KIBOGORA POLYTECHNIC

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF BIOMEDICAL LABORATORY SCIENCES

EFFECT OF HEPATITIS B VIRUS AMONG HIV POSITIVE PATIENTS UNDER ANTIRETROVIRAL THERAPY ATTENDING KIBOGORA DISTRICT HOSPITAL, RWANDA.

Case study: Kibogora district hospital

A research Paper submitted in partial fulfillment of the requirements for the Bachelor's degree

With honor in Biomedical and Laboratory Sciences

SUPERVISOR:

NIYIBIZI J.Baptiste (Assistant lecturer)

PAPER PREPARED BY:

Steven NDIKUMANA

REG NO: 1500398

Jeannette IMANISHIMWE

REG NO: 1500239

Kibogora, September, 2018

DECLARATION

Declaration by the Candidate

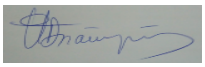
We do hereby declare that this is our own original work and not a duplication of any similar academic work. It has therefore not been submitted to any other institution of higher learning.
All materials cited in this paper which are not our own have been duly acknowledged.

Steven NDIKUMANA
Signed
Date
Jeannette IMANISHIMWE
Signed
Date

Declaration by the Supervisor

I declare that this work has been submitted for examination with my approval as KP Supervisor

SUPERVISOR'S NAME

SIGNED 

DATE

DEDICATION

To my Good, Almighty

To Our Parents

To My beloved husband and Fiancé

To Our beloved brothers and sisters

To Our all Lecturers and clinical instructors especially our supervisor

To All our classmates and Friends

To Kibogora polytechnic staff members

I whole-heartedly dedicate this work.

ACKNOWLEDGEMENTS

We extend sincere thanks to our God for his existence in our life, Jesus who is crucified to save us and the Holy Spirit who continues to guide us in our everyday life.

We would also like to thank Kibogora Polytechnic especially Biomedical Laboratory Sciences department staff for their good assistance, their diligent effort and guidance that enabled us to accomplish this project.

We would like to convey our profound thanks to Kibogora District Hospital administration for their approval to conduct this study.

We are highly addressing our special thanks to our parents, husband, Fiancé, brothers and sisters for their assistance, diligent effort and guidance may God bless them.

ABSTRACT

HIV and HBV share the routes of transmission, as a consequences infection with Hepatitis B Virus are expected to occur in HIV infected patients. The co-infection of Hepatitis B Virus with the Human Immunodeficiency Virus have become a major health care problem as it complicates the clinical course, management and therapy for HIV infection. Hence it is important to identify them as early as possible. HBV and HIV infections shared common routes of transmission, therefore should be a specific program to screen for HBV among HIV infected patients, such a program currently doesn't exist in referral hospital.

The main objective of this study was to assess the effect of hepatitis B virus among HIV positive patients under ART. The specific objectives of this study was to assess liver function tests among HBV positive and HBV negative in HIV patients attending KIBOGORA DH, to assess kidney function tests among HBV positive and HBV negative in HIV patients attending KIBOGORA DH, and To determine CD4 Cells among HBV positive and HBV negative in HIV patients attending KIBOGORA DH. A cross sectional study was to carry out at KIBOGORA DH on 150 HIV positive patients under antiretroviral therapy using convenience sampling technique. Selected participants were tested for HBsAg and code number was used for patients and samples identification. In order to assess liver and Kidney function tests, Aspartate Aminotransferase (AST), Alanine amino transferase (ALT) and creatinine was measured using Humastar 80. CD4 count was done using flow cytometry approach using BD Facscount. Data were analysed using MS excel and SPSS software. Data were accessible by researchers only in order to maintain confidentiality. The findings from the current study helped stakeholders to improve the diagnosis, treatment and management of hepatitis B virus infections in HIV positive patients under ART.

According to patients who are HBV positive, Based on liver function tests especially ALT and AST; in 8 patients all of them (100%) they have elevated values of ALT and AST which are out of range, this means that they have liver disease.

Based on kidney function tests especially creatinine 12.5% of patients have low creatinine whereas 87.5% of patients are within normal range to mean that 12.5% of patients have renal disease and 87.5% of patients are normal.

Based on Immunological tests like CD4 count in 8 patients who are HBV Positive 25% of patients they are below the normal range whereas at 75% they are within the normal range.
It is evident that HBV infections increase pathogenic effect on different organs and systems of the body as revealed from the findings of the current study For patients with HBV negative, 21.9% patients have liver disease, 5.6% patients have renal disease and 21.1% patients have the low number of CD4 comparing to those who were HBV positive, where 100% were having liver disease, 12.5% of patients had renal disease and 25% of patients they were below the normal range. HBV co infection is common in HIV serology positive and can cause significant morbidity and mortality due to the liver injury, severe hepatotoxicity and renal failure and decreased in CD4 Cells. For these reasons, we recommend to Ministry of health, Kibogora District hospital, that the prevention and treatment of HBV infection is mandatory in HIV serology positive.

We also recommend to confected patients to follow the rules of taking drugs and avoid the spreading of infection.

LIST OF ABBREVIATION AND ACRONYMS

ABS: antibody

AG: antigen

CD4: cluster of differentiation

DH: District Hospital

HBsAg: Hepatitis B surface antigen

HIV: Human immune deficiency virus

WHO: World Health Organization

ART: Antiretroviral therapy

HCC: Hepatocellular Carcinoma

CHB: Chronic Hepatitis B

LIST OF TABLES

TABLE OF CONTENTS

CHAPTER ONE: GENERAL INTRODUCTION

1. 0 DEFINITION OF KEY TERMS

Virus: is an infectious agent, of small size, possessing one type of nucleic acid (DNA or RNA). It reproduces only when it is inside a living cell (V. Racaniello, 2009).

The surface antigen: is heterogeneous lipoprotein complex specific to the hepatitis B virus (Tarr, 2018).

Hepatitis: this refers to the inflammation of the hepatic parenchyma. These hepatic diseases are caused mostly by viruses of types A, B and C, but sometimes can also be caused by others like viruses of type D and E, hepatic toxicity, alcoholic hepatitis and bacterial hepatitis (CDC, 2017).

Viruses of hepatitis: There are many viruses that are responsible for hepatic infection. These includes; herpes bar viruses (EBV), cytomegary viruses (CMV), Arbor virus (e.g: yellow fever), and filovirus (e.g: Ebola virus), (CDC, 2018).

ARV: Antiretroviral therapy (ART), treatment that suppresses or stops a retrovirus, one of the retrovirus is the human immunodeficiency virus (HIV) that causes AIDS. Retroviruses are so named because they carry their genetic information in the form of RNA rather than DNA so that the information must be transcribed in reverse direction from RNA into DNA (WHO, 2012).

HIV: Human Immunodeficiency Virus, and is the virus that causes AIDS.HIV destroys certain blood cells that are crucial to the normal function of the immune system, which defends the body against illness (WHO, 2018).

Opportunistic infection: An infection by a microorganism that normally does not cause disease but becomes pathogenic when the body's immune system is impaired and unable to fight off infection (World Health Organization, 1998).

1.1 BACKGROUND OF THE STUDY

Various studies have shown that more than 240 million people are chronically infected with HBV, These numbers far exceed the number of people living with HIV, estimated at 34 million.Co-infection with viral hepatitis and HIV becomes a serious public health problem.According to world health organization (WHO, 2012)

10% of people who lives with HIV are mostly affected by chronic hepatitis B virus (HBV) infection. With variation among geographical regions depending on the nature of the epidemic and other factors (WHO, 2012)

In the United States and Western Europe, co-infection with hepatitis B virus (HBV) and HIV is also common, 70-90% of HIV-infected have evidence of past or active infection with HBV, and this infection is often acquired in adolescents and adults by sexual intercourse. Although HBV clearance which is acquired in adulthood is estimated at >90% of immunocompromised individuals, HIV-infected persons are the most likely persons who clear spontaneously HBV. For that reason, chronic HBV infection occurs in 5-10% of HIV-infected individuals who are exposed to HBV; at a higher rate (10 times) than that for the general population. In the United States, HIV/HBV co-infection rates are seen among men who have sex with men (MSM), while in Asia and sub-Saharan Africa, the prevalence of HBV among co-infected individuals is also higher at an estimated range of 20-30% where vertical and early childhood exposure are the most common modes of transmission, respectively, and overall HBV prevalence is higher (Hoffmann, 2007).

HBV and HIV have common routes of transmission, but HBV is about 100 times more infectious (Thio, 2002). Consequently, in some settings up to two thirds of all HIV-infected people have a blood marker of past or present HBV infection (Thio, 2002)

The goal of HBV treatment for persons with HIV coinfection include suppressing HBV viral replication and minimizing ongoing hepatic damage, Antigens loss and seroconversion to Antibodies indicate that active HBV disease is resolved in HIV/HBV coinfected patients, therefore treatment of HBV coinfected patients is often required (Lok, 2001)

ART has potent activity against both HIV/HBV include as follow lamivudine(3TC),TDF or emtricitabine at any level of CD4 count in all HBV/HIV co-infected patients with evidence of active liver disease (WHO, 2010)

HIV/HBV co-infected patients with an indication for ART should be started on HIV treatment that includes effective anti-HBV treatment. TDF with 3TC or FTC combination is recommended as a highly effective first-line treatment for HBV. Individuals who cannot take TDF because they have problem with their renal function (renal insufficiency) or other intolerance may take entecavir treatment for HBV instead of TDF. Treatment with 3TC or FTC as the only HBV-active agent in ART (i.e., HBV monotherapy) is not recommended due to a high risk of developing HBV drug resistance over time and the drug should therefore preferably always be combined with TDF (Benhamou, 2005)

In view of this project, we decided to conduct this study because special attention are taken to prevent only healthy HIV negative individuals against HBV, there is need to increase also the prevention among HIV positive patients against HBV, this study seeks to establish the occur ence of HBV among HIV positive patients which can serve as a baseline information generally in Rwanda (Benhamou, 2005).

1.2 PROBLEM STATEMENT

Hepatitis B virus (HBV) infection presents a global health problem. Worldwide, at least 2 billion people or one third of the world's population have been infected with HBV. Approximately 378 million people are chronic carriers and 620,000 people die each year from acute and chronic sequelae of HBV infection. Furthermore, 4.5 million new HBV infections occur worldwide each year, of which a quarter progress to liver disease (CDC, 2015).

In Nigeria, hepatitis B virus (HBV) infection has reached hyper endemic levels and its nature and origin have been described as a puzzle and this study was investigated the molecular epidemiology and epidemic history of HBV infection in two semi-isolated rural communities in North/Central Nigeria. It was expected that only a few, if any, HBV strains could have been introduced and effectively transmitted among these residents, reflecting limited contacts of these communities with the general population in the country (CDC, 2005)

For this reason we are going to assess the effects of HBV among HIV positive patients under antiretroviral therapy attending Kibogora District Hospital

Although the effect of HBV on HIV patients is known worldwide, information regarding effect of HBV infection in HIV seropositive patients in our hospitals is limited and strategies for HBV prevention among HIV positive patients are not reinforced. Lack of data prevents early detection of effect of HBV infection in HIV positive patients under antiretroviral therapy leading to a high rate of morbidity and mortality, consequently special attention should be taken to estimate the effect of HBV among HIV positive patients under ART. Patients infected with HBV are at high risk of developing liver and kidney failure as the inflammation got severe due to such coinfection and antiretroviral drugs. Furthermore the CD4 count may depleted due to immune suppression caused by coinfection. Moreover, there are no specific and effective programs to prevent HBV among HIV infected patients (CDC, 2005).

Although, it was reported in different studies that HBV cause serious complications among HIV patients, the actual effects of this virus among HIV patients under antiretroviral therapy are not well documented at Kibogora District Hospital, that's why there is a need to carry out this research (WHO, 2016).

1.4 RESEARCH QUESTIONS

What are the effects of HBV among HIV Positive Patients?

1.5 OBJECTIVES OF STUDY

1.5.1 Main Objective

To assess the effects of HBV among HIV positive patients under antiretroviral therapy attending Kibogora District Hospital

1.5.2 Specific objectives

1. To assess liver function tests among HBV positive and HBV negative among HIV positive patients under antiretroviral therapy attending KIBOGORA DH.

2. To assess kidney function tests among HBV positive and HBV negative HIV positive patients under antiretroviral therapy attending KIBOGORA DH.

3. To determine CD4 Cells among HBV positive and HBV negative among HIV positive patients under antiretroviral therapy attending KIBOGORA DH.

1.6 SIGNIFICANCE OF THE STUDY

Information obtained from the study attracts the attention of health officials and partners in the health sector in order to propose corrective actions among HBV/HIV co-infected patients. The present study might help researchers to improve skills and knowledge in terms of laboratory diagnosis of HBV infection. The study also provides the much needed data for all partners in health to implement sustainable care strategies for HBV/HIV co-infected patients in the country. Data from this study have shown the need of increase HBV early diagnosis among HIV patients and ensure that HBV/HIV co-infected patients get treatment at an early stage of infection.

1.7 LIMITATIONS OF THE STUDY

To date there is no enough resources that will help people to do a health systems researches.
Unavailability of test kits to use when we are performing some tests during the case study.
The people who are concerning in the case study they are not available at the same time leading to a high delaying to collect data.

Several problems were encountered including limited time to accomplish the study, inadequate financial support to purchase reagents and test kit.

Delayed permission to collect data, unwillingness of patients to participate in the study.

1.8 SCOPE OF THE STUDY

The study was carried out for three months from July up to September at KIBOGORA District Hospital, located in NYAMASHEKE District, KANJONGO Sector in Kibogora city, this hospital has been selected as the study area because it is the District hospital that serve almost all the people of NYAMASHEKE District and has a center in charge of HIV patients under ART.

CHAPTER TWO: LITERATURE REVIEW

2 .1. INTRODUCTION

Hepatitis B virus (HBV) is the most important and prevalent infectious agent leading to inflammation of human liver. Recent reports stated that 360 millions of people are globally suffering from the chronic forms of HBV infection (CHB). It has been documented that prolonged forms of hepatitis B, including active and in-active CHB, can be considered as major candidates for induction of several complications such as hepatocellular carcinomas (HCC) and cirrhosis. In addition to HCC and cirrhosis development, hepatitis B infection is also able to develop active and acute forms of HBV infection in congenital and/or acquired immunodeficiency and also following immunosuppressive therapy. Human acquired immunodeficiency virus (HIV) attacks CD4+T cells, as critical cells in both cellular and humoral immunity, leading to defective cell-mediated and humoral immune responses and predisposing patients to future infectious diseases (Iran J Public Health, 2014).

EMPIRICAL LITERATURE

2.2 Literature relating to the assessment of liver function tests among HBV positive and HBV negative in HIV patients attending KIBOGORA DH according to age and sex

According to A retrospective study was conducted, on eligible treatment-naive patients who presented between August 2004 and February 2007 to the University College Hospital (UCH), Ibadan, Nigeria. Demographic data and pre-treatment laboratory results (hepatitis B surface antigen (HBsAg), HCV antibodies (anti-HCV), ALT, CD4 count and viral load) were retrieved from the medical records. Fisher's exact, two sample t-tests, and the Wilcoxon rank sum tests were used to compare groups. A logistic regression model was fitted to explore characteristics associated with co-infection status. A total of 1779 HIV-infected patients (male: female ratio, 1:2) met inclusion criteria. HBsAg was present in 11.9%, anti-HCV in 4.8% and both markers in 1%. HBsAg was more common among males than females (15.4% vs. 10.1%, respectively $p = 0.001$) while anti-HCV was detected in a similar proportion of males and females (5.3% versus 4.6%, respectively $p = 0.559$). HIV-infected patients with anti-HCV alone had a lower mean baseline CD4 count compared to those without anti-HCV or HBsAg (197 cells/mm3 vs. 247

cells/mm3, respectively p = 0.008). Serum ALT was higher among patients with HBsAg compared to those without HBsAg or anti-HCV (43 International Units (IU) vs. 39 IU, respectively p = 0.015). Male gender was associated with HBV co-infection on logistic regression. More HIV-infected females than males presented for care in this cohort identified a relatively high prevalence of HBV and HCV co-infection in general, and a higher rate of HBV co-infection among males than females. Pre-treatment CD4 count was significantly lower among those with HCV co-infection, while ALT was slightly higher among those with HBV co-infection. Triple infection with HIV, HBV and HCV was present in a small but significant proportion of patients. These findings underscore the importance of testing for HBV and HCV in all HIV-infected persons in our setting. The clinical and public health implications of the convergence of the human immunodeficiency virus (HIV) epidemic and chronic viral hepatitis in sub-Saharan Africa are poorly understood. This study was designed to determine the seroprevalence of hepatitis B virus (HBV) and hepatitis C virus (HCV), and the impact of co-infection on baseline serum alanine transaminase (ALT), CD4+ T lymphocyte (CD4) count, and plasma HIV-RNA (viral load) in a cohort of HIV-infected (CDC, 2015).

2.3 Literature relating to the assessment of kidney function tests among HBV positive and HBV negative in HIV patients attending KIBOGORA DH according to age and sex

Chronic hepatitis B virus (CHB) infection is one of the most common causes of chronic liver disease, cirrhosis, and hepatocellular carcinoma (HCC) worldwide. Many patients with CHB have variable degrees of functional renal impairment, and approximately 2 to 15% of patients on hemodialysis have CHB. Several therapeutic regimens have been developed in the past years, among which oral nucleoside and nucleotide analogues have been demonstrated to be efficient and well tolerated. However, they all are excreted in the urine and may thus require dosage adjustment in patients with decreased renal function. Furthermore, a number of them may in addition be toxic to the kidneys, especially in those patients presenting with renal insufficiency (John Collins, 2014).

CHB has been linked to renal disease for decades. Renal abnormalities (RA) associated with hepatitis B virus (HBV) may be of multiple origins. Glomerulonephritis (GN) is a well-described complication of chronic hepatitis B. HBV-associated glomerulonephritis has been frequently reported in the literature and the association of HBV and glomerulopathy is striking, especially

in children with reported incidences of nephrotic syndrome, nephritic syndrome, and both of them in 64%, 57%, and 35%, respectively. Epidemiological studies have shown that chronic carriage of HBV in adult individuals may lead to the development of nephrotic syndrome, the commonest histological type being membranous nephropathy. In total, the different morphological forms of HBV-associated renal injuries may include membranous nephropathy, membranoproliferative glomerulonephritis, mesangial proliferative glomerulonephritis, immunoglobulin A (IgA) nephropathy, focal segmental glomerulosclerosis, and polyarthritis nodosa.

Renal injury caused by HBV may be related to immune reactions, with glomerular deposition of immune complexes or virus-induced specific immunological effector mechanisms (specific T lymphocyte or antibody). Such reactions may damage the kidney or have indirect effects from virus-induced cytokines/mediators on renal tissue. HBV antigens (hepatitis B surface antigen (HBsAg) and hepatitis B core antigen (HBcAg) and HBeAg) are also expressed in renal tubular epithelial cells. They can up regulate complement mediated inflammatory gene pathways and contribute to the pathogenesis of nephropathy (John Collins, 2014).

2.4 Literature relating to the determination of CD4 Cells among HBV positive and HBV negative in HIV patients attending KIBOGORA DH according to age and sex

The emergence of chronic infection due to Hepatitis B Virus (HBV), in the context of immunosuppression in patients infected with Human immunodeficiency virus (HIV), remains a public health problem. According to the World Health Organization (WHO, 2015)

Nearly 36.7 million people in the world, are living with HIV/AIDS (PLHA) and 2/3 of those are living in Sub-Saharan Africa. In addition, this area is hyper endemic for HBV with an exposure rate up to 90%. Around 257 million people living with hepatitis B and in 2015 around 1.34 million people die of viral hepatitis, near to HIV death rate (WHO, 2017)

Due to its highly contagious capacity and some transmission routes in common with HIV, HIV-HBV co-infection is frequent in resource-limited settings (RLS), where 10% of HIV infected are co-infected with HBV. Chronic HBV infection is responsible for about 60% of the total liver cancer in RLS. Studies highlight the negative impact of co-infection. HIV favors the progression of HBV infection to cirrhosis and hepatocellular carcinoma. Studies show that HIV promotes an

expansion of HBV DNA VL and increases the risk of liver-related disease particularly among patients with low CD4 cell counts (less than 200 cells/mL). Thus, HIV/HBV co-infection negatively impacts immunological recovery as compared to HBV mono-infection (WHO, 2017).

2.5 Any other relevant and related literature to support the study

The majority of HIV-infected patients were screened and vaccinated for HBV infection and underwent surveillance for hepatocellular carcinoma. Decisions regarding the performance of liver biopsy, threshold to initiate therapy, and criteria to discontinue therapy varied, reflecting inconsistencies in available treatment guidelines. Treatment decisions reflected concerns regarding future drug resistance in patients who are naive to antiretroviral therapy and the emergence of drug resistance in patients receiving antiretroviral therapy
(Sarah Hackenmueller, PhD. 2013).

CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

3.0INTRODUCTION

This chapter states the methods that have been used while carrying out the study.It includes the description of the study area,the research design,the study population,the study sample and sampling techniques,procedures of data collection,data analysis,and ethical consideration.

3.1. STUDY AREA

This study was at KIBOGORA District Hospital, located in NYAMASHEKE District.

3.2. STUDY DESIGN

This study was a cross-sectional study that was carried out at KIBOGORA District Hospital

3.3. TARGET POPULATION

The population is composed of the number of HIV infected patients under anti-retroviral treatment attending Kibogora District Hospital.

3.4. SAMPLE SIZE

The study sample is 150 cases among HIV patients co-infected with HBV at Kibogora DH. The size of the sample was obtained by using the following formula

$$N = \frac{P \times Q}{(E/1.96)^2}$$ (Robert, 1997)

Where:

N: Sample size

P: Target population=10 % (Francisco center, 2009).

Q=100-P=100-10 %=90 %

E: Error=5%

$N=0.1\times0.90/ (0.05/1, 96)^2$

N=145

This sample size of 145 should be the minimum so we decided to work with 150 participants who accepted voluntary to be part of our study.

3.5. RESEARCH INSTRUMENTS FOR DATA COLLECTION

The code number was used for patient identification and blood samples are collected from all HIV positive patients fulfilled our inclusion criteria in vacutainer tubes with red tubes without anticoagulant. In the immunoserology laboratory unit, samples are centrifuged by using centrifuge. HBsAg test and HIV rapid test are performed, patients who are found reactive to HIV antibodies during HIV testing are included in the study group and tested for HBsAg test, data collection form is designed to record information obtained.

Materials

- Gloves
- Micropipette
- Strips
- Red tubes without anticoagulant
- Arele combo HIV test
- Start pack HIV Test
- Timer
- Rapid HBsAg test

3.6 DATA COLLECTION PROCEDURES

This study was conducted in Kibogora DH in charge of HIV infected patients and laboratory departments (immunoserology unit).The data collection will take a period of four weeks after an approval from Kibogora DH clinical Research Department committee, we will have gone to Kibogora DH department in charge of HIV infected patients. These patients normally came for their CD4 count test. And then blood samples will be collected by researchers.

3.6.1 HIV Testing and Procedure

1. Take 50 microliters of serum
2. Put on rapid test kit already labeled with patient code number
3. Wait for 10-20 minutes for reading the results.
4. Test results are read visually without any other instruments.

Result interpretation:

Test was negative if one control line appeared on test kit and positive if both control and test lines appeared in red color.

3.6.2 HBV Testing and Procedure

A screening diagnosticRapid Test Kits (HBsAg) of hepatitis B infection was used.

1. Take 50 microliters of serum.
2. Put on rapid test kit already labeled with patient code number.
3. Wait for 10-20 minutes for reading the results.
4. Test results are read visually.

Result interpretation:

Test is reported negative if one control line appears on test kit and positive if both control and test lines appear in red color.

Procedure for ALT/AST and creatinine measurement

The automated Machine (Cobas C311) has been used and following the SOPs Referring to the manufacturer's Instructions.

INCLUSION CRITERIA

- People who are HIV Positive
- People who are under Anti-Retroviral Therapy
- People who are HBV- and HBV+

EXCLUSION CRITERIA

* Pregnant females
* Patients who were receiving ARV drugs therapy
  From other centers
* Patient not giving consent for the study.
* People who are HIV Negative
* Those People who are not under Anti-Retroviral Therapy

3.8DATA ANALYSIS

Data was analyzed using Microsoft Excel and SPSS Version 21. Results were presented in the form of tables using Microsoft word according to the specific objectives of our study.

3.9. ETHICAL ISSUES

An authorization letter is given by Kibogora Polytechnic and presented to the General Director of Kibogora District hospital, chief of service in charge of HIV patients under ART and also to the Clinical Research Department. The consent forms given to the patients after an explanation to the patients about the research. The outcome was presented to the Kibogora DH research committee and to the department in charge of HIV infected patients in order to follow those patients ensuring that all information coming from the research outcome is safe and well-kept so that there is no anyone else able to know about these research outcome unless those who are concerned.

CHAPTER FOUR: DATA PRESENTATION, ANALYSIS, INTERPRETATION AND SUMMARY

4. 0. INTRODUCTION

In this chapter the data from the data collection for HIV Patients under Anti-Retroviral Therapy attending KIBOGORA District Hospital are presented, analyzed and interpreted. The following points are going to be discussed: the data presentation and analysis, discussion of findings and summary of findings. The data were presented in form of tables. As stated in previous chapters, in the research project, the researcher has taken a sample size of 150 respondents from KIBOGORA District Hospital.

4.1. PRESENTATION OF FINDINGS + INTERPRETATIONS

In this part of the dissertation, the investigator is presenting the data and interpreting responses from the respondents. Other information was obtained from the investigator's observation and the tests performed during the Research. The researcher has conducted his research among the HIV positive patients under Anti-Retroviral Therapy attending KIBOGORA District Hospital.

Table 1: Frequency Tables

POSITIVE	8	5.3
NEGATIVE	142	94.7
Total	150	100.0

- Within 150 patients tested 5.3% were HBV Positive whereas 94.7% were HBV Negative.

Table 2: AGE

Range	Frequency	Percent
10-20	3	2.0
21-30	4	2.7
31-40	7	4.7
41-50	74	49.3
51-60	49	32.7
61-70	13	8.7
Total	150	100.0

* As these ages are arranged in form of interval, 2% of the participants were aged between10-20 years,
* Between 21-30 years there was 2.7% patients,
* Between 31-40 years we have 4.7%Patients,
* Between 41-50 years we have 49.3% patients,
* Between 51-60 years we have 32.7% patients,
* And between 61-70 years we have 8.7% patients.

Table 3: SEX

sex	Frequency	Percent
MALE	55	36.7
FEMALE	95	63.3
Total	150	100.0

In 150 patients that have been tested;

* 36.7% patients were males

* 63.3% patients were females

Table 4: ALT

Range	Frequency	Percent
0-20	32	21.3
21-40	84	56.0
41-60	21	14.0
61-80	8	5.3
81-100	3	2.0
101-120	1	.7
141-160	1	.7
Total	150	100.0

In accordance with the patients that have been tested for ALT they attended and got the following

Results in percentages.

- 32 patients attended and they had results ranging between 0-20 at 21.3 percent
- 84 patients attended and they had results ranging between 21-40 at 56 percent
- 21 patients attended and they had results ranging between 41-60 at 14 percent
- 8 patients attended and they had results ranging between 61-80 at 5.3 percent
- 3 patients attended and they had results ranging between 81-100 at 2 percent
- 1 patient attended and he had results ranging between 101-120 at 0.7 percent
- 1 patient attended and he had results ranging between 121-140 at 0.7 percent

Table 5: AST

Range	Frequency	Percent
0-20	21	14.0
21-40	83	55.3
41-60	28	18.7
61-80	12	8.0
81-100	2	1.3
101-120	1	.7
121-140	2	1.3
141-160	1	.7
Total	150	100.0

According to the patients that have been tested for AST they attended and got the following Results in percentages.

- 21 patients attended and they had results ranging between 0-20 at 14 percent
- 83 patients attended and they had results ranging between 21-40 at 55.3 percent
- 28 patients attended and they had results ranging between 41-60 at 18.7 percent
- 12 patients attended and they had results ranging between 61-80 at 8 percent
- 2 patients attended and they had results ranging between 81-100 at 1.3 percent
- 1 patient attended and he had results ranging between 101-120 at 0.7 percent
- 2 patients attended and they had results ranging between 121-140 at 1.3 percent
- 1 patient attended and he had results ranging between 141-160 at 0.7 percent

Table 6 CREATININE

	Range	Frequency	Percent
	0-0.5	18	12.0
	0.6-1.6	124	82.7
	>1.6	8	5.3
	Total	150	100.0

In this research 150 people have been tested for creatinine and have gotten the following results

- 18 people had the results ranging between 0-0.5 at 12 percent
- 124 people had the results ranging between 0.6-1.6 at 82.7 percent
- 8 people their results were >1.6 at 5.3 percent

Table 7:CD4

Range	Frequency	Percent
<200	4	2.7
201-400	29	19.3
401-600	44	29.3
601-800	43	28.7
801-100	18	12.0
1001-1200	8	5.3
1201-1400	2	1.3
1401-1600	1	.7
1601-1800	1	.7
Total	150	100.0

In fact, within 150 patients tested for CD4 they got the following results

- 4 patients had the results below 200 CD4 at 2.7 percent
- 29 patients had the results ranging between 201-400 CD4 at 19.3 percent
- 44 patients had the results ranging between 401-600 CD4 at 29.3 percent
- 43 patients had the results ranging between 601-800 CD4 at 28.7 percent
- 18 patients had the results ranging between 801-1000 CD4 at 12 percent
- 8 patients had the results ranging between 1001-1200 CD4 at 5.3 percent
- 2 patients had the results ranging between 1201-1400 CD4 at 1.3 percent
- 1 patients had the results ranging between 1401-1600 CD4 at 0.7 percent
- 1 patients had the results ranging between 1601-1800 CD4 at 0.7 percent

Frequency Tables for HBV negative patients

Table 8:AGE

Range	Frequency	Percent
10-20	3	2.1
21-30	4	2.8
31-40	7	4.9
41-50	69	48.6
51-60	46	32.4
61-70	13	9.2
Total	142	100.0

According to this table all these HBV negative patients as they are grouped in age interval

It is remarkable that many people (69) are frequently ranging between 41-50 years at 48.6%.

Table 9:SEX

Sexe	Frequency	Percent
MALE	51	35.9
FEMALE	91	64.1
Total	142	100.0

A big number of people who are HBV negative are females

As they are presented at 64.1%.

Table 10:ALT

Range	Frequency	Percent
0-20	31	21.8
21-40	80	56.3
41-60	20	14.1
61-80	7	4.9
81-100	2	1.4
101-120	1	.7
141-160	1	.7
Total	142	100.0

For these people who are HBV negative, 111patients (31+80) at 78.1% (21.8+56.3)

Have the normal value of ALT whereas 31patients at 21.9% are out of range.

Table 11:AST

Range	Frequency	Percent
0-20	20	14.1
21-40	80	56.3
41-60	26	18.3
61-80	10	7.0
81-100	2	1.4
101-120	1	.7
121-140	2	1.4
141-160	1	.7
Total	142	100.0

For this table of AST, 100 patients (20+80) at 70.4% (14.1+56.3)

Are within the normal range whereas 42 patients at 29.6% are out of range.

Table 12:CREATININE

Range	Frequency	Percent
0-0.5	18	12.7
0.6-1.6	116	81.7
>1.6	8	5.6
Total	142	100.0

94.4% of patients are within normal range for creatinine test but

5.6% of patients are out of range.

Table 13:CD4

Range	Frequency	Percent
<200	2	1.4
201-400	28	19.7
401-600	41	28.9
601-800	42	29.6
801-1000	17	12.0
1001-1200	8	5.6
1201-1400	2	1.4
1401-1600	1	.7
1601-1800	1	.7
Total	142	100.0

30 patients (2+28) at 21.1% are out of normal range because they have low CD4 Count, 112 patients at 78.9% are within the normal range.

Frequency Tables for HBV positive

Table 14:HBV

Range	Frequency	Percent
POSITIVE	8	100.0

Table 15 :AGE

Range	Frequency	Percent
41-50	5	62.5
51-60	2	25.0
61-70	1	12.5
Total	8	100.0

The patients who are HBV positive at 62.5%

Most frequently they are ranging between 41-50 years.

Table 16 :SEX

Range	Frequency	Percent
MALE	2	25.0
FEMALE	6	75.0
Total	8	100.0

Most frequently females are the patients who are HBV positive

At 75%.

Table 17 :ALT

Range	Frequency	Percent
41-60	1	12.5
61-80	4	50.0
81-100	1	12.5
101-120	1	12.5
141-160	1	12.5
Total	8	100.0

For those patients who are HBV positive at 100%

All of them they are out of range for ALT test.

Table 18 :AST

Range	Frequency	Percent
41-60	1	12.5
61-80	3	37.5
81-100	1	12.5
101-120	1	12.5
121-140	1	12.5
141-160	1	12.5
Total	8	100.0

For those patients who are HBV positive at 100%

All of them they are out of range for AST test.

Table 19 :CREATININE

Range	Frequency	Percent
0-0.5	1	12.5
0.6-1.6	7	87.5
Total	8	100.0

87.5% of patients are within normal range for creatinine test but

12.5% of patients are below normal range.

Table 20:CD4

Range	Frequency	Percent
<200	1	12.5
201-400	1	12.5
401-600	2	25.0
601-800	1	12.5
801-1000	2	25.0
1001-1200	1	12.5
Total	8	100.0

For those patients who are HBV positive, at 25% they are below the normal range whereas at 75% they are within the normal range

For CD4 Count test.

4.2 DISCUSSIONS OF FINDINGS

The prevalence of HBV-HIV co infection in our study was found to be 5.3% (8/150) which was comparable to the prevalence rate found in other studies like a retrospective study that was conducted, on eligible treatment-naive patients who presented between August 2004 and February 2007 to the University College Hospital (UCH), Ibadan, Nigeria.

Another study was done at a referral Hospital in Northern India. Total 620 HIV positive patients were studied, HBV co-infection was detected in 2.25% patients (Paul J. 2007).

According to the first objective of this study, 21.9% of patients who were HBV negative, they have liver disease whereas 100% of patients who are HBV positive present liver disease.

On the second objective of this study, 5.6% of patients who are HBV negative have renal disease whereas 12.5% of patients who are HBV positive have renal disease

According to the third objective, 21.1% patients who are HBV negative have the low number of CD4 whereas 25% of patients who are HBV positive are below the normal range.

Whereas other studies showed 42% of the sites initiated therapy when patients' levels of alanine aminotransferase and aspartate aminotransferase were elevated (Paul J. Gaglio Richard Sterling Eric Daniels Ellen Tedaldi, et al, 2007).

4.3.SUMMARY OF FINDINGS

According to patients who are HBV negative, Based on liver function tests especially ALT; in 142patients 78.1% have no liver disease, Whereas 21.9% they have liver disease and for AST in 142 HBV negative patients 70.4% have no liver disease whereas 29.6% have liver disease, this means 21.9% patients have liver disease,7.7% have other disease.

Based on kidney function tests especially creatinine; 94.4% of patients are within normal range for creatinine test but5.6% of patients are out of range, this means 5.6% patients have renal disease.

Based on Immunological tests like CD4; 21.1% patients have the low number of CD4,

78.9% patients have the big number of CD4.

According to patients who are HBV positive, Based on liver function tests especially ALT and AST; in 8 patients all of them (100%) they have elevated values of ALT and AST which are out of range, this means that they have liver disease.

Based on kidney function tests especially creatinine 12.5% of patients have low creatinine whereas 87.5% of patients are within normal range to mean that 12.5% of patients have renal disease and 87.5% of patients are normal.

Based on Immunological tests like CD4 count in 8 patients who are HBV Positive 25% of patients they are below the normal range whereas at 75% they are within the normal range.

CHAPTER FIVE: GENERAL CONCLUSION AND RECOMMENDATIONS

5.0 INTRODUCTION

This chapter contains general conclusion of the study, the implications of the current situation, suggested improvements, the questions raised and the suggestions for further research.

5.1 CONCLUSION

It is evident that HBV infections increase pathogenic effect on different organs and systems of the body as revealed from the findings of the current study For patients with HBV negative, 21.9% patients have liver disease, 5.6% patients have renal disease and 21.1% patients have the low number of CD4 comparing to those who were HBV positive, where 100% were having liver disease, 12.5% of patients had renal disease and 25% of patients they were below the normal range.

5.2 RECOMMENDATIONS

HBV co infection is common in HIV serology positive and can cause significant morbidity and mortality due to the liver injury, severe hepatotoxicity, renal failure and decreased in CD4 Cells. For these reasons, we recommend to Ministry of health, Kibogora District hospital, that the prevention and treatment of HBV infection is mandatory in HIV serology positive.

We also recommend to confected patients to follow the rules of taking drugs and avoid the spreading of infection.

5.3 SUGGESTION FOR FURTHER STUDY

Further studies will determine the exact cause of creatinine and CD4 count decreasing.

REFERENCES

Rosen HR, Keefe EB (2000). *Evaluations of abnormal liver enzymes use of liver tests and The serolology of viral hepatitis*: Liver disease, diagnosis and management. 1st Ed. New York; ChurchillLivingstone publisher; 24-35.

1. Yale J Biol Med (1977). Journal of Biology and Medicine, **50**(2): 99–113, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2595391/

2. Valeria (2013). Journal of General Virology, **94**,143–149

3. Doreid Berros (1995). Respiration and Growth Defects, **140**:285-302

4. AlbertiA, Clumeck N, Collins S, et al. Short statement of the first European Consensus Conference on the treatment of chronic hepatitis B C in HIV co-infected patients
, 2005, **42**: 615-24.

5. SorianoV, Puoti M, Bonacini M, et al. Care of patients with chronic hepatitis B HIV co-infection: recommendations from an HIV-HBV international panel, 2005
, **19**,221-40.

6. Brook M, Gilson R, Wilkins E, et al. HIVA Guidelines on HIV chronic hepatitis: coinfection with HIV hepatitis B virus infection, 2005,
6, 84-95.

7. Soriano V, Miro JM, Garcia-Samaniego J, et al. Consensus conference on chronic viral hepatitis HIV infection: updated Spanish recommendations,
2004, **11**, 2-17.

8. Thio CL, Sulkowski MS, Thomas DL.
Treatment of chronic hepatitis B in HIV-infected persons: 2005, **41**, 1035-40.

9. Brook MG, Jones K, Dale AW, Miller RF. Management of HIV hepatitis B or C co-infection in 15 HIV treatment centres: 2003, **14**, 469-72.

10. Salmon D, Robain M, Rockstroh JK, Benhamou Y. Therapeutic management of hepatitis HIV infection in co-infected patients: 2006, **44**,2-5.

11. Tedaldi EM, Baker RK, MoormanAC, et al. Hepatitis A B vaccination practices for ambulatory patients infected with HIV, 2004, **38**, 1478-84.

12. Opravil M, Hunziker R, Luthy R, et al. Chronic hepatitis B C in HIV infected patients, 1998, **123**,753-60.

13. Beck EJ, Mandalia S, Leonard K, et al.
Case-control study of sexually transmitted diseases as cofactors for HIV-1 transmission, 1996, **7**, 34-8.

14. Di Martino V, Thevenot T, Colin JF, et al. Influence of HIV infection on the response to interferon therapy the long-term outcome of chronic hepatitis B, Gastroenterology, 2002, **123** 1812-22.

15. Bonacini M, Louie S, Bzowej N, et al.
Survival in patients with HIV infection viral hepatitis B or C: 2004, **18,** 2039-45.

16. Brau N, Xiao P, Trikha A, et al.
Hepatocellular carcinoma in HIV-infected patient's influence of HIV viral load on surviva, 2004, **4**, 308.

17. Rockstroh JK. Influence of viral hepatitis on HIV infection, 2006, **44**, 25-7.

18. Paul J. Gaglio, Richard Sterling, Eric Daniels, Ellen Tedaldi, Terry Beirn, Community Programs for Clinical Research on AIDS Hepatitis Working Group: 2007, **45**(5), 618–623,

19. WHO, 2015. Comprehensive public health action on population ageing is urgently needed. Accessed on 30 September 2015, http://www.who.int/ageing/events/world-report-2015-launch/en/.

20. Erika Steele (2018). Hepatitis A Virus: Structure and Function. Accessed on 13 Sept 2018, https://study.com/academy/lesson/hepatitis-a-virus-structure-and-function.html

21. CDC, 2006. Sexually Transmitted Disease Surveillance Accessed on 4 August 2006, https://www.cdc.gov/std/treatment/2006/default.htm

22. ADAP reference: fact sheet on state ADAP programs from HRSA Available at http://hab.hrsa.gov/programs/factsheets/adap1.htm. Accessed 27 January 2007

APPENDICES