AFRICA UNIVERSITY
(A United Methodist-Related Institution)

ASSESSMENT OF RENAL FUNCTION AMONG DIABETIC PATIENTS MANAGED AT PATHOLOGY LABORATORY FROM JANUARY TO MAY 2023

BY

THADDEE NKUNDIMANA

A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF BACHELOR OF MEDICAL LABORATORY SCIENCES (HONOURS) IN THE COLLEGE OF HEALTH, AGRICULTURE AND NATURAL SCIENCES

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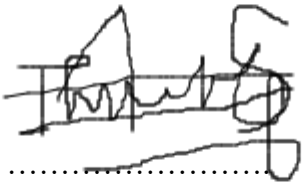
ABSRACT

Diabetes mellitus is the main cause of kidney diseases including end stage renal failure. Studies have found that diabetes affect more than 8% of the global population, and more than 40% of people with diabetes are predicted to develop chronic kidney disease including a significant number who will develop end stage renal kidney diseases (ESKD). It is important to monitor the status of renal function in diabetic patients as a way to provide appropriate health care to patients, which reduces incidences of progression to critical stages of renal diseases. The purpose of the study was to assess renal function status and to identify sociodemographic factors related to abnormal renal function in diabetic patients whose samples were processed at Pathology Laboratory, Harare, from January to May 2023. A retrospective study on the assessment of renal function among diabetic patients at Pathology Laboratory was conducted. A random sampling was done on diabetic patients whose samples were processed for glomerular filtration rate (GFR) and glycated hemoglobin (HbA1c) from January to May 2023.The study recruited 106 diabetic patients whose glomerular filtration rate (GFR) and glycated hemoglobin (HbA1c) were tested and recorded alongside their age and sex in the Laboratory information system at Pathology Laboratory. The prevalence of abnormal renal function among diabetic patients at Pathology Laboratory was 51%. Progression to critical abnormal renal function was found to increase with the age of patients as 7/59 cases with a GFR of less 60ml/min/1/73m^2 were less than 64 years old against 9/46 cases in patients older than 64 in that range of GFR. Male patients with critical abnormal renal function were many compared to females counterpart Regarding to sex, the study found that there were more males than females with critical abnormal renal function; there were 7/38 males against 9/68 females with a GFR of less than 60 ml/min/1.72m^2. Patients with uncontrolled diabetes mellittus presented a high prevalence of critical abnormal renal function compared with patients with controlled DM. There were 14/48 cases with a GFR of less than 60ml/min/1/73m^2 in patients with uncontrolled DM against 2/58 cases in that range of GFR in patients with controlled DM. The study showed that it is important to keep blood glucose level within the normal range as a way to prevent progression to severe renal diseases including end stage renal disease. Findings from this study show the importance of keeping the glucose in normal ranges in DM patients to reduce progression to severe renal diseases including end stage renal diseases, and this is of much importance in aging diabetic patients as the study showed that they are more prone severe diabetic kidney diseases than young ones.

Keywords: Diabetic kidney diseases, Gromerular filration rate (GFR), Glycated Haemoglobin (HbA1c), Diabetes Mellitus (DM)/ diabetes

Declaration

I Thaddée Nkundimana, hereby declare that this is my original work that has not been presented in any academic institution for any award. The other authors' work used in this proposal have been acknowledged accordingly.



Thaddée Nkundimana
……..
Student Name

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Signature

…Mr G. Malunga…..
Supervisor's Name

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Signature

Acknowledgement

My special thanks goes to my supervisor, Mr Garikai Malunga for his timely and constructive feedback when I was writing this proposal. I would like to thank my classmates for their encouragement and support when I was doing this research project proposal.

Dedication Page

I would like to dedicate this work to my late elder brother Felix Niyonsaba for believing in me that one day I was going to make him, his legacy, and our entire family proud and the support he provided from primary school till my third year of undergrad when he passed away. I am very grateful for the sacrifices he made for me.

Acronyms and abbreviations

DM Diabetes mellitus

DN Diabetic nephropathy

DKD Diabetic kidney disease

GFR Glomerular filtration Rate

CC: Creatinine Clearance

CKD Chronic kidney

ESRD End stage renal disease

MDRD Modified of Diet in Renal Disease

MODY Maturity-onset diabetes of the young

T1DM Type 1 diabetes mellitus

T2DM Type 2 diabetes mellitus

UACR Urine albumin-to-creatinine ratio

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CHAPTER 1 INTRODUCTION

1.1. Introduction

Diabetes mellitus (DM) is a metabolic disease, involving inappropriately elevated blood glucose levels (Sapra & Bhandari, 2023). There are many types of DM including type 1, type 2, maturity-onset diabetes of the young (MODY), gestational diabetes, neonatal diabetes, and steroid-induced diabetes (Sapra & Bhandari, 2023). The main types of DM are type 1 and 2.

DM leads to different complications including chronic kidney disease (CKD) and kidney failure(Kaur, Sharma, & Kumbala, 2023). Monitoring the renal function of diabetic patients contributes in early identification of kidney damage, early medical help for patients, and therefore decreasing deaths caused by renal failure. Glomerular filtration rate (GFR) is one of the methods of assessing renal function. GFR measures the rate at which the kidneys' glomeruli filter plasma in order to process it and remove waste products from it (Dabla, 2010).

1.2. Study background

1.2.1. Pathophysiology of DM

Glucose is the main source of energy that living organisms use to carry out their metabolic activities. As for all other metabolites, blood glucose level must remain within certain ranges for a normal functioning of the body. The physiological range of fasting blood glucose is 3.5-5.5 mmol/l (Güemes et al., 2015). Blood glucose level increases after a meal but then rapidly returns back within this normal range (Kaufman, 2000).

Glucose homeostasis is controlled by insulin. Problems arise when insulin level is low or when body cells resist to the action of it; both scenarios result in hyperglycemia, also known as diabetes mellitus. There are two major types of DM. There is type 1 DM (T1DM) that is linked to low production of insulin, most prevalent in young people and type 2 DM (T2DM) that is linked to insulin resistance, most common in adults and elders. Their main common characteristics is that they cause hyperglycemia.

Hyperglycemia results in disruption of many bodily mechanisms including carbohydrates, fat, and protein metabolism (Mujeeb, et al., 2021).As a result, patients can experience acute life-threatening complications such as ketoacidosis (Burtis &,Bruns, n.d). As the disease progresses, patients are at high risk of developing chronic complications including diabetic retinopathy leading to blindness, nerve damage also known as microvascular complications, atherosclerosis also known as macrovascular complication which may result in stroke, gangrene, or coronary disease. Diabetic patients are also at high risk of developing diabetic nephropathy leading to renal failure (Burtis& Bruns, n.d), which was the main focus of this study.

1.2.2. Diabetic nephropathy

According to Selby and Taal (2020), diabetic nephropathy (DN) is a clinical illness marked by progressive decrease in renal function and chronic albuminuria. The renal damage occurs due to hydration causing renal perfusion deterioration; as a result, plasma urea and creatinine increase. Furthermore, the kidney damage happens as a result of the formation of sugar alcohols, sorbitol, through the action of aldose found in glomerulus. So in hyperglycaemia, high intracellular glucose leads to increased sorbitol which cannot pass through cell membranes and therefore remains trapped intracellular. As consequence, water accumulates due to osmotic effects and this is thought to be the cause of nephropathy.

1.2.3. Laboratory assessment of diabetic nephropathy

There are many laboratory tests used to investigate renal function. GFR stands as the best overall indicator of the glomerular function; GFR is the rate in milliliters per minute at which substances in plasma are filtered through the glomerulus (Gounden , Bhatt &Jialal, 2023). The GFR is calculated from the clearance of creatinine. Creatinine is a waste of creatine metabolism, and is cleared from the body through the kidney at a constant rate. The creatinine clearance can be measured using either urine (tested within 24 hours of collection) or serum. The formula for calculation of creatinine clearance refers to the renal clearance formula. Renal Clearance is the ratio of the renal excretion of the substance to its concentration in the blood plasma. The renal clearance formula as seen in Gounden , Bhatt &Jialal, (2023) is the following:

$$\text{Clearance of A} = (U \times V)/ P$$

Where

U is the urinary concentration of substance A

V is the urinary flow rate (mL/min)

P is the plasma concentration of substance A

The units of clearance are mls/min; the normal range = 120-145ml/min

The renal clearance formula presents practical problems of accurate urine collection and volume measurement. As an alternative, a serum or plasma based formula for creatinine clearance (CC) has been developed. That formula is the Cockcroft & Gault formula which is related to body mass, age, and sex. The Cockcroft & Gault formula is the following:

$CC = k[(140\text{-Age}) \times \text{weight(Kg)})] / \text{serum Creatinine } (\mu mol/L)$

Where k = 1.224 for males & 1.04 for females

An increase or decrease outside the physiological range of serum creatinine concentration are indications of kidney impairment. There are many formulae for GFR calculation. The other formula is the Modification of Diet in Renal Disease (MDRD), which also has different version depending on the parameters included in these formula. One of the MDRD formula is the MDRD 4; it takes into consideration factors like age, ethnicity, gender, and serum creatinine. The MDRD 4 formula for GFR is the following:

GFR in mL/min per $1.73m^2$ = (186.3 x Cr^-1.154 x age^-0.203 x GNF x ETF)

(Romero et al., 2012)

where GNF: gender factor (1.0 for male, 0.742 for female)

ETF: Ethnicity factor (1.0 for non black, 1.212 for black).

A blood sample for GFR test is collected in a plain tube, then centrifuged to get serum which is then tested for creatinine level from which GFR is derived. The GFR presents some limitations as an indicator of renal function. Creatinine clearance is influenced by some factors including tubular creatinine secretion and by non-renal factors such as muscle mass, liver function, and non-renal (gastrointestinal) elimination (Doi et al, 2009). Despite these limitations, GFR remains the most used methods in laboratories as it is time and cost effective, and it is derived from a chemical that is supposed to be excreted from the body at a 100%.

Urea or BUN (blood-urea-nitrogen) is also used as a renal function test. Urea is a compound formed in the liver as the end product of protein metabolism and the urea cycle, and it is excreted at 85% by the kidney with the remaining being excreted via the gastrointestinal(GI) tract (Gounden , Bhatt &Jialal, 2023). These same authors state some weaknesses of serum urea test; these weaknesses include the increase of serum urea in conditions not related to renal diseases such as upper GI bleeding, dehydration, catabolic states, high protein diets, and a decrease of serum urea in starvation, low-

protein diet, and severe liver disease. They argue that serum creatinine is a more accurate assessment of renal function than urea though urea is increased earlier in renal disease (Gounden , Bhatt &Jialal, 2023).

Another test for renal function is measurement of albumin in urine. Presence of albumin levels above 300mg/l is termed microalbuminuria and it is a marker for the detection of incipient nephropathy in diabetics. Microalbuminuria is an independent marker for cardiovascular diseases since it shows increased endothelial permeability, and it is also a marker for chronic renal impairment (Gounden , Bhatt &Jialal, 2023). The measurement of albumin in urine is obtained by performing a urine albumin-creatinine ratio test or urine albumin test (Miller et al., 2009). The sample of choice for urine albumin is a one-time urine sample that compares the ratio of albumin to creatinine, and a 24-hour urine collection (Lu, 2022).

1.3. Problem statement

At Pathology Laboratory in Harare, most diabetic patients were usually assessed for renal function by measuring blood electrolytes, urea and creatinine levels from which is derived the GFR. The researcher noticed that most of the GFR results that were obtained from the laboratory were abnormally low. However, there was no study that has been conducted to compile and analyze these renal function tests to come with a prevalence of kidney function abnormalities among patients whose samples were processed at Pathology Laboratory, Harare in diabetic patients. This prompted the researcher to embark on this study.

1.4. Study justification

Monitoring renal function in diabetic patients helps early diagnosis of diabetic nephropathy, and reducing complications including deaths as patients start treatment at an early stage.

1.5. Research objectives

1.5.1. Broad objective

The aim of this study was to assess renal function in diabetic patients whose samples were processed at Pathology Laboratory, Harare, from January to May 2023.

1.5.2. Specific objectives

1. To identify sociodemographic factors associated with abnormal renal function among diabetic patients whose samples were processed at Pathology Laboratory from January to May 2023.
2. To assess the GFR of diabetic patients whose samples were processed at pathology laboratory, Harare, from January to May 2023.
3. To determine prevalence of abnormal renal function among diabetic patients whose samples were processed at Pathology Laboratory from January to May 2023.

1.6. Study questions

1. What are the sociodemographic factors associated with abnormal renal function among diabetic patients whose samples were processed at Pathology Laboratory from January to May 2023?

2. What is the GFR status of diabetic patients whose samples were processed at pathology laboratory, Harare, from January to May 2023?

3. What is the prevalence of abnormal renal function among diabetic patients whose samples were processed at Pathology Laboratory from January to May 2023?

1.7. Study limitations

The study based conclusions on GFR as renal function index; it failed to include urine albumin-creatinine ratio which is another good test for renal function. Furthermore, the study assessed the renal function in one setting.

1.8. Study delimitations

The study consisted of patients living with diabetes mellitus whose samples were processed at Pathology laboratory and whose GFR and HbAIC had been tested. These patients must have visited pathology laboratory in the interval of January to May 2023.

1.9. Chapter Summary

This chapter introduced the proposal of the study title "Assessment of renal function in diabetic patients at pathology laboratories from January to May 2023." In this chapter, the researcher defined diabetes mellitus as a disease consisting of abnormally elevated levels of blood glucose. In the background of the study, this chapter discussed the pathophysiology of DM, diabetic nephropathy, and laboratory assessment of diabetic nephropathy. The chapter highlighted that the aim of the study was to assess renal function in diabetic patients using GFR which gave an idea of the burden of kidney diseases in those patients; this will help in early management of kidney diseases in diabetic patients, hence reducing cases of renal failure and deaths caused by diabetic kidney diseases. This chapter also highlighted the objectives through which the study satisfied the aim above mentioned. This chapter concluded showing the delimitation and limitations to the study.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

Studies have found that kidney disorder, also known as diabetic nephropathy, is an alarming health problem in diabetic patients. Gheith et al, (2016) state that diabetes affect more than 8% of the global population (nearly more than 350 million people), and that estimation is predictable to grow to over 550 million people by the year 2035. The same author adds that more than 40% of people with diabetes are predicted to develop chronic kidney disease including a significant number who will develop ESKD requiring renal replacement therapies (dialysis and or transplantation) (Gheith et al., 2016). Researchers have explored the issue of diabetic kidney disease on different aspects. This chapter reviews existing literature on the prevalence of diabetic nephropathy (DN) in different parts of the world, and the relationship between DN and conditions like hypertension, metabolic disorders, uncontrolled hyperglycemia, and sociodemographic factors like age, sex, body weight and diet.

2.2 Conceptual framework for diabetic kidney disease

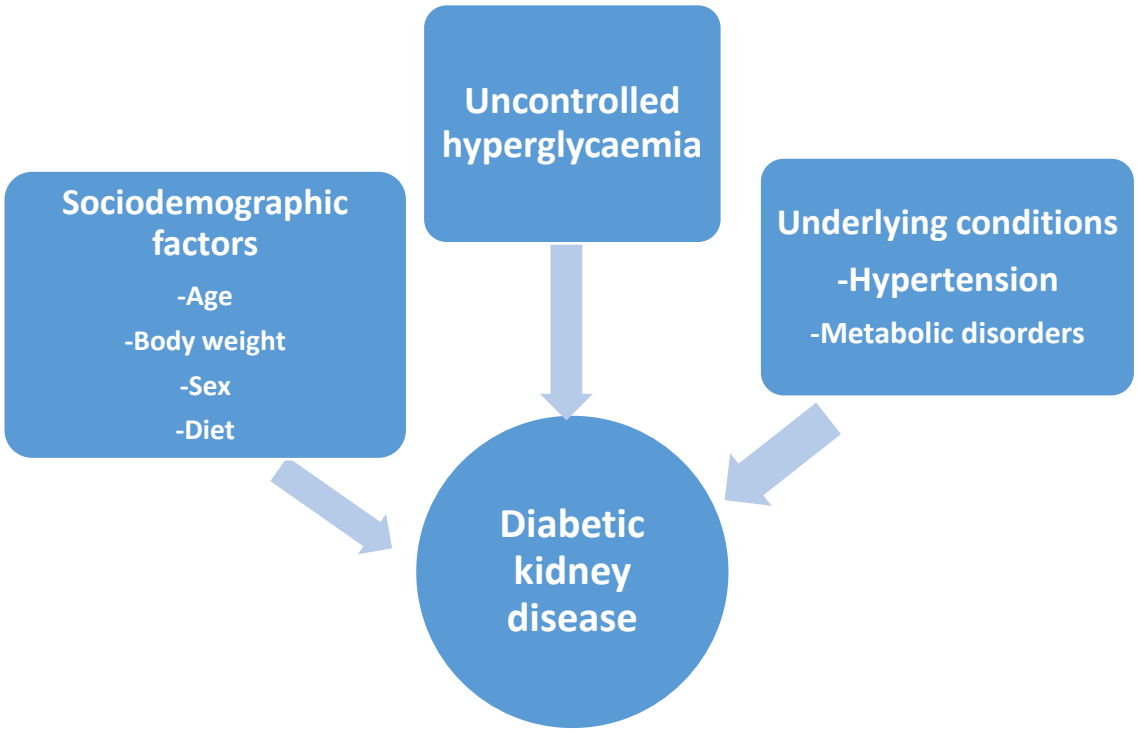

Fig 1. Conceptual framework for diabetic kidney disease

Singh, (2023) defines a conceptual framework as an idea or model representing the subject or phenomena you intend to study. The author adds that a conceptual framework includes key concepts, variables, relationships, and assumptions that guide the academic inquiry (Singh, 2023). In the present study, the conceptual framework links different independent variables- hypertension, metabolic disorders, uncontrolled hyperglycemia, and sociaodemographic factors like age, sex, body weight and diet- that influences the dependent variable which is diabetic kidney disease.

2.3. Literature review in relation to objectives

According to De Boer, (2011) DM is the major cause of diabetic nephropathy leading to end stage renal disease. Diabetic kidney disease (DKD) also known as diabetic nephropathy occurs in 20–40% of all diabetic patients (Gheith, 2016). In the UK,

diabetes nephropathy accounts for 28% of patients starting renal replacement therapy, compared to 44% in the US and 38% in Australia（Selby & Taal, 2020). DN is typically associated with arterial hypertension and increased cardiovascular morbidity and mortality (Selby & Taal, 2020). Moreover, diabetic kidney disease can progress to end stage renal disease (ESRD). Banerjee et al.,(2005) states that glycemic control, baseline albumin excretion, hypertension, dyslipidaemia, age, sex, and duration of diabetes mellitus (DM), ethnicity and smoking status are factors associated with progression of diabetic nephropathy to ESRD. Some others studies have investigated the prevalence of these socio-demographic factors in diabetic patients who have kidney diseases.

In Africa, a study aiming to determine the prevalence and incidence of DN and factors associated with DN was conducted in 16 countries (Noubiap, Naidoo & Kengne, 2015). That study consisted of analyzing publications on DN in those countries. In 32 publications that made the study, the prevalence of DN in those countries varied from 11% to 83.7% of which about 35% may develop end-stage renal disease after 5 years and 18% die from nephropathy after 20 years of disease duration. According to that study, hypertension, obesity, poor glycemic control and diabetes duration were the main risk factors of chronic kidney disease among diabetic patients in Africa. In those countries, the study states that laboratory testing methods varied, with the urine protein test being the most used while urine albumin-to-creatinine ratio and GFR were also used though to a lesser extent.

Another study conducted in Rwanda in 2019 revealed similar findings, with some additions on the factors associated with DN. According to that study done in Rwanda, the prevalence of DN is 14% of diabetic patients (Niyodusenga et al. 2019).That same study found that DN was most prevalent in males. That study adds that long duration of disease, elevated glycosylated hemoglobin (HbA1C), poor adherence to diabetic

medication, elevated creatinine, lower level of education and positive C- Reactive – Protein were factors associated with DN.

In Zimbabwe, a cross sectional study conducted on 344 diabetics patients attending an outpatient clinic in Harare found that 44.8% of these patients had DN (Machingura et al., 2017). Out of 250 females participants, 109 had DN while 45 out of 94 males had DN. Uncontrolled hyperglycemia was one of the factors associated with DN in those patients.

Uncontrolled glycaemia and duration of DM have repeatedly been associated with diabetic nephropathy. Khan, (2023) explains this by mentioning that it take years for kidney damage to occur in diabetic patients. That author adds that the early stages of DKD are characterized by an inability of internal organs and tissues to respond to insulin. With the renal failure progression, the ability of the kidneys to filter out waste is reduced (Khan, 2023). A study conducted in Ethiopia by Mariye et al., (2020) agrees with Khan, (2023) as it found that every year of diabetes duration presented odds of 1.83 times higher of having diabetic nephropathy. Mariye et al., (2020), also found that old age in diabetic patients is a determinant of diabetic nephropathy. These researchers argued that the high prevalence in people with long duration of DM is due to poor possible increase in poor glycemic control and comorbidity, which affect renal functions through vascular damage (Mariye et al., 2023). These researchers also found that hypertension, nonadherence to exercise, diet, and medication were found to be the predictors of diabetic nephropathy among DM patients. These factors also emphasize the role of uncontrolled hyperglycemia in diabetic patients as exercise, diet,and medication (mostly insulin) are meant to try maintain blood glucose in normal ranges.

The diagnosis of diabetic nephropathy was based on urine albumin testing in the study done in Harare as well as the one done in Rwanda. The laboratory diagnostic method

of diabetic nephropathy was not specified in the study done in Ethiopia. While urine albumin test is an accepted test for assessment of kidney function, glomerulus filtration rate (GFR) is also a renal function test. Narva & Bilous, (2015) argues that chronic kidney disease (CKD) is identified by two laboratory tests which estimated glomerular filtration rate (eGFR) as a measure of kidney function, and urine albumin-to-creatinine ratio (UACR) as a measure of kidney damage. Hence, GFR can also be used as a diagnosis method of diabetic nephropathy. GFR is considered abnormal when it is lower 60 mL/min/1.73 m2. Studies have demonstrated that there is a high prevalence of abnormal GFR in diabetic patients. For instance, a study conducted in Thailand showed that almost 40% of 30,377 studied patients with T2DM had GFR less than 60 mL/min/1.73 m2 (Nata et al., 2020). That study revealed that advanced age, albuminuria, high serum uric acid, high systolic BP, HA1C <6%, and HA1C >7% were the major factors associated with impaired GFR. These is also another study from the UK by New et al., (2007) that showed a prevalence of clinically and significantly impaired GFR less than 60 mL/min/1.73 m2 of 31% among patients with T2DM. In Asia. To add on that, data from Asian populations also revealed the prevalence of approximately 24-40% and 30% of albuminuria and CKD respectively among patients with T2DM (Wu et al., 2004; Jia et al.,2009). The current study exclusively assessed the renal function of diabetic patients at Pathology laboratory using GFR to come up with the prevalence of abnormal renal function and factors associated while focusing on age, sex, and HbA1C.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Introduction

This chapter discusses the type of the research design which was used to conduct the research study, the data collection tools, methods of data collection, study population, sampling, data analysis, and ethical consideration.

3.2 Research design

The study design of choice for this study was a retrospective cross sectional design. Retrospective study suited best this research as it presents many advantages. According to Nickson, (2020) a retrospective study analyses preexisting data and is inexpensive, easy, allows identification of potential risk factors and information can be retrieved easily for follow ups. In this study laboratory request forms were reviewed for diabetic patients whose GFR and HbA1C were measured from January to May 2023. This study used a cross sectional study design which is defined by Vega et al., (2021) as a research at a single point in time which can show prevalence of a condition but also can be analytical as it can evaluate the association between two or more variables. This denoted the choice of cross sectional study design for the current study as the prevalence of kidney disorders in diabetic patients and the association between renal disorders and hyperglyicemia and sociodemographic factors were evaluated.

3.3 Study population

The study participants for this research were patients living with diabetes mellitus whose samples were processed for GFR at Pathology laboratory Harare from January to May 2023.

3.4 Sampling

A random sampling method was used to select the study participants. Laboratory numbers of laboratory requests forms meeting selection criteria were written on small pieces of papers. These papers were put together in a box. From the box, a number of papers corresponding to the sample size were randomly picked.

3.5 Inclusion criteria

- All diabetic patients whose samples were processed for GFR at Pathology laboratory Harare from January to May 2023.

3.6 Exclusion criteria

- Non diabetic patients
- Diabetic patients whose GFR and HbA1C were not measured
- Diabetic patients with missing data
- Diabetic patients whose samples were processed at Pathology Laboratory earlier than January 1st 2023 or later than May 31 , 2023

3.7 Sample size

The sample size for this study was 106 participants, calculated using a 90% confidence interval, 0.5 standard deviation and a margin of error of 8% on patients living with diabetes. These conditions of sample calculation mean that the findings were within 8% of the real population value 90% of the time (Indeed Editorial Team, 2023).

According to Nishat (n.d.), the formula for sample size calculation is the following:

$S= Z^2 \times P \times (1-P)/e\text{^}2$

Where:

S=Sample size

Z= Z score for 90% Confidence Interval which is 1.645

P=Standard deviation; for this study, P = 0.5

e=Margin of error; for this study, e =8%

Therefore, the sample size for this study is the following:

$$S = \frac{(1.645)^2 \times (0.5)\,(1-0.5)}{(8/100)^2}$$

Necessary sample size= 105.7

As human beings are always considered as whole numbers, and the 0.7 is above 0.5, rounding off 105.7to a whole number becomes 106

3.8 Study setting

This study was carried out at Pathology Laboratories, Harare branch. Pathology Laboratories is a private a laboratory in Zimbabwe. The main branch is at Baines Intercare Medical Centre, 15 Baines Avenue, Harare. They have another branch in Murambi, Mutare and another one at Athlon Clinic, Harare. The Harare branch of Pathology Laboratory, where this study was conducted, processes samples from Baines Intercare clinic, Athlon clinic, referrals from partner doctors and sometimes referal from the Murambi branch.

3.9 Data analysis and organization of data

The data for this research were presented in form of tables pie charts, and bar graphs through the application of Microsoft Excel to illustrate the data statistics.

3.10 Ethical consideration

This study was conducted after approval by AUREC (Africa University Research Committee). The laboratory manager at Pathology Laboratory provided an approval letter to conduct the study at the Laboratory. That letter was submitted to AUREC together which the research proposal. After approval by AUREC, the study was then conducted. Names of study participants were collected, and information obtained in this study was used for research purpose only.

3.11 Chapter Summary

This chapter mainly focused on methods which were used for this research. The chapter starts by indicating that the researcher used a retrospective cross sectional study as the study consisted of analyzing secondary data to come up with prevalence of kidney disorders in diabetics patients while evaluating factors associated with kidney disorders in those patients. This chapter also indicates that a random sampling method was used to select 106 participants who met inclusion criteria that were also discussed. The chapter discussed data analysis methods which were tables pie charts, and bar graph. This chapter concluded on ethical consideration where it mentioned that this study was conducted after AUREC and research site approval, and information from this study was used for research purpose only.

CHAPTER 4 DATA PRESENTATION

4.0. Introduction

This chapter presents the findings from the data collected and analyzed using Microsoft Excel. Below is a presentation of the data analysis describing the data in pie charts and tables.

4.1. Sociodemographic characteristics of study participants

From the 106 study participants, 68 were females and 38 were males. The age of participants ranged from 10 to 89; 1(0.9%) participant was under 15 years old, 59 (55.6%) participants were between 15 and 64 years old, and 46 (43.4%) participants were elders of 65 years old and above. The socociademographic distributon of the participants are summarized in Table 1.

Table 1: Sociodemographic characteristics of study participants

Age range (yrs)	**Males N(%)**	**Females N(%)**	**Total N(%)**
<15	1 (0.9)	0 (0)	1 (0.9)
15-64	19 (17.9)	40 (37.7)	59 (55.6)
>64	18 (17)	28 (26.4)	46 (43.4)
Total	38 (35.9)	68 (64.1)	106 (100)

4.2. Renal function status of study participants.

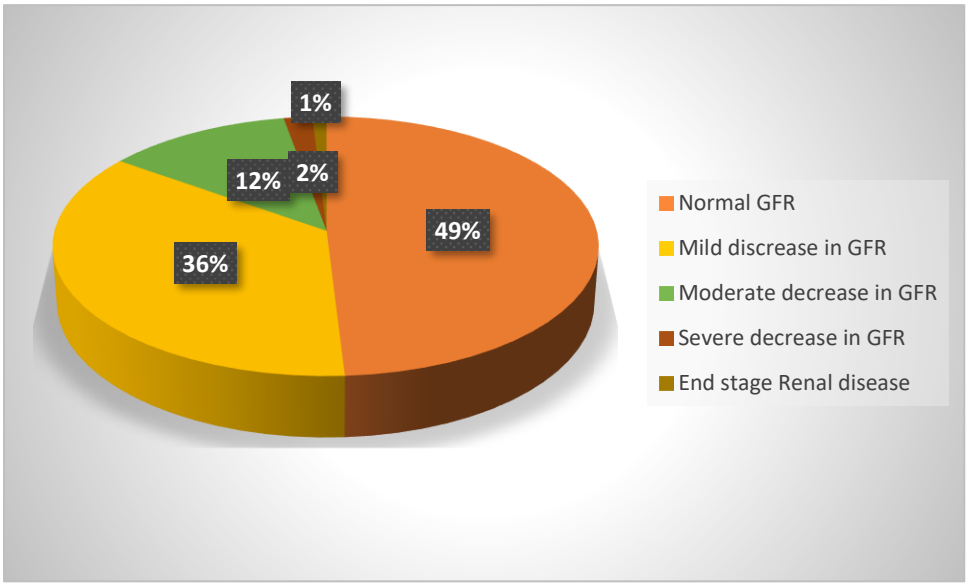

Fig 2: Renal function status of study participants.

Table 2: Interpretation of renal function status in relation to GFR

Renal function status	GFR Values in ml/min/1/73m^2
Normal	>89
Mild decrease in GFR	60-89
Moderate decrease in GFR	30-59
Severe decrease in GFR	15-29
End stage renal disease	<15

Figure 1 shows the renal function status of diabetic patients at Pathology Laboratory from January to May 2023. Fifty two out of one hundred and six participants, representing 49% of study participants, had a normal GFR. Thirty eight out of one hundred and six representing 36% of study participants had a mild decrease in GFR. Thirteen out of one hundred and six (12%) participants had a moderate decrease in GFR. Two out one hundred and six or 2% of study participants and one or 1% of study participants had severe decrease in GFR and end stage renal disease respectively.

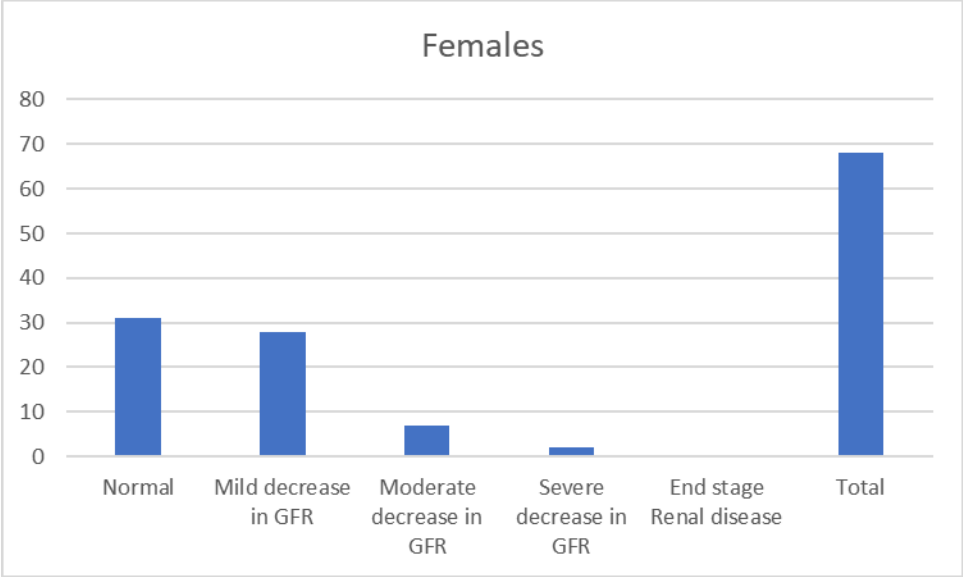

Fig 3. Renal function status of female study participants

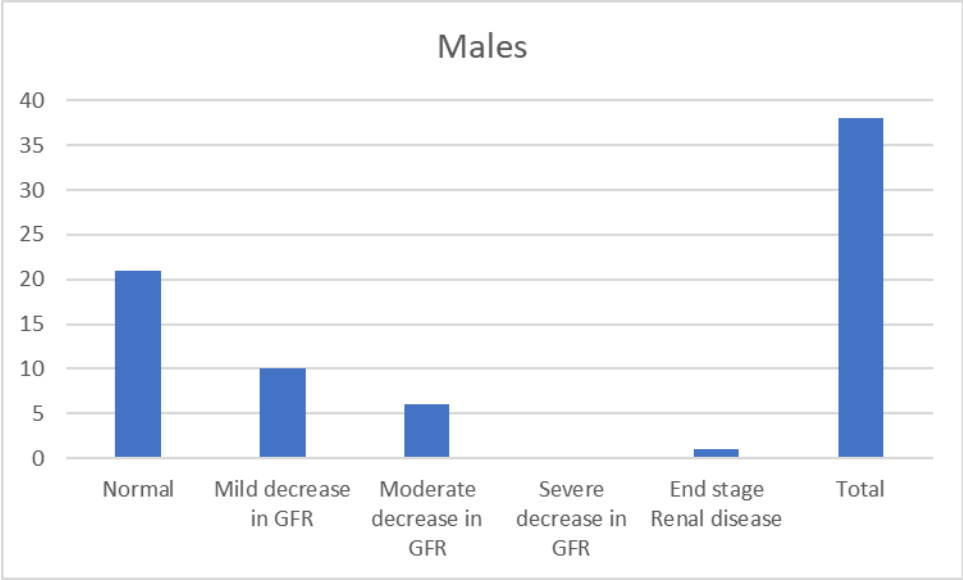

Fig 4. Renal function status of male study participants

Fig 3 and Fig 4 show the gender distribution of renal function status of diabetics patients at Pathology Laboratory from January to May, 2023. Thirty one (29.2%) females against 21(19.8%) males had a normal GFR. Twenty eight (26.4%) females and 10 (9.4%) males had a mild decrease in GFR. Seven (6.6%) females and 6 (5.8%) males had a moderate decrease in GFR. Two (1.9%)females had a severe decrease in GFR while no male felt in that category. One (0.9%) male was in the end stage renal disease while no female was found in that category.

Table 3 shows the renal function status of diabetic patients at Pathology Laboratory from January to May 2023 according to age groups. Only 1(0.9%) participant was under 15 years; the GFR was moderately decreased. In group of 15 to 64 years old, 31 (29.2%) participants had a normal GFR, 22 (20.8%) participants had a mild decrease in GFR, 6 (5.7%) participants had a moderate decrease in GFR; none has a severe or end stage renal disease in this age group. In the group of 65 years old and above, 21(19.8%) participants had a normal GFR, 16 (15.1%) participants had a mild decrease in GFR, 6 (5.7%) participants had moderate decrease in GFR, 2 (1.9%) participants had a severe decrease in GFR, and 1(0,9%) participant was in the end stage renal disease.

Table 3: Renal function status of study participants according to age ranges

Renal function status	**Under 15 years old N(%)**	**15 to 64 years old N(%)**	**≥ 65 years old N(%)**	**Total N(%)**
Normal	0 (0)	31 (29.2)	21 (19.8)	52 (49)
Mild decrease in GFR	0 (0)	22 (20.8)	16 (15.1)	38 (35.9)
Moderate decrease in GFR	1 (0.9)	6 (5.7)	6 (5.7)	13 (12.3)
Severe decrease in GFR	0 (0)	0 (0)	2 (1.9)	2 (1.9)
End stage Renal disease	0 (0)	0 (0)	1(0.9)	1 (0.9)
Total	1 (0.9)	59 (55.7)	46 (43.4)	106 (100)

Table 4 shows the renal function status of diabetic patients at Pathology Laboratory from January to May, 2023 according to whether the diabetes was controlled or uncontrolled using HbA1c results. In participants with controlled DM, 30 (28.3%) participants had a normal GFR, 26 (24.5%) participants had a mild decrease in GFR, 2 (1.9%) participant had a moderate decrease in GFR; no participant was recorded in the

category of severe decrease of GFR or end stage renal disease. In participants with uncontrolled DM, 22 (20.7%) participants had a normal GFR, 12 (11.3%) participants had a mild decrease in GFR, 11 (10.4%) participants had a moderate decrease in GFR; there were 2 (1.9%) participants and 1 (0.9%) participant in the category of severe decrease in GFR and end stage renal disease respectively.

Table 4: Renal function and DM status of study participants

Renal function status	**Controlled DM N(%)**	**Uncontrolled DM N(%)**	**Total N(%)**
Normal	30 (28.3)	22 (20.7)	52 (49)
Mild decrease in GFR	26 (24.5)	12 (11.3)	38 (35.8)
Moderate decrease in GFR	2 (1.9)	11 (10.4)	13 (12.3)
Severe decrease in GFR	0 (0)	2 (1.9)	2 (1.9)
End stage Renal disease	0 (0)	1 (0.9)	1 (0.9)
Total	58 (54.7)	48 (45.3)	106 (100)

The parameters “controlled DM” and “Uncontrolled DM” are as per the HbA1c reporting model at Pathology Laboratory. The interpretation is the following:

Controlled DM: HbA1c of 4.0-6.4%

Uncontrolled DM: HbA1c of >6.4%.

CHAPTER 5. DISCUSSION AND RECOMMENDATIONS

5.1 Introduction

This chapter summarizes and discusses the major findings on the assessment of renal function in diabetics at Pathology Laboratory from January to May 2023. Study

limitations, implication of the results on the public health, and dissemination of the results are also discussed. The chapter concludes by providing recommandations for further studies in relation to the present research.

5.2 Discussion

The assessment of renal function among diabetic patients at Pathology Laboratory showed that 51% of participants had abnormal renal function. This confirmed DM as risk factor of kidney diseases as renal abnormalities were present in more than half of the participants. The majority of renal abnormalities were in the category of mild decrease in GFR, a category that represented 36% of all participants (38 participants). The second largest group of abnormalities of renal function was the moderate decrease in GFR with 12%, followed by severe decrease in GFR and end stage renal disease representing 3% altogether of study participants.

Out of the 38 participants with mid decrease in GFR, DM was controlled in 26 of them against 12 with uncontrolled DM. This study found that the majority of advanced abnormalities of GFR cases, which are moderate decrease of GFR, severe decrease of GFR, and end stage renal disease were observed in participants with uncontrolled DM. These categories of GFR abnormalities were constituted of 15 participants with uncontrolled DM against only 2 participants whose DM was controlled DM. These findings show that patients with uncontrolled DM were more likely to develop severe GFR decrease than those whose DM is controlled. This study was in agreement with other scholars like Machingura et al., 2017, Niyodusenga et al. 2019, as alluded to in the literature review, who pinpointed that poor hyperglycaemia control as as a factor associated with diabetic kidney diseases.

In regard to age, the findings of the study showed that 9 participants with a GFR below 60 mls/min/1.73m^2 were 65 of age and above, while 6 were in the range of 15 to 64 ages old. Only one participant was below 15 years old, with a a moderately decreased GFR. 22/ 59 participants from 15 to 64 ages old had a mild decrease in GFR against 15/46 participants aged 65 and above. These findings showed that the renal function is less likely to progress to severe decrease in GFR in young and adults than in elders. This can be due to a possible long duration of DM in elders which, as mentioned by Mariye et al., (2020), is most often accampanied by poor glycemic control and comorbidity affecting renal functions through vascular damage. Another possible explanation of the remarked decrease in GFR is the normal decrease of renal function as every organ tend to lose its normal function in aging people.

In relation to gender, the study revealed that advanced abnormal renal function was more prevalent in males participants than in females. The ratio of participants with a GFR of less than 60 ml/min/1.72m^2 was 9/68 females and 7/38 males. This was in agreement with a study conducted in Rwanda by Niyodusenga, 2019, which found that diabetic kidney disease was more prevalent in males than in females.

5.3 Limitations

The sample size looked small for this study. Different subgroups of participants chosen to generate potential trends in renal functions in diabetics saw low number of participants which was a limiting factor for generalization of the findings. Subsequent studies should use a big sample size or a different method of sampling; as the population size was 630, census would be a better sampling method.

Beside the sample size weakness, the study failed to record the duration of DM in participants. The longer a patient lives with a disease, the more the effects of the disease

appear. The renal functions status of participants would have accurately been attributed to DM depending on its duration.

Moreover, the study did not track and eliminate other diseases that can influence renal function. Subsequent studies should eliminate comorbidity that are known to affect the renal function.

5.4 Study implications to public health

The study served as a call to raise awareness among health providers, diabetic patients, and the general population about the strong connection between DM, and renal renal diseases. Educational campaigns explaining this link and promoting screening for renal diseases in DM patients would help early detection of renal diseases. This would contribue to prevention of progression to severe renal diseases as the patients would be managed earlier, hence relieving burden caused renal diseases. This would beneficial to the patient, as life would be safer, but also to the public health in general as costs related to renal diseases care would decrease and ressources channeled to other needier sectors of public health.

This study showed also the importance of glycemic control in alleviating long term complications of DM. Diabetics should adhere to medications, diet, exercises when possible, as prescribed to them by health care provider in order to maintain glucose level within normal ranges. By doing so, they would significantly reduce the risk of developing diabetes complications including renal failure.

5.5 Conclusion

The study found that there was a high prevalence of abnormal renal function cases in diabetic patients at Pathology Laboratory. Among 106 participants, 51% of the had abnormal renal function ranging from mild decrease in GFR to end stage renal failure.

Another finding of the study was that patients with uncontrolled DM were more likely to progress to severe abnormal renal diseases compared to patients with controlled DM. Among patients with uncontrolled DM, there were 14 cases with a GFR of less than 60 ml/min/1/73m^2 against 2 cases in patients with controlled DM. This finding showed the importance of keeping the glucose in normal ranges in DM patients in regard to renal function.

In relation to age, the study found that progression to critical abnormal renal function increased with the age of patients. There were 7/59 cases with a GFR of less 60ml/min/1/73m^2 in patients of less than 64 years old against 9/46 cases in patients older than 64 in that range of GFR.

Regarding to sex, the study found that there were more male than females with critical abnormal renal function; There were 7/38 males against 9/68 females with a GFR of less than 60 ml/min/1.72m^2.

5.6 Dissemination of results

The results of the study will be shared with the department of Health Sciences at Africa University and AUREC. Upon the permission of the department, the research project report will also be shared with Pathology Laboratory.

5.7 Study Recommendations

Aside from demonstrating the association between the DM and renal function abnormality especially in patients with uncontrolled DM, it is left to know the effect of duration of DM on the kidney. Consequently, further studies are needed to investigate the relationship between the duration of DM and renal function.

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APPENDICES

Appendix 1. Study Site approval letter

To whom it may concern,

23/02/2024

Dear Sir/Madam

RE: PERMISSION TO CARRY OUT RESEARCH

This letter serves as a permission to allow Thaddee Nkundimana to conduct the research at pathology Laboratories under the research topic, "Assessment of renal function among diabetic patients whose samples were processed at Pathology Laboratory from January 2023 to May 2023"

Yours Faithfully,

For and on behalf of

PATHOLOGY LABORATORIES

D. Chowawa

D.C CHOWAWA[MS]

LABORATORY MANAGER

PATHOLOGY LABORATORIES
NO. 15 BAINES AVENUE
HARARE. ZIMBABWE
2 3 FEB 2024
TEL: 0242 796335/6
CELL: 0731 492 866 / 0783 281 175

DR T.V JAVANGWE
PATHOLOGIST
MBChB(UZ) M.Med(UZ) Dip Forensic Medicine, Pathology(SA), MBA(MSU)

Appendix 2: AUREC research proposal approval letter

Investing in Africa's future

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC)

P.O. Box 1320 Mutare, Zimbabwe, Off Nyanga Road, Old Mutare-Tel (+263-20) 60075/60026/61611 Fax: (+263 20) 61785 Website: www.africau.edu

Ref: AU3170/24

11 March, 2024

THADDEE NKUNDIMANA
C/O Africa University
Box 1320
MUTARE

RE: **ASSESSMENT OF RENAL FUNCTION AMONG DIABETIC PATIENTS MANAGED AT PATHOLOGY LABORATORY FROM JANUARY TO MAY 2023**

Thank you for the above-titled proposal that you submitted to the Africa University Research Ethics Committee for review. Please be advised that AUREC has reviewed and approved your application to conduct the above research.

The approval is based on the following.

a) Research proposal

- **APPROVAL NUMBER** AUREC3170/24
  This number should be used on all correspondences, consent forms, and appropriate documents.
- **AUREC MEETING DATE** NA
- **APPROVAL DATE** March 11, 2024
- **EXPIRATION DATE** March 11, 2025
- **TYPE OF MEETING**: Expedited
  After the expiration date, this research may only continue upon renewal. A progress report on a standard AUREC form should be submitted a month before the expiration date for renewal purposes.
- **SERIOUS ADVERSE EVENTS** All serious problems concerning subject safety must be reported to AUREC within 3 working days on the standard AUREC form.
- **MODIFICATIONS** Prior AUREC approval is required before implementing any changes in the proposal (including changes in the consent documents)
- **TERMINATION OF STUDY** Upon termination of the study a report has to be submitted to AUREC.

AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE (AUREC) APPROVED P.O. BOX 1320, MUTARE, ZIMBABWE

Yours Faithfully

MARY CHINZOU
ASSISTANT RESEARCH OFFICER: FOR CHAIRPERSON
AFRICA UNIVERSITY RESEARCH ETHICS COMMITTEE