

Monitoring of some Liver Enzymes in HIV Patients on HAART

Ifeyinwa N. Chijioke-Nwauche ¹, Amaka M. Awanye ^{2,*}, Amaka A. Mgbahurike ¹, Chidozie N. E. Ibezim ² and Noel N. Wannang ³

¹ Department of Clinical Pharmacy and Management, Faculty of Pharmaceutical Sciences, University of Port Harcourt, Nigeria.

² Department of Pharmaceutical Microbiology and Biotechnology, Faculty of Pharmaceutical Sciences, University of Port Harcourt, Nigeria.

³ Department of Pharmacology, Faculty of Pharmaceutical Sciences, University of Jos, Nigeria.

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Abstract

Administration of Highly Active Antiretroviral Therapy (HAART) to HIV patients has changed the prognosis of the disease leading to decreased morbidity and mortality but has been shown to affect liver function leading to abnormal liver function tests. About 14 – 18% of deaths in HIV-infected patients have been associated with liver diseases. The study was aimed at determining abnormalities in liver enzymes of HIV-infected patients on HAART (Tenofovir, Lamivudine, and Dolutegravir) and to identify factors associated with the enzyme elevation among these patients. 210 adult participants comprising 120 HIV-positive (HAART-treated) and 90 HIV-negative volunteers were recruited for the study. Blood samples, self-administered questionnaires, and hospital case notes were used to collect information on the participants. Statistical analysis was performed using IBM SPSS version 23 software, using Chi-square analysis, Pearson's, and Spearman's correlations. Results were presented in frequencies, tables, and bar charts. P values < 0.05 were considered significant. HIV persons comprised mostly of females, 63.7%, median age range of 40 – 49, 50% married, 45% of them had been on treatment for a duration of 5 – 9 years. The study revealed higher- than- normal enzyme activity. An AST:ALT ratio was significantly higher in HIV-subjects compared to the negative control group, with HIV status of a person exerting significant effect (42.5%) in the observed variation. Furthermore, duration of HAART showed a significant influence on AST:ALT ratio in the HIV-positive group, reflecting a treatment-related impact from the study. From the findings, routine monitoring of these enzymes will serve as early indicators of liver dysfunction in HIV patients.

Keywords: HAART; HIV; Liver enzymes; AST; ALT

1. Introduction

The human immunodeficiency virus (HIV) has remained a global health challenge since its first discovery. The first case of AIDS was reported in the USA amongst homosexual men [1]. Since then, HIV has become a pandemic that affected the whole world. An estimated 34 – 47 million people were infected with HIV/AIDS in 2006, with approximately 4.3 million of these being newly diagnosed infections; the burden of this is primarily in Sub-Saharan Africa [2]. Current statistics report an estimated 37.7 million people including 1.7 million children at the end of 2020, out of which 25.4 million are in the WHO African region, while the death rate of HIV and its related course as reported by WHO in 2020 was 680,000. Around 16% of these people (6.1 million) do not know that they have the virus. Since the start of the epidemic, an estimated 79.3 million people have become infected with HIV and 36.3 million people have died of AIDS-related illnesses [3].

* Corresponding author: Amaka M. Awanye. E.mail: amaka.awanye@uniport.edu.ng

Nigeria has the second- highest burden of HIV infection in the world, with about 3.6 million people infected. The first two cases of HIV and AIDS in Nigeria were identified in 1985 and were reported at an international AIDS conference in 1986 [4]. Consequently, the number of people living with HIV/AIDS steadily increased and the epidemic became established with an increase of HIV-seroprevalence from 1.8% in 1991 to 5.8% in 2001 and 5.0% in 2003. This meant that Nigeria had 3.5million infected persons, and the third highest in the world [5]. As at 2011, an estimated 3.1 million people were living with HIV/AIDS and national prevalence was 4.1% [6]. A more current report shows that the prevalence of HIV among adults is 1.4%, accounting for about 1.9 million people living with HIV in Nigeria, and the fourth largest in the world [7]. The estimated HIV burden in Nigeria is 1.9 million, the fourth largest in the world. The prevalence according to states shows Akwa-Ibom with the highest prevalence of 5.5% and Katsina with lowest of 0.3%, and prevalence rate in Rivers State at 3.8% above the national prevalence of 1.4% [7].

The drug treatment for HIV disease is a three-prong process comprising antiretroviral therapy, management of opportunistic infections or malignancies and symptom control. The aim of the first of these, antiretroviral therapy is reducing the HIV viral load as much as possible, for as long as possible and restoring immune function. Following the deployment of Azidothymidine (AZT) as the first drug [8] for treatment of HIV/AIDS, the whole course of the disease prognosis and management has changed such that with the administration of ARVs, there is decreased morbidity and mortality [9] and many infected persons now live extended periods of time [10]. Several drugs have been developed for the treatment of HIV/AIDS and currently there are seven classes of antiretroviral drugs based on the site and mechanism of action [11].

Despite these advances in HIV/AIDS therapeutic management, there has been an associated adverse drug reactions of which the toxic effects on the liver and renal system are major concerns [12]. Consequently, routine biochemical monitoring is essential for these patients especially those on prolonged antiretroviral therapy.

Aminotransferases are the most common and reliable biochemical markers of hepatocellular status. They include aspartate aminotransferase (AST) and alanine aminotransferase (ALT). Both enzymes detected from liver function tests (LFT) are involved in the breakdown of amino acids [13]. Elevated serum activity of the enzymes ALT and AST has been established as a reflection of liver cell injury [14] manifested in acute or chronic liver injury; hence, they are useful surrogates for the degree of liver damage.

Liver function tests among HIV patients have been shown to exhibit some abnormalities [15]. These abnormalities may be a result of the induction of direct inflammation of the liver cell by the HIV organism, gall bladder disease, and bacterial or viral infection. Although reports of elevations of these liver enzymes in HIV-infected patients are common, direct reports of hepatocellular damage are limited. HIV contributes to hepatic inflammation and fibrosis, leading to changes in the timing of antiretroviral therapy initiation and to improved diagnosis and management of liver disease in patients with HIV [16]. Liver diseases in HIV patients are mainly caused by organisms responsible for the infection, especially HBV, HCV [17, 18]. A co-infection with hepatitis B (HBV) worsens the prognosis with decreased HBV clearance and a significant decrease in survival [19]. It has also been reported that the fifth leading cause of death in the Western world among HIV patients is chronic liver disease, especially due to HBV infection.

The initial diagnosis of HIV is based on the detection of antibodies against the virus. Once diagnosis is confirmed and therapy is initiated, there is a need for assessment of other features such as viral load, CD4 cell count, viral genotype assay to detect resistance, haematological parameters (complete blood count), biochemical parameters (fasting glucose/haemoglobin A1C, blood urea nitrogen and creatinine, AST and ALT and total bilirubin. These are important assessments for medication toxicity.

Elevation of liver enzyme levels is a common problem encountered on HAART. The damage done to the liver cells by antiretroviral drugs occurs through the active metabolites or by direct toxicity. There is a significant association between the degree of hepatic damage among HIV patients on HAART and age, gender, lifestyle, obesity, and herbal medications. About 50% of the deaths among hospitalized HIV-infected patients in the HAART era have been attributed to liver disease. It ranges from mild elevations of liver enzymes, to cirrhosis and end-stage liver disease with all its complications (e.g., ascites, oesophageal varices, and hepatic encephalopathy), with liver cirrhosis having the more serious consequences. Studies have reported elevated AST and ALT among HIV patients on HAART in comparison to HIV-negative persons [20]. Liver disease has emerged as the most common non-AIDS-related cause of death among HIV infected patients, accounting for 14–18% of all deaths [21]. Nearly half of deaths among hospitalized HIV infected patients in the HAART era have been attributed to liver disease [22, 23]. There is evidence that a major reason for shift or discontinuation of antiretroviral therapy is as a result of toxicity of HAART [20].

The study was aimed at investigating the liver enzyme levels of people living with HIV, determining abnormalities in liver enzymes of HIV-infected patients on HAART as well as identifying factors associated with the enzymes' elevation among these patients and evaluate AST: ALT ratio among these patients.

2. Methods

Ethical approval was obtained from the Ethics Committee of the Hospital (No: UPTH/ADM/90/S.II/VOL.XI/1334) prior to the study. A sample size of 116 (approximately 120) was calculated based on the HIV prevalence of 8.3% obtained in a 2012 study by [24].

Two-hundred and ten (210) volunteer participants comprising of 120 HIV-positive (HAART-treated) and 90 HIV-negative volunteers were recruited for the study. HIV-participants were attendees of the ARV Clinic of the University of Port Harcourt Teaching Hospital (UPTH) and who have been on treatment for at least one year. Information sheet about the study was given to the participants and the purpose of the study was thoroughly explained to them. All participants signed the informed consent prior to commencing the study.

A self-administered questionnaire comprising of 13 questions was distributed to the HIV-positive participants to collect relevant information ranging from demographics (age, gender, marital status, education, occupation), ARV medications, duration they have been on, last viral load checked and every relevant information after they have signed their written informed consent to participate in this study. HIV-negative participants have a six-item questionnaire for collection of data on demographic information.

Study included participants that receive treatment at the ARV unit aged 18 years and above, patients currently receiving ARV drug (HAART regimen) from the ARV Unit and willingness to sign the consent form. The HIV-negative participants were recruited from the hospital and University community to serve as the control group. HIV-negative control group were confirmed negative through point of care (POC) test using Alere HIV 1/2 Ag/Ab Determine Combo rapid test kit (Batch Number: 09075K200A) produced by the Alere Medical Co. Ltd, Matsuhidai, Japan. Analysis of liver enzymes (AST and ALT) was done using a fully automated random access clinical chemistry analyser with photometric throughput of 240 tests per hour.

Collected data from the questionnaire, patients' case notes and results obtained from the analysis were all entered in an Excel Sheet (MS Excel LTSC, 2019). All statistical analysis was done with the IBM SPSS version 23 software. Statistical analysis was done using Chi square (χ^2) analysis, cross tabulation, Pearson's and Spearman's correlations, linear regression. Independent sample t-test were used for inferential analysis. Results were presented in frequencies, tables and bar charts. P value < 0.05 was considered significant for all results.

3. Results

A total of 210 participants consisting of 120 HIV-positive persons and 90 HIV-negative were included in the study, but two of the participants had missing data so the general frequency without splitting into HIV positive and HIV negative patient group is 208. There were 103 (54.2%) females and 87 (45.8%) males. More than half (51.3%) of the participants were married and about 29.5% were in the age range of 30 – 39 years. HIV-positive persons were 118 while the HIV-negative were 90, overall mean ALT value was 30.06 IU/L while mean AST value was 28.43 IU/L (Table 1).

Table 1 Demographic Characteristics of Study Participants

	Frequency	Percent (%)	χ^2	p-value
Gender				
Male	87	45.8	6.281	0.012
Female	103	54.2		
Total	190	100.0		
Marital Status				
Single	64	40.5	111.235	0.0001
Married	81	51.3		

Widow/widower	12	7.6		
Divorced	1	0.6		
Total	158	100.0		
Age				
18 – 29 years	29	15.0	27.686	0.0001
30 – 39 years	57	29.5		
40 – 49 years	54	28.0		
50 – 59 years	39	20.2		
>60 years	14	7.3		
Total	193	100.0		
HIV Status				
Positive	118	56.7	21.235	0.0001
Negative	90	43.3		
Total	208	100.0		

3.1. Prevalence of abnormalities and levels of liver enzymes

All the HIV-positive persons were on Tenofovir + Lamivudine and Dolutegravir (TLD) (TDF + 3TC + DTG) regimen. There were very few abnormal values of the enzymes obtained. Based on the accepted normal value of 38 IU/L in UPTH, the prevalence of enzyme abnormality was 28 (13.5%) for AST and 29 (13.9%) for ALT for both arms of study (Table 2).

Table 2 Comparison of the AST and ALT values

		Frequency	Percent (%)
AST VALUES	Normal values (<38 IU/L)	180	86.5
	Abnormal values (>38 IU/L)	28	13.5
	Total	208	100.0
ALT VALUES	Normal values (<38 IU/L)	179	86.1
	Abnormal values (>38 IU/L)	29	13.9
	Total	208	100.0

Further analysis of the data showed that more of the abnormal values were seen among the HIV-positive persons (Figure 1). A cross-tabulation analysis also showed that the HIV-negative participants had more normal AST (91.1%) and ALT (87.8%) values than HIV-positive participants (83.1% and 84.7% respectively). Although fewer abnormal values were observed in both participant groups, the frequency of occurrence of both abnormal AST and ALT values were observed more in HIV-positive patients (16.9%, 15.3%) than HIV-negative patients (8.9%, 12.2%) respectively. However, a chi square analysis showed no significant difference between AST and ALT values in both participant group ($\chi^2=2.847$, $p=0.092$).

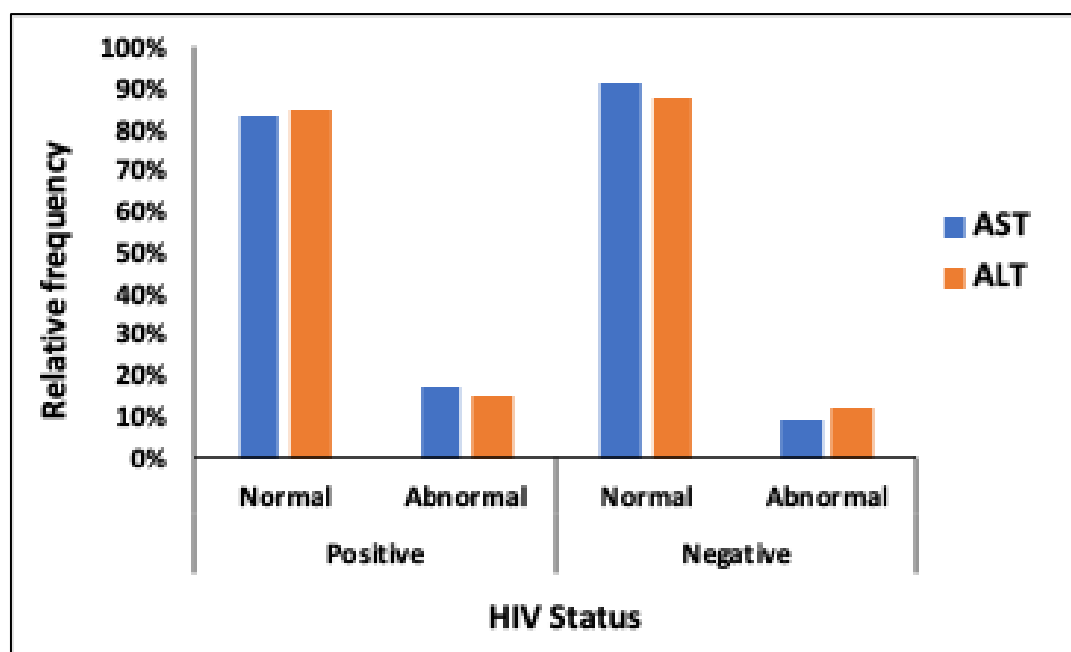


Figure 1 Relative frequency (%) of HIV-positive and HIV-negative patients having normal and abnormal AST and ALT values (n = 208)

Evaluation of the AST:ALT ratio (Table 3) showed a significant difference in the mean AST:ALT ratio of the HIV-positive and HIV-negative patients ($t = 6.985$, $p = 0.0001$). Linear regression also revealed a moderate relationship between HIV status and AST:ALT ratio ($r = 0.425$, $p = 0.0001$), indicating that HIV status influences AST:ALT ratio by 42.5 % ($r \times 100\%$).

Table 3 Analysis of AST:ALT Ratio

	HIV status	N	Mean	Std. Deviation	t	p-value
AST/ALT Ratio	Positive	118	1.0145	0.18731	6.985	0.0001
	Negative	90	0.8543	0.14351		

3.2. Factors associated with elevation of liver enzymes

The factors that may be associated with elevation of the enzymes were analysed using Spearman Correlation, it was found that there is no correlation between HIV status of a patient and their liver enzyme values. That means that in the present study, HIV status of a participant did not a significant effect their liver enzyme values ($p = 0.092$ and 0.534 for the AST and ALT values respectively). Generally, there was a slight increase in the liver enzymes (ALT and AST) when compared to the values obtained among HIV-negative Control group. However, it can be seen that the HIV status of a patient does not significantly increase the liver enzymes. All the factors tested in this study showed no relation to the increase in value of the liver enzymes. Other factors of influence among HIV-positive participants, include gender ($p = 0.015$) and duration of treatment ($p = 0.0001$). The latter exerts a significant 34.2% influence on the AST: ALT ratio of the patients (Table 3).

4. Discussion

This study investigated the levels of liver enzyme aminotransferases: aspartate transferase (AST) and alanine aminotransferase (ALT) in HIV-positive patients on highly active antiretroviral therapy (HAART) in University of Port Harcourt Teaching Hospital, Port Harcourt (UPTH). Furthermore, abnormalities in the enzymes and factors associated with the abnormalities were evaluated. HIV infection has long been established with elevation of liver enzymes [15]. The additional influence of HAART on increased enzyme levels as well as hepatic damage as established in many studies emphasizes the need of monitoring of patients who are on antiretroviral treatment [25, 26]. Abnormal values of the enzymes obtained among the HIV subjects were higher in comparison to the control group but there was no significant

difference in AST ($p = 0.092$) as well as for ALT ($p = 0.532$). This underlines the effect of HIV infection as well as HAART on liver enzymes [15, 26].

The results of the study show that the mean AST and ALT levels of 30.47 ± 20.58 and 30.19 ± 17.55 for AST and ALT obtained for HIV-positive subjects were higher than that of the control group 25.477 ± 14.215 and 29.90 ± 12.767 . This has long been established and reported due to the influence of both the infection and the effect of HAART [27, 28]. A similar study carried out among HIV patients on HAART and naïve patients with negative control group also established higher levels of elevated AST and ALT in Sokoto, Northern Nigeria [29]. A Saudi study established a chronic elevated level of ALT among patients on HAART, majority of which were on regimen containing lamivudine even though the causality could not be established [30]. Majority (45%) of participants in the present study have been on HAART for duration of 5 – 9 years. In southwestern Nigeria elevated AST and ALT has been observed among HAART patients compared to HAART naïve subjects or control groups. And the elevations were higher in females. This is similar to the Cameroonian study by [20].

The study also established a significant difference in the mean AST:ALT ratio of the HIV-positive and the HIV-negative patients of 1.0145 ± 0.18731 vs. 0.8543 ± 0.14351 ($p = 0.0001$) with the HIV-positive patients having a higher mean AST:ALT ratio even though it did not reach the physiological significant value of 1.5. AST:ALT ratio that tends to be greater than 1 has been associated with impairment of liver functions and complications such as cirrhosis [31, 32]. AST:ALT ratio is an important marker in the assessment of the progression and severity of liver diseases and can also be used in assessment of metabolic syndrome, muscle damage and biliary obstruction.

In disease conditions such as cirrhosis, biliary obstruction and muscle damage, the ratio may become elevated over 1. The scope of the present study did not include the assessment of these conditions but should note that a ratio above normal is still a concern as it also indicates some liver damage especially since drugs have been implicated in elevation of this ratio. In persons with lifestyle that involve alcohol drinking, it therefore calls for close monitoring of HIV patients on HAART to assess their health status especially for those of them that take alcohol as part of their lifestyle since high AST:ALT ratio can also suggest alcoholic liver disease.

As a result of the toxicological effects of the ART, the need for monitoring cannot be over emphasized. A major area of monitoring is the toxicological effect of the liver which is the primary organ for metabolism and detoxification of the body. Toxicological effects of Tenofovir have been reported [33]. Furthermore, hepatotoxic effect of Dolutegravir has also been reported. HIV-liver-transplant patients were switched from a protease inhibitor-based regimen to Dolutegravir-based ART with a resultant increase in serum transaminases [34].

5. Conclusion

The study revealed higher values of liver enzymes (AST and ALT) thereby confirming the long-established report of influence of HAART on liver enzymes. Additionally, there was higher AST:ALT ratio in HIV-subjects compared to the negative control group, with HIV status of a person exerting significant affect (42.5%). Duration of HAART was shown to have significant impact on the AST:ALT ratio. In conclusion, the higher values of AST:ALT ratio as established from the study as well as the influence of duration of treatment on this ratio with the higher levels of enzyme abnormality underline the importance of monitoring of HIV patients for possible drug toxicity. As advocated by the National Guidelines, monitoring of patients on HAART should go beyond just measuring viral load and CD4 count which do not show possible drug toxicity or organ damage that may affect the patients. The need for larger studies in the same facility is very imperative.

Compliance with ethical standards

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Disclosure of conflict of interest

All authors have no competing interest to declare.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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