experience kidney complications diagnosed from Kenyatta national hospital and other facilities are treated and enrolled for therapy and follow up through the renal unit. This renal unit offers various services like registration and admission, kidney transplantation for patients with end-stage renal disease (ESRD), outpatient services and hemodialysis which run throughout the week. It also offers services like pre- post-transplant clinics and renal biopsy both done once weekly.

There were approximately 160 post renal transplant recipients who were on follow up at the Kenyatta National Hospital renal unit and clinic.

3.3 Target population and study population

The target population for this study was adult males and females who have undergone a renal transplant in KNH and other hospitals like Aga khan, Nairobi hospital, MP Shah among others and are on follow up at the Kenyatta National Hospital over the last five years.

The study population was renal transplant recipients aged 18 years and above and who met the inclusion criteria. The study population was selected based on the inclusion criteria.

3.5 Eligibility criteria

3.5.1 Inclusion criteria

I. Records of post-transplant recipients less than five years since the transplantation procedure.

II. Adult post renal transplant recipients who were transplanted in KNH and other facilities both locally and abroad.

3.5.2 Exclusion criteria

I. Post renal transplant patients with incomplete records or RTRs whose records have

II. incomplete information regarding the current study.

3.6 Sample size

The primary outcome of this study was the prevalence of post renal transplant infections. The Fischer et al formula was used in the calculation of the sample size as follows

$n=Z^2pq/d2$

Where; n=Sample Size;

Z=1.96 (the value of Z corresponding to 95% confidence level).

P=prevalence=69.4%=0.694(the average estimated prevalence of post renal transplant infections from previous studies)

q=l-p=l-0.694=0.306;

d=0.05(the desired precision for this study was 0.05 which is generally the expected margin of error for most scientific research as well as categorical variables in descriptive studies

By substituting z, p, q, and d;

$n= (1.96^2x0.694x0.694x0.306)/0.05^2$

n= (0.8158175424/0.0025)

n=326

Since in the normal population this sample size is way beyond what we can get, therefore we used Cochran formula for the finite population.

$$n = \frac{no}{1 + {no}/{N}}$$

The n= minimum sample size required

no= calculated size

N= total number of patients attending the renal clinic at Kenyatta National Hospital (160)

$$n = \frac{326}{1 + {326}/{160}}$$

n= 107.325˜107

n=107

3.7 Sampling technique

A systematic random sampling method was used to sample files that met the established eligibility criteria set for this study. The files of these patients had an equal chance of being selected for the study.

The patient's population list was obtained from KNH health records and then the files were sampled in the renal unit. The investigator evaluated the files to ascertain whether they met both eligibility criteria. These files were assigned random consecutive numbers 1 to N. Afterwards a list of random numbers was obtained using random number tables. From this list, files were selected until the required sample was achieved.

3.8 Data collection and study variables

Data on post-renal transplantation infections was abstracted from the study participant's files using data collection forms in September and partly in October (Appendix 2). The data was collected by the help of two research assistants who were thought thoroughly before the actual study. The study was carried out on patients who had been attending the clinic over the past five years. These included data on the types of infections prevailing in post-renal transplantation including the most common type of infection to the least common type that is bacterial, viral, and fungal. The trend of post-renal transplantation infections was checked too including the infections which commonly affected post-renal transplantation recipients. The use of immunosuppressive therapy was ascertained too.

3.8.1 Exposures of interest

The exposures were the type of surgical intervention involved, pre-existing infections in renal transplant donors and the immunosuppression therapy the renal transplant recipient was on in his or her lifetime.

3.8.2 Outcome of interest

The main outcome of interest in this study was the prevalence of infections in post-renal transplantation recipients in Kenyatta National Hospital. Possible confounding variables were either age that is as one ages the immune response goes down, gender, and other comorbidities in which the recipients may be surviving along with including diabetes mellitus, hypertension, and other diseases that suppress one's immune response making him or her vulnerable to infections.

3.9 Research instruments

Information obtained from research participants file was recorded in the data collection form (Appendix 2) and later analyzed. The following are various study research tools that were used.

3.9.1 Data collection forms

This is a form that was used to capture all the information concerning the study from either the patient records or the patients themselves. The study tool contained biodata, clinical information, sociodemographic, causes of ESRD, comorbidities the RTRs were suffering from, hospital admission status, post renal prophylaxis regimen, prescribing patterns of antimicrobials for RTRs, immunosuppressive regimen various infections the patient is ailing from e.g. whether bacterial, fungal or viral among others (Appendix 2).

3.9.2 Eligibility screening form

This was a form that was used to assess whether the files were suitable for selection into the study. It contained both inclusion and exclusion criteria and the study information (Appendix 1).

3.10 Pilot study

A pilot study was conducted to test the research tools the ability to capture the desired data in a small subset of the target population. This was carried out with 10 files (about 10 % of the study sample) in the month of September by the principal investigator. The study tools were pre-tested at the KNH renal clinic which is the same location the actual study was conducted.

The principal investigator (PI) went through the patient's files to ascertain those that met the eligibility criteria. This was achieved by using the data eligibility screening form (Appendix 1). Then the principal investigator assigned random numbers to those files. Then he/she used random tables to pick ten random files which were utilized in carrying out the pilot study.

Data on patient social demographics were obtained from the patient files which have been selected for the pilot study. This information was recorded on the data collection form (Appendix 2). Data on types of infections, the time they occurred since the transplantation procedure, regimen used for prophylaxis of the infection, regimen used for the management of the various infections were collected too and recorded on data collection form (Appendix 2). Further, the information of the ten participants was analyzed using STATA software version 13. This helped us to assess and adjust the validity of the study tool before the actual study. The study tools were adjusted accordingly if they had a deficit about data collection. This was by redesigning the eligibility screening form (Appendix 1) and the data collection form (Appendix 2).

3.11 Validity

This was maintained by ensuring that the research tool has adequate and relevant information required for this study. Therefore, to do that the research tool had to answer various questions clearly to ensure that objectives of the current study are met. These questions include the type of infections experienced by RTRs, pre- and post-exposure prophylaxis of post renal transplant infections, time at which the RTR experienced the infections, methods applied in the prevention of post renal transplant infections and regimen used to treat a particular infection. This was to minimize internal validity. Besides, the research tool had to answer the type of immunosuppressive regimen used by the RTRs and when they began using it. The data collection tool will contain short, clear and concise questions. The sample size of approximately 107 RTRs

was adequate hence it represented the entire post-transplant patients with infections. This was to ensure that results from the current study applied to entire RTRs in the country. This further maximized external validity. Moreover, external validity was maximized by selecting the study site to be Kenyatta National Hospital which is the largest referral hospital in the country and hence people who attend its renal clinics are from all over Kenya and some from our neighboring countries. It enabled results from this study to apply to a wider population.

3.12 Reliability

Data collection tools underwent pre-testing by the principal investigator as described under the pilot study to determine the internal reliability of the results prior to the actual study. This was done to ensure clear and precise responses throughout the study. Correct information was collected without any manipulation and no amendments that was made on the research instruments at the time of the actual study. Reproducibility was ensured by collecting all relevant information from patients' records.

3.13 Data collection techniques

The raw data was collected using a data collection tool upon obtaining permission from the University of Nairobi ethics and research committee (UoN-ERC-P451/06/2019) which was in September. Since the sample size was already determined, files of study participants who met the inclusion criteria were obtained and screened by the principal investigator. Information obtained was analyzed for data management. Treatment schedules, prescriptions and medical records belonging to study participants were also reviewed.

3.14 Data management

3.14.1 Data processing

The data collected was recorded in an appropriate form (Appendix 2). Cleaned data was entered in data analysis software known as STATA version 13. The data was then interpreted into usable information that could be read and be utilized effectively.

3.14.2 Data analysis

Data analysis was done using STATA version 13 statistical software. Exploratory data analysis (EDA) was used to summarize the main characterization such as age, gender, residence, level of education, alcohol drinking status, marital status, and cigarette smoking status among others by use of visual methods such as bar charts, histograms and box plots.

Quantitative variables such as patients age, duration lapse since the transplantation procedure and number of infections affecting the RTRs were presented by the measures of central tendency e.g. mean mode, interquartile range (IQ) and standard deviation. Categorical variables such as gender, level of education, residence, smoking status, alcohol intake status among others were presented in the form frequencies and percentages. Chi-square tests were conducted to analyze the relationship between dependent variable including infections in post-renal recipients and independent variables such as age, sex, the technology of surgical procedures involved during transplant, level of education and socioeconomic status.

Data on the risk factors was analyzed using a 2 by 2tables and chi-square for categorical data. A comparison of means was done by ANOVA for linear data. Multivariate logistic regression analysis was further used to determine if gender, age residence, and level of education can predict the prevalence of post renal transplant infections. The odds ratio (OR) and respective confidence interval (CI) was calculated in this analysis for each variable. The level of significance was set at 0.05.

3.15 Ethical approval

Before carrying out the study, ethical approval was sought from the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee (KNH/UoN-ERC-P451/06/2019). To access patients' files, permission had to be granted from Kenyatta National Hospital administration before the study. Throughout the entire study, information obtained was kept safely. The data that was kept in a computer, it was password protected and the one that was kept in a locker it was under the lock and key. The data was kept until the research was completed and this was approximately for a three months. In addition, information on study participants was not be revealed elsewhere except for this study and patient names were not used instead unique identification numbers were utilized.

3.16 Confidentiality

All information collected during the study was confidential and it was used for the intended purpose only. A review of files was done by the PI within the renal unit and general records office to ensure the confidentiality and safety of renal transplant recipients files.

Participants' unique numbers were generated and utilized instead of their actual names or hospital numbers to conceal their true identities. Data collection materials were kept under lock and

key for the duration of up to three months which is the duration approximated for data collection and analysis.

3.17 Risks involved

The present study did not involve dealing directly with any patients hence there was minimal or no risks involved at all.

3.18 Benefits of the study

The current study helped in identifying various infections that RTRs contract after the transplantation procedure. It also identified the trend of the various infections in RTRs. Moreover, it identified the risk factors involved in contracting those infections. The information helped the clinicians to improve RTRs care and to be able to prepare in advance to prevent those infections before the transplantation procedure.

3.19 Dissemination

The research findings of the present study will be shared with various departments like the renal department, the research department, the medical wards among others. Moreover, research findings will be shared with regular clinicians attending the renal transplant recipients who include the consultants, medical officers, pharmacists, nurses among others. This will be accomplished through CMEs, scientific conferences, peer-reviewed journals with hope of improving patient care through proper prophylaxis and best medical attention to the post renal transplant recipients. Research findings will also be shared with the Ministry of Health (MoH) aiming at influencing treatment guidelines and policymaking. Besides, a dissertation will be done and it will be made accessible to everyone through the University of Nairobi (UoN) repository.

CHAPTER 4: RESULTS

4.0 Introduction

This chapter describes the results obtained after descriptive and inferential data analyses. It includes the sociodemographic characteristics of the study population, the prevalence of infection in post renal transplant patients and the trends and the risk factors associated these infections. Besides, it also includes the antimicrobial agents used in prophylaxis and management of post renal transplant infections.

4.1 Sociodemographic characteristics of the study population

In total, 120 patient files were perused and data abstracted from them. 13 files were excluded for they did not have sufficient information regarding the current study. Slightly more males than females were enrolled in the study (53.27% vs 46.73% respectively, (Table 1). The mean age of the study participants was 41.3 years (± 12.5) with the youngest being less than 30 years and the oldest being more than 50 years. The age group of 30-50 years represented the largest number of participants.

The largest proportions of the participants were highly educated up to the tertiary level (45, 42.06%) with the least number being that of uneducated (8, 7.48%). It was noted that most participants never took alcohol in their entire life (66, 61.68%) while those who are currently taking alcohol were the least (5, 4.67%). Of the 107 participants, 84 (78.51%) had never smoked before. It was also noted that the majority of the participants were unemployed (54, 50.47%). In addition, most participants who took part in the study were married (67, 63.4%).

Most RTRs attending KNH renal unit for follow-up were from Nairobi county (20, 18.69%), and the neighboring counties like Kiambu (16, 14.95%), Murang' a (13, 12.15%), Nakuru (9, 8.41%) and Nyeri (6, 5.61%). Elgeyo Marakwet, Trans-Nzoia, Laikipia, Kwale, Kisumu, Kilifi, Kericho, Kakamega, Garissa, Bungoma, and Bomet had the lowest turn up (1, 0.93%)

Table 1 Sociodemographic characteristics of the renal transplant recipients.

Variables	Frequency (n)	Percentage (%)
Age Years		
<30	23	21.5
30-50	58	54.21
>50	26	24.3
Age (mean ±SD) Years	41.3(±12.5)	
Sex Male	57	53.27
Female	50	46.73
Alcohol status		
Never drunk	66	61.68
Previous drinker	36	33.64
Currently drinking	5	4.67
Smoking status		
Never smoked	84	78.51
Previous smoker	18	16.82
Currently smoking	5	4.67
Education level		
Uneducated	8	7.48
Primary	10	9.35
Secondary	44	41.12
Tertiary	45	42.06
Employment status		
Unemployed	54	50.47
Self-employed/ business	30	28.04
Formally employed	23	21.5
Marital status		
Married	67	63.21
Separated	4	3.77
Single	33	31.13
Widowed	2	1.89

4.2 Clinical characteristics of the study population

4.2.1 Factors leading to end stage kidney disease

The primary causes of end stage renal disease were analyzed and highlighted in the table below. Hypertension was discovered to be a major factor cause of ESRD (77, 71.96%). It was noted that hypothyroidism was the least contributing factor to ESRD (1, 0.93%) (Figure 2).

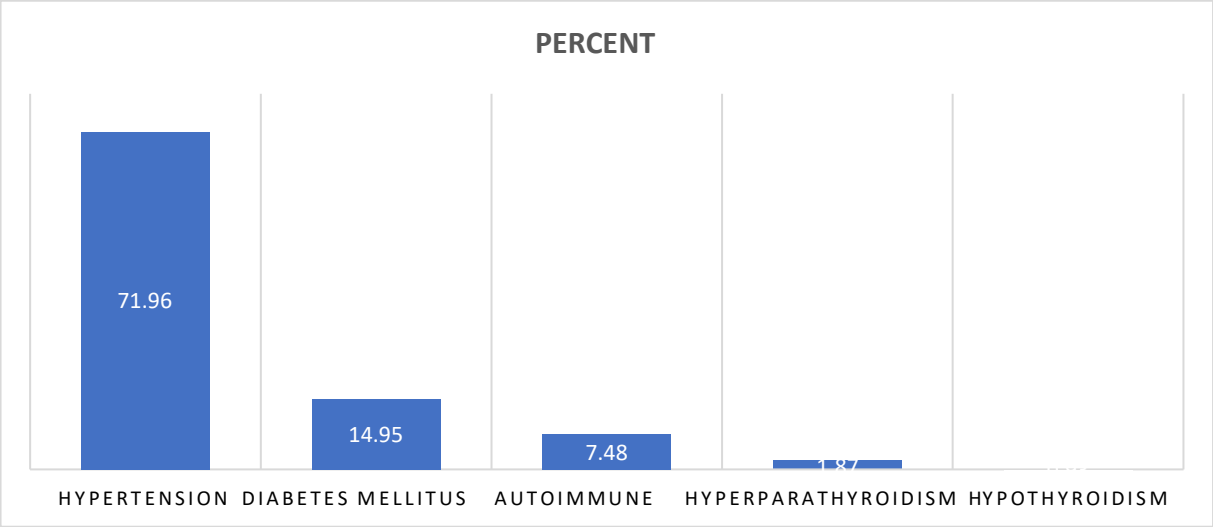

Figure 2 Factors exacerbating to ESRD

4.2.2 Prevalence of infections in the study population

Various types of infections were diagnosed in the 107 RTRs. Bacterial infections were the most prevalent (92, 86.79%) followed by viral infections (10, 9.43%). Fungal infections emerged less in the 107 RTRs on follow up in KNH (4, 3.77%) (Figure 3).

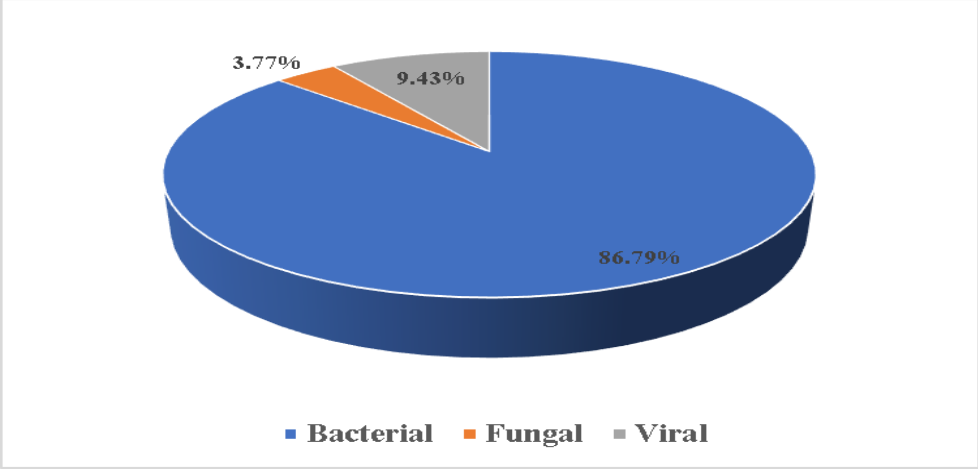

Figure 3 Prevalence of infections in the study population

4.2.3 Types of bacterial infections found within the study population

From Table 2 below, urinary tract infections were the most experienced among the bacterial infections (54, 48.21%). They were closely followed by community acquired pneumonia (39, 34.82%). A few cases experienced miliary tuberculosis (3, 3.57%) while the least prevalent among the bacterial infections were vancomycin resistant enterococci and helicobacter pylori (1, 0.89%). Out of 107 patients whose data was collected, most of them had single bacterial infection (78, 40.63%) while few had more than one bacterial infection (17, 8.85%).

Table 2 Bacterial infections found within the study population

Bacterial infections	n	percent
Urinary tract infection	54	48.21
Community acquired pneumonia (CAP)	39	34.82
Upper respiratory infection	10	8.93
Military tuberculosis (MTB)	4	3.57
Methicillin resistant staphylococcus aureus (MRSA)	3	2.68
H pylori infection	1	0.89
Vancomycin resistant enterococcus (VRE)	1	0.89

4.2.4 Types of viral infections experienced by the study population

These were the most common type of infections among the study population after bacterial infections. Among the viral infections, herpes zoster was the most common (5, 31.25%) followed by cytomegalic viral infections (3, 18, 75%). Epstein Barr, Hepatitis B, Hepatitis C, Human papilloma virus, Kaposi's sarcoma human herpes virus and parvo virus were noted least among the study participants each contributing (1, 6.25%) of the viral infections (Table 3).

Table 3 Viral infections found within the study population

Viral infections	n	Percent
Herpes zoster virus (HZV)	5	31.25
Cytomegalic virus (CMV)	3	18.75
Rota virus	2	12.5
Epstein bar virus (EBV)	1	6.25
Hepatitis B virus (HBV)	1	6.25
Hepatitis C virus (HCV)	1	6.25
HPV	1	6.25
Kaposi's sarcoma associated herpes virus (KSHV)	1	6.25
Parvo virus	1	6.25

4.2.5 Types of fungal infections among the study population

A few fungal infections were noted among the study population. The most common among the study population were vaginal candidiasis and oral candidiasis (4, 30.77%). Pneumocystis pneumonia and tinea followed in prevalence (2, 15.38%) while the least acquired among the fungal infections was cryptococcus (1, 7.69%) (Table 4).

Table 4 Fungal infections among the study population

Fungal infections	Freq.	Percent
Candida(vaginal)	4	30.77
Candida (Oral)	4	30.77
Cryptococcus	1	7.69
Pneumocystis pneumonia (PCP)	2	15.38
Tinea	2	15.38

4.3: Trends of post renal transplant infections.

Various infections were acquired by the study population at different times in the post-transplant duration. The following results show the point at which bacteria, fungal and viral infections were prevalent. Most of the bacterial infections were acquired in less than 6 months into the post-transplant period (29, 50%). Few of the infections occurred in 12-18 months after the transplantation procedure (11, 18.97%). Most viral infections were acquired in a period of more

than 18 months following transplantation (16, 94.12%). None of the viral infections occurred in 0-6 months and less than 6 months post transplantation procedure (Fig 4.3).

More fungal infections occurred within 18 months of the transplantation procedure (10, 83.33%) while fewer infections were acquired in posttransplant period of 3-6 months and 6-12 months (1, 8.33%). There were no viral infections experienced in the period of 0-6 months post transplantation surgery (Figure 5).

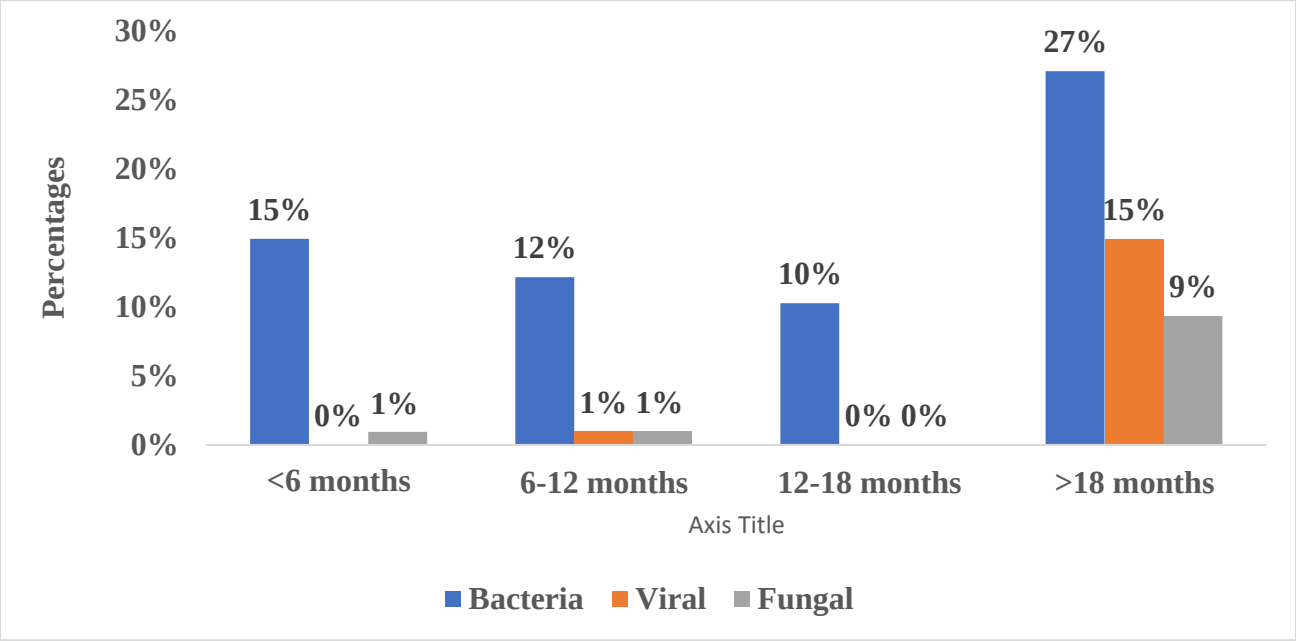

Figure 4 Trends of post renal transplant infections

4.4 Hospital admission status

Upon the diagnosis of infections emergent in various RTRs, most of them experienced conditions that could be handled without being admitted (81, 76.42%) while a few were admitted (25, 23.58%)

Among the RTRs which were admitted, sixty percent of them were admitted approximately for two weeks. The least number of days an RTR would be admitted were two days.

4.5 Action that was taken on prevalent infections

Most of the infections that were diagnosed on RTRs were treated by suitable antimicrobial agents (89, 95.7%). The few which were untreated were the self-limiting viral infections (4, 4.3%)

4.5.1 Antimicrobial regimens used in prophylaxis and management of post renal transplant infection among the renal transplant recipients.

Most antimicrobials prescribed were antibiotics mainly penicillin, antifungals, and antivirals. In addition, quinolones, aminoglycosides, cephalosporins, nitrofurans, carbapenems among others were dispensed. Among the bacterial infections, amoxicillin/clavulanic acid was the most preferred one handling up to 19.86% of the cases. Amoxicillin/clavulanic acid was closely followed by ciprofloxacin. A combination of rifampicin, isoniazid, pyrazinamide, and ethambutol was used for tuberculosis infection in intensive phase while for continuous phase a combination of rifampicin and isoniazid was preferred. For admitted RTRs various antibiotics including amoxiclav® intra venous, meropenem injections, peropenem, ceftriaxone injectables, levofloxacin was used among others. Esclam kit® which contain clarithromycin, esomeprazole and amoxicillin was used to manage stomach ulcers.

For viral infections, many antiviral drugs were prescribed, among them, acyclovir cream for topical applications, valganciclovir and acyclovir tablets for systemic viral infections and a combination of tenofovir, lamivudine, and efavirenz were prescribed for HIV infections.

For topical fungal infections, mostly betazole and miconazole creams were used for infections such as tinea, nystatin oral drops for oral candidiasis and clotrimazole pessaries for vaginal candidiasis among others (Table 5).

Table 5 Antimicrobials for management and prophylaxis of post renal transplant infections among the study population

Antimicrobials for treatment	Freq.	Percent
Amoxicillin/clavulanic acid	29	19.86
Ciprofloxacin500mg	19	13.01
Metronidazole	11	7.53
Levofloxacin500mg	11	7.53
Meropenem1gminjection	10	6.85
Acyclovir cream	6	4.11
Augmentin1g IV®	6	4.11
Azithromycin	5	3.42
Ceftriaxone	5	3.42
Cefuroxime	5	3.42
Nystatin oral	4	2.74
Rifampicin, isoniazid, pyrazinamide, and ethambutol (RHZE)	4	2.74
Amoxicillin500mgcaps	3	2.05
Valganciclovir	3	2.05
Acyclovir tablets	2	1.37
Calamine lotion	2	1.37
Ceftazidime	2	1.37
Cefixime 400mg	2	1.37
Nitrofurantoin100mg	2	1.37
Acyclovir cream	1	0.68
Acyclovir injection	1	0.68
Betazole cream	1	0.68
Co-trimoxazole	1	0.68
Cefuroxim750mgiv	1	0.68
Esomeprazole/clarithromycin/amoxicillin kit	1	0.68
Nystatin oral	1	0.68
Clotrimazole pessaries100mg	1	0.68
Flucloxacillin 500mg iv	1	0.68
Flucloxacillin 500mg tablets	1	0.68
Levofloxacin 750mg iv	1	0.68
Meropenem 500mgtablets	1	0.68
Miconazole cream	1	0.68
Peropenem injection	1	0.68
Tenofovir/ lamivudine/ efavirenz	1	0.68

4.5.2 Prophylaxis antimicrobials among the study population

After the transplantation procedure, it was noted that various antimicrobials were used for prophylaxis. The commonly used antibiotics were metronidazole (79, 44.13%) and ceftriaxone injectables (61, 34.08%). In most cases, metronidazole was used alongside other antibiotics. The least used antibiotics were cefuroxime, benzyl penicillin, amoxicillin/clavulanic acid injectable, meropenem tablets and tazocin (1, 0.56%) (table 6)

Table 6 Prophylaxis antimicrobials among the study participants

Prophylaxis antibiotics post- transplant	**n**	**Percent**
Metronidazole	79	44.13
Ceftriaxone	61	34.08
Levofloxacin 750mg iv	18	10.06
Levofloxacin oral	6	3.35
Amoxicillin/clavulanic acid 1g IV	3	1.68
Amoxicillin/clavulanic acid 625mg	3	1.68
Ceftazidime	2	1.12
Cefuroxime 750mg iv	2	1.12
Cefuroxime	1	0.56
Benzyl penicillin	1	0.56
Amoxicillin/clavulanic acid	1	0.56
Meropenem 500mg tablets	1	0.56
Tazocin	1	0.56

4.5.3 Immunosuppressive use among the study participants

Immunosuppressive agents were given in order to avoid graft rejection slightly before, on and immediately after renal transplantation procedure. Induction therapy was used on transplantation procedure while maintenance therapy was used after transplantation. Maintenance therapy was given on long term basis.

4.5.3.1 Induction therapy

Methylprednisolone was the most commonly used agent in induction therapy (104, 98.11%). Tacrolimus and cyclosporin were less used (1, 0.94%) (Fig 6).

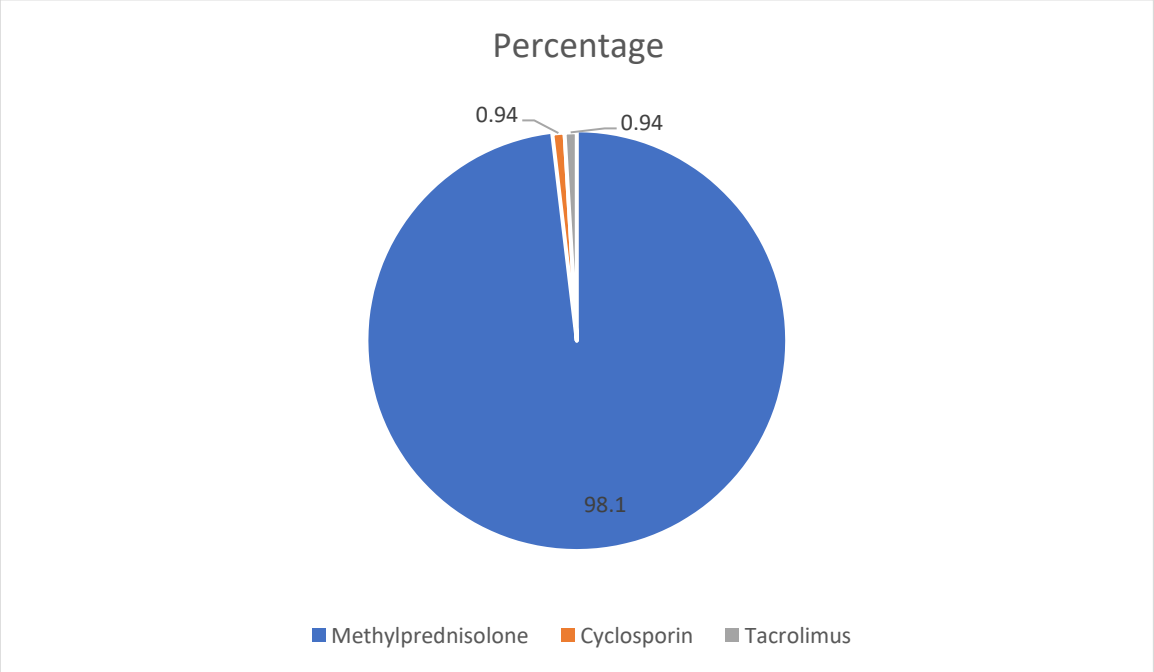

Figure 5 Induction therapy used by the study population

4.5.3.2 Maintenance therapy

In maintenance therapy, mycophenolate mofetil was preferred compared to other agents (48, 45.28%). Azathioprine (4, 3.77%) and everlolimus (1, 094%) were used in some individuals. The immunosuppressive agents were mostly used in a combination of two or three (Fig 7).

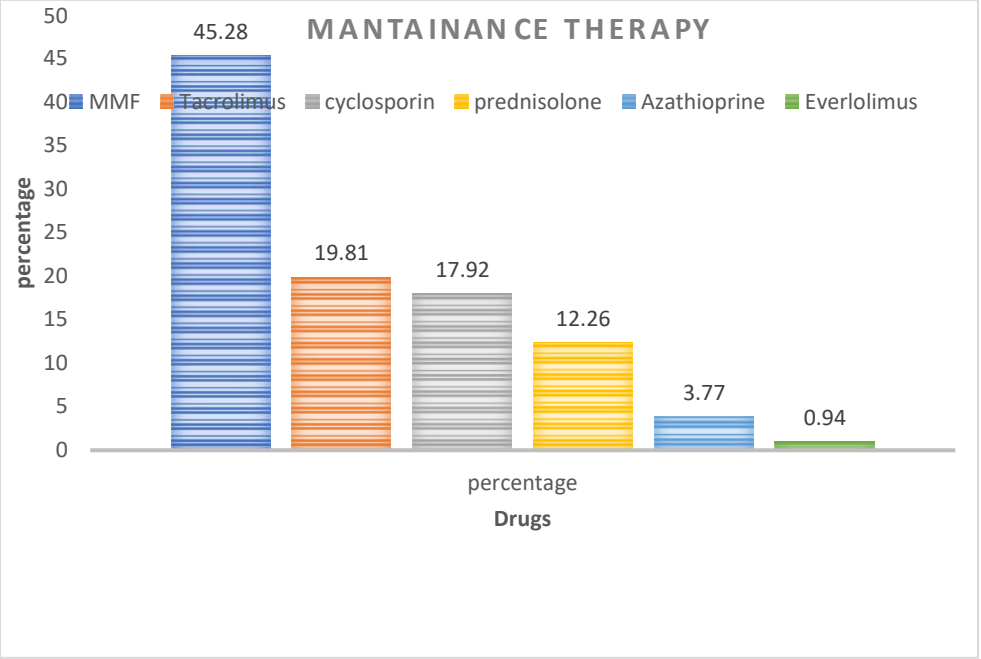

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Figure 6 Maintenance therapy used by the study population

4.6 Outcome status on the post renal transplant infections upon treatment

Upon treatment with various antimicrobials, most infections resolved (84, 79.25%), two cases did not improve. Among the two who did not improve one underwent transplantation procedure again and one underwent dialysis few cases improved (21, 19.81%) (Fig 8).

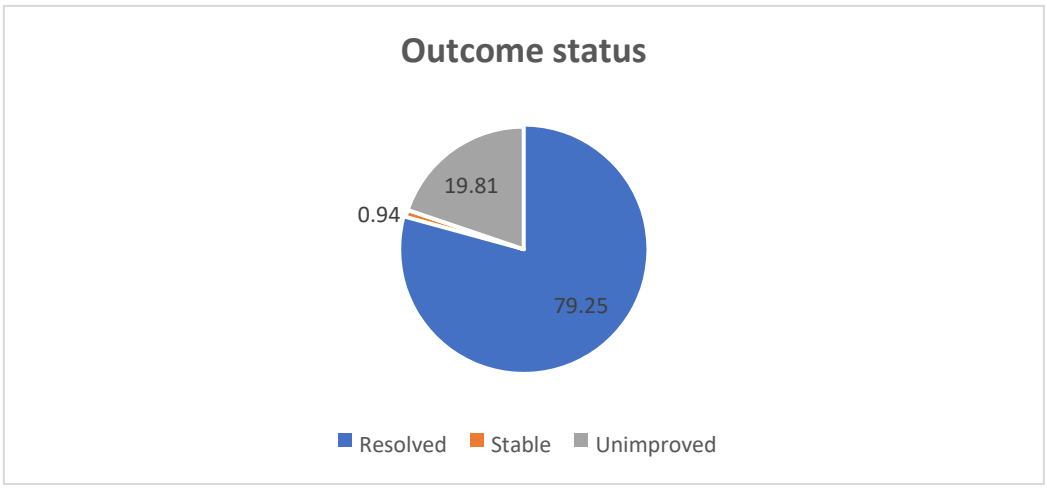

Figure 7 Outcome statuses of the RTRs upon antimicrobials intervention

4.7 Comorbidities/ diseases among the study population

A relatively higher number of the study population had comorbidities (55, 52.38%)

The most prevalent comorbidity was diabetes mellitus (24, 40.68%) followed by hypertension (23, 39.66%). Ulcers, acquired immunodeficiency syndrome (AIDS) among others experienced the least in the study population (1, 1.72%) (Table 7)

Table 7 Comorbidities among the study population

Comorbidity	Freq.	Percent
Diabetes Mellitus	24	40.68
Hypertension	23	39.66
Connective tissue disorder	3	5.17
Stomach ulcers	3	5.17
Acquired immunodeficiency syndrome (AIDS)	1	1.72
Chronic pulmonary disease	1	1.72
Gastro esophageal reflux disease (GERD)	1	1.72
Myocardial infarction	1	1.72
Conjunctivitis	1	1.72
Hypothyroidism	1	1.72

4.7.1 Duration of existence of comorbidities among the study population.

Many comorbidities/diseases in the study population had existed for 2-3 years (15, 34.09%) while a small amount had been present for a shorter period (7, 15.91%) (Figure 9)

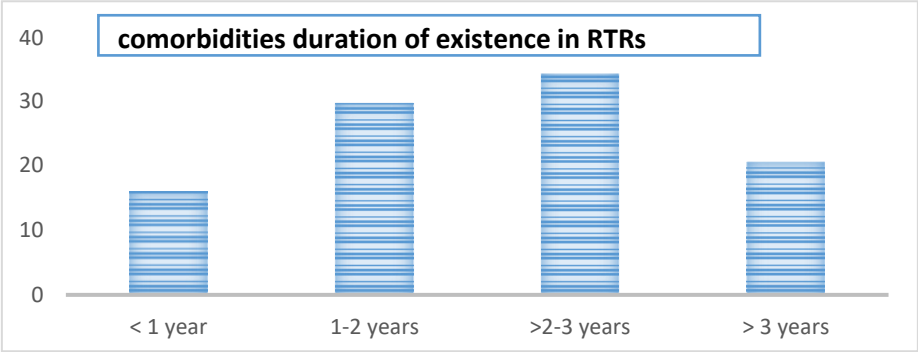

Figure 8 Comorbidities/disease duration of existence among the RTRs

4.8 Graft survival status upon transplantation.

It was noted that most RTRs improved in terms of graft survival (97.17%). few were unimproved and hence they were recommended further medical attention (2.83%) which were dialysis and subsequent transplant. (Figure 10).

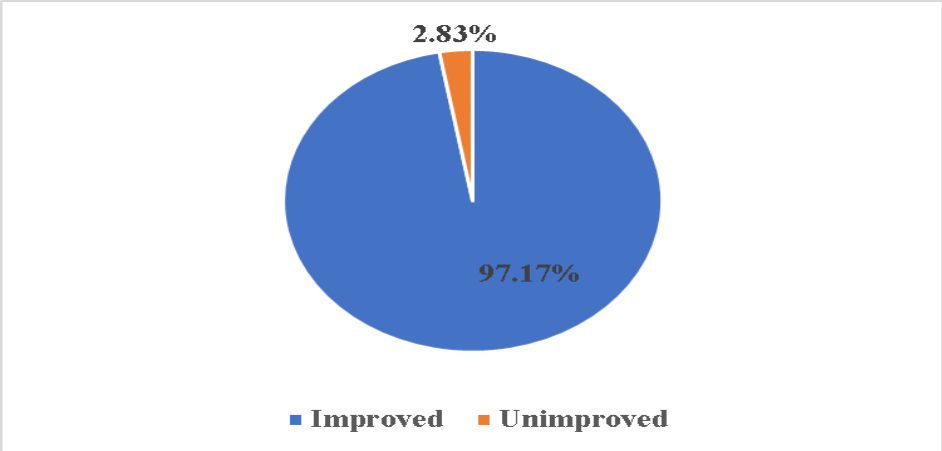

Figure 9 Graft survival statuses upon transplantation

4.9 Association between social demographic characteristics and the presence of an infection

Association between sociodemographic characteristics and presence or absence of post renal transplant infections among patients on follow up in KNH for the last five years was carried out using Fischer's exact test. Female sex (p=0.035) and alcohol intake status (p=0.018) had a significant association with the presence of an infection in RTRs. Further on analysis comparing the various counties, the RTRs were coming from and the presence of infections, it was noted that RTRs from Murang' a carried a greater risk of getting bacterial infections (p=0.018). Besides, coming from Nairobi carried a risk of getting viral infections (p=0.038). None of the remaining sociodemographic characteristics had a significant association with the presence of bacterial, viral and fungal infections. However, age, level of education, employment status, and alcohol intake status had a higher p values before the renal transplantation procedure; 0.816, 0.363, 0.551, 0.586 respectively. Results are shown in the table below (Table 8)

Table 8 Comparison between sociodemographic characteristics and presence of infection in the study population

Variables	Bacterial	Fungal	Viral	P-values	Test used
Sex					
Female	45	2	3	**0.035**	Fisher exact
Males	47	2	7		
Age					
<30	22	0	1	0.816	
30-50	49	3	6		
>50	21	1	3		
Level of education					
Uneducated	6	1	1	0.363	
Primary	7	1	1		
Secondary	38	1	5		
Tertiary	41	1	3		
Employment status					
Unemployed	46	2	6	0.551	
Self-employed/business	26	2	1		
Formally employed	20	0	3		
Smoking status					
Never smoked	73	2	8	0.096	
Previous smoker	14	2	2		
Current smoker	5	0	0		
Alcohol intake status					
Never taken alcohol	59	2	5	**0.018**	
Previous alcoholic	28	2	5		
Current alcoholic	5	0	0		

4.10 Comparison between clinical characteristics and the presence of an infection

Comparisons between clinical characteristics and the presence of any post renal transplant infection was assessed by Fischer's exact method. It was noted that there was a significant association between the presence of infection and when an infection is unresolved after intervention ($p < 0.01$) (Table 4.9).

Table 9 Clinical characteristics and presence of an infection among the study population

Primary cause of ESRF	**Bacterial**	**Fungal**	**P-value**
Autoimmune	8	0	0.930
Diabetes mellitus	15	0	
Hypertension	63	4	
Others	3	0	
hyperparathyroidism	2	0	
Hypothyroidism	1	0	
Immunosuppressant use			
No	1	1	0.083
Yes	90	3	
Outcome status			
Unresolved	12	3	***<0.001**
Resolved	79	1	

Key * statistical significance

4.10 Independent predictors for the presence of post renal transplant infections

Bivariable and multivariable logistic regression analysis were performed to determine the independent predictors for the presence of any type of infections in RTRs. The results were summarized in Table 10. In bivariate analysis, alcohol intake status (p=0.016) and sex(p=0.035) had a statistical association on comparison with presence of infection in RTRs. In multivariate analysis using the best fit model, sex, and diabetes mellitus (P- 0.016, 0.035) respectively were

noted to be independent factors which were statistically significant as predictors for the presence of infection in RTRs on follow-up in KNH. There was no other predictor that sustained significance after multivariable regression analysis was conducted (table 10)

Table 10 Independent predictors for the presence of infection within the study population

Variables	**Bivariate analysis**		**Multivariate analysis**	
	COR (95% CI %)	p-values	AOR (95% CI %)	p-values
Duration of admission for RTRs	0.44(0.10-1.91)	0.33	0.15(0.12-1.80)	0.13
Diabetes mellitus	073(0.26-2.05)	0.55	0.02(0.001-0.76)	**0.035**
Other comorbidities	0.66(0.29-1.54)	0.34	20.95(1.00-437.25)	**0.05**
Nairobi	0.53(0.16-1.72)	0.16	0.46(0.14-1.54)	0.2070
Alcohol intake	0.3(0.14-0.83)	**0.018**	0.4(0.15-1.30)	0.138
Sex	0.4(0.17-11.36)	**0.035**	0.27(0.09-0.78)	**0.016**

CHAPTER FIVE: DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Discussion

The prevalence of post renal transplant infections among patients on follow-up at the KNH renal clinic was as follows; bacterial - 86.79%, viral - 10% and fungal - 4%. This is similar to a study carried out in the United States of America (USA) by Khoury *et al.* (2) which highlighted that following transplantation procedures, infections commonly emerge in the RTRs. Among the KNH RTRs who were on follow up for the last five years, bacterial infections were the most prevalent followed by viral infections. Moreover, a few patients experienced fungal infections. Some studies have shown a similar trend pointing to bacterial infections as the most common type of post renal transplant infections (60). In the first year during the transplantation procedure, urinary tract infections were the most prevalent bacterial infections followed by community acquired pneumonia in KNH. Mashhad University located in Iran (20). The study ascertained that UTI was the most commonly experienced type of post renal transplant infection even though it didn't identify pneumonia being common in RTRs in the first year following kidney transplantation. However, another study carried out in Belgium found bacterial pneumonia as one of the commonest bacterial infection in the first year following kidney transplantation which is in line with our study (61). Viral infections were the second most prevalent among the study population. Herpes zoster viruses were more prevalent in the study population followed by cytomegalic viral infection. This is almost similar to other studies carried out in the USA suggesting CMV to be the most common cause of viral infections (3). The slight deviations maybe attributed to risk factors and the study set up among others. Parvo, Kaposi's sarcoma-associated herpes virus (KSHV), human papilloma virus (HPV), hepatitis C and B and Epstein bar virus emerged in less numbers among the study participants. This is identical with similar studies carried out in Asia (10). This study further suggests that there is an increase of infections among the RTRs which are probably obtained during dialysis and blood transfusion. For instance, in Thailand, hepatitis C and hepatitis B viral infections are very common (62). Besides, fungal infections were the least experienced among the study participants. Vaginal candidiasis and oral candidiasis were the most common among the study participants. Cryptococcal infections were few among the fungal infections facing the study participants. The situation is almost identical to several studies already carried out in the USA under similar circumstances (63)

Normally after any surgical procedure, the patients are given some antimicrobials for approximately five days for prophylaxis (64). RTRs on follow up in KNH were no exception. Despite the post renal transplant prophylaxis using antimicrobials, there were still some infections in RTRs. This may be attributed to the resistance to several antibiotics in various clinical set-ups (65). Most RTRs on follow-up in KNH after the transplantation procedure were prescribed for a combination of drugs mostly comprising metronidazole and ceftriaxone. Others had various antibiotics which included levofloxacin tablets, levofloxacin injectables, amoxicillin/clavulanic acid and intravenous injectables among others. Moreover, meropenem, cefuroxime 750mg injectables, cefuroxime among others were prescribed too on rare circumstances for prophylaxis. This practice too on antimicrobial prophylaxis in KNH is similar to clinical setups as quoted by some studies carried out in in India among others. (51).

In terms of management of post renal transplant infections, it was noted that Augmentin® was commonly used for the management of bacterial infections among the RTRs. Ciprofloxacin, metronidazole, levofloxacin, and meropenem were also used on many occasions to manage various bacterial infections like UTI, upper respiratory tract infections (URTI) among others. Various viral infections were managed by antiviral drugs like valganciclovir, acyclovir tablets, acyclovir cream among others. Patients with fungal infections were commonly prescribed with nystatin oral drops, clotrimazole pessaries among others. This was found to be similar with practices of management of post renal transplant infections in other hospitals like Maastricht university hospital in Netherlands (64).

Post renal transplant infections that emerged among the study population were found to follow a particular trend. For instance, most bacterial infections were experienced during the few first months of the post transplantations period. The bacterial infections which were experienced early were mostly nosocomial infections like *Staphylococcus aureus*, *Escherichia coli* among others. A similar trend was reported by *Sriram et al*. (66). He further reported that post renal transplant infections were determined by time lapse after transplantation procedure, immunosuppression therapy, and environmental factors. Few of the bacterial infections were acquired later as duration progressed after the transplantation procedure. The opportunistic infections like milliary tuberculosis usually emerged in a period of one year after the transplantation procedure. This was

similarly reported by *Sundaram et al*. (25). This is because the immunity had already decreased due to use of long-term immunosuppressant therapy (67).

Viral infections mostly emerged in late stages of post renal transplant period approximately more than eighteen months in after the renal transplant procedure. This may be attributed to the long-term use of immunosuppressive therapy with intention of avoiding allograft loss. With time the regimen weakens one's immune system making him/her to be vulnerable to viral infections (10). The few that emerge in the early stages of the post transplantation period may probably be from the donors who are already infected (68).

Fungal infections were most prevalent in more than eighteen months of the post renal transplant procedure. This may be due to low immunity resulting from the use of immunosuppressants (69). The few viral infections that emerged in the early stages of the post- transplant procedure were the invasive fungal infections candida albicans, aspergillus fumigates among others (69).

Both bivariate analysis and multivariate analysis were carried out to determine the association between social demographics, clinical characteristics, medication used in prophylaxis of infections and the presence of post renal transplant infections. The analysis was also carried out between the presence of infections in RTRs and the medication used in management of post renal transplant infections. From bivariate analysis, it was noted that there was a significant association between female sex and alcohol intake status with presence of post renal transplant infections in RTRs undergoing follow up in KNH. It was also noted that RTRS who were residing in Murang'a County had a greater risk of bacterial infections. Moreover, residing in Nairobi County was associated with viral infections. On multivariate analysis, diabetes mellitus as a comorbidity and female sex stood out. This is similar to a study carried out in Brazil in the year 2010 (70). This study successful identified female sex as a risk factor associated with the presence of post renal transplant infections. This study also came up with similar findings to those of *Swamy et al.* (71) who demonstrated that diabetes mellitus as a comorbidity is a risk factor for post renal transplant infections

5.2 Summary and conclusions

The results of this study revealed that there is still a burden of post renal transplant infections among the RTRs on follow up in KNH. Three forms of infections were identified among the study population. The most prevalent nature of infection was bacterial followed by viral infection. Fungal infections also had a significant contribution too among the study population. Among the bacterial infections, UTI was the most commonly experienced among the study population. Some severe infections like tuberculosis were rarely experienced too. It was also discovered that all RTRs underwent post renal exposure prophylaxis with a combination of ceftriaxone and metronidazole being the medication combination mostly utilized in this case. Almost all post renal transplant infections were treated accordingly. The ones which were not treated were mostly viral hence self-limiting. A greater percentage of post renal transplant infection resolved after antimicrobial intervention. The ones which did not improve lead to graft failure hence resulting to the RTR undergoing a transplantation procedure again although these cases were very few among the study population. It was also noted that female sex had a more risk of post renal transplant infections. Besides, patients who had diabetes mellitus as comorbidity had a greater chance of being infected.

5.3 Study strengths and weakness

These studies highlighted on how infections are still a burden in RTRs on follow up in KNH. This study also illustrated the trend of post renal transplant infections which are commonly emerging in KNH. Moreover, this study evaluated the risk factors attributed to post renal transplant infections among RTRs on follow up in KNH.

The study was a cross sectional retrospective hence some information might have not been easily obtained from the files since some of the medical practitioners may have forgotten to record or evaded it deliberately. After laboratory culturing some laboratories could not identify the exact nature of infections hence being a challenge in identifying the causative organism and hence not choosing the most suitable antimicrobial.

5.4 Recommendations

1. We recommend that whenever the RTRs have an infection, culture and sensitivity should be done to identify the microorganisms associated with the infections hence facilitating the best treatment possible.

2. We recommend that post renal transplant prophylaxis should commence even before the renal transplantation procedure. This includes screening of donors and recipients, use of uninfected blood products, use of leukocyte filters during transfusion, treatment of existing infections, and vaccination among others.

3. We also recommend regular monitoring of RTRs for the emergence of post renal transplant infections.

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APPENDIX 1: ELIGIBILITY SCREENING FORM

All participants will be screened to meet the eligibility criteria based on inclusion and exclusion criteria as follows

1. Study information

Title	Prevalence, trends and risk factors of infections in post-renal transplant recipients in Kenyatta National Hospital
KNH/UoN/ERC Protocol number	
Investigator	DR. Albert Bikundo Ongosi

2. Participant information

Patients code	
Gender	

3. Inclusion criteria

Inclusion criteria	Yes	No	Number of patients
Has the patient been diagnosed with post-renal? transplant infections?			
Is the patient 18 years and above?			
Is the patient 5 years and below since the renal transplant procedure?			

4. Exclusion criteria

Exclusion criteria	yes	No
Does the patient file contain incomplete information regarding our study?		

Eligibility statement

The patient is eligible ☐ / not eligible ☐ for the study

APPENDIX 2: DATA COLLECTION TOOL

1. **Social demographics**

a) Age ☐ (Years)

a) Sex

Male	Female

b) Weight ☐ (kgs)

c) Residence

The unique number of patients	County of residence

d) Level of education

Uneducated	Primary	Secondary	Tertiary

e) Employment status

Business/ self-employment	Formal employment	Unemployed

f) Marital status

Single	Married	Separated	Windowed	Divorced

g) Smoking status

Current smoker	Previous smoker	Never smoked	Number of cigarettes per day

h) Alcohol intake status

Currently drinking	Previously drinking	Never drunk	Quantity of alcohol consumed per day

2. CLINICAL PROFILE

a) The primary cause of end-stage renal failure

Hypertension	Diabetes mellitus	AUTOIMMUNE	ONES

b) What was/ were the type of infections diagnosed in the RTR?

Bacterial	Viral	Fungal	Protozoan

c) What was the specific type of infections diagnosed in the RTR?

Bacteria	**Type**
Urinary tract infections	
Mycobacterium tuberculosis	
Community acquired pneumonia	
Methicillin resistant staphylococcus aureus	
Vancomycin resistant enterococci	
Infection with norcardia	
Infection with rhodococcus	
Viral	**Type**
Epstein bar viral infection	
BK polyomavirus infection	
HCV infection	
HBV infection	
HIV infection	
Fungal	**Type**
Pneumocystis pneumonia	
Histoplasmosis	
Coccidioidomycosis	
Blastomycosis	
Paracoccidioidomycosis	
Aspergillus	
Candida	
Cryptococcus	
Zygomycoses	

d.) The point of post-transplant at which infection was first diagnosed in the RTR

Less than 3 months	3-6 months	6-12 months	12-18 months	Above 18 months

d) Was/is the patient admitted for this / these conditions?

Yes	No

f) If yes, what's the duration of admission?

g) Was the infection treated?

Yes	No

e) If yes, what was the regimen used for the management of the infection and its duration?

Regimen type	Dose	Frequency	Duration

f) Does the RTR has/have any other diseases(comorbidities)

Yes	No

g) If yes which comorbidity from the table below and forhow long has the RTR been having it?

No	Comorbidity	Present	Absent	Duration
1	Cancer			
2	Diabetes mellitus			
3	Hypertension			
4	Myocardial infarction			
5	Connective tissue disease			
6	Dementia			
7	Chronic pulmonary disease			
8	Congestive heart failure			
9	Peripheral vascular disease			
10	Cerebral vascular disease			
11	Connective tissue disease			
12	Ulcers			
13	Cancer			
14	Aids			
15	Leukemia			
16	Moderate to severe liver disease			
17	Metastatic solid tumors			
18	Others			

h) What were the prophylaxis antimicrobials given before the transplantation procedure and in what duration?

RTR code	Prophylaxis antimicrobial type before transplantation	Dose frequency	Duration
1			
2			

i) Were there complications during the transplantation procedure?

Yes	No

j) If they were there, how were they solved?

Cardiovascular complications	Intervention
Blood clots	
Bleeding	
Leaking from or blockage of the ureter	
Infection	
Failure of a donated kidney	
Rejection of the donated kidney	
Heart attack	
Stroke	

k) Was the immunosuppressant therapy begun immediately?

Yes	No

l) What was the immunosuppressant medication given in the post-transplant period and for how long?

Therapy type	Medications	Duration
Induction therapy		
Maintenance therapy		

m) How was the hygiene of the RTR like?

Unhygienic	Hygienic

n) How was/ were the infections managed and what were the outcome status?

Condition	Medication/medications	Outcome status

o) Was there an improvement in terms of graft survival after the intervention?

Improved	Unimproved

p) If not, what was the ultimate end?

Dialysis	Re-transplant	Death