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Immune-virological status in people with HIV from naïve to six months on cART at Ahmadu Bello University Teaching Hospital Zaria, Nigeria.

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Abstract

The implementation of Combine Antiretroviral Therapy (cART) to treat HIV infection has been an incredible success and has saved millions of lives by improved clinical outcomes. Antiretroviral treatment reduces viremia to undetectable levels in people living with HIV (PLWH) by suppressing viral replication and allowing immune reconstitution. However, ongoing background inflammation continues in most PLWH, despite virological suppression, in particular in those individuals who started cART in the acute phase of infection. In this study, we investigated the plasma viral load of HIV-infected treatment naive participants at baseline and after six (6) months on treatment. We demonstrated that the plasma viral load of HIV-infected treatment naive participants at baseline and after six (6) months on treatment were significantly suppressed. Systematic assessment for antiretroviral treatment response is a fundamental aspect in addressing the issues associated with the poor clinical consequence including immunologic failures among HIV-positive patients on cART. We employed quasi experimental design, where non-probability sampling techniques were used in recruiting thirty-eight (38) cART naive HIV patients up to six (6) months on cART and ten (10) controls. We quantified the plasma HIV RNA using Hologic Panther Platform. The mean ±SD age of the HIV-infected cART naive participants was 36.16 (±8.5) years. Most of the participant were female constituting 68.4% (26/38) of total number of cases studied. The median and interquartile range (IQR) of the viral load of HIV-infected cART naive participants at baseline and on treatment were 761,420 copies /ml (240794-2704986) and 30 copies /ml (30-30) respectively. The result shows a high percentage of plasma viral suppression in 6 months with viral load 82% (<30 copies/ml) and 18% (≥30 copies /ml) virological failure. This study shows the beneficial effect of immune-virological suppression following the introduction of cART. This may be the reason for the early initiation of cART (test and treat policy) and commitments of the center in terms of counselling, follow up and regular assessment.

Keywords: Viral Load, Combine Antiretroviral Therapy cART, HIV infection, people living with HIV.

Introduction

Acquired immunodeficiency syndrome (AIDS) caused by the human immunodeficiency virus (HIV) is a viral infection that attacks the body's immune system, specifically the white blood cells called CD4+ T cells (Kiros *et al.,* 2022). This can make individuals more susceptible to several infections including bacterial, viral, and fungal agents (Gaebler *et al.,* 2022). Globally, among the 36.9 million people living with Human Immunodeficiency Virus (HIV), only 21.7 million were accessing ART in 2017. About 1.8 million people were newly infected with HIV and one million people died from Acquired Immune Deficiency Syndrome (AIDS) related illnesses in 2017. Nigeria shares a portion of this estimate with a recent national prevalence of people living with HIV among adults (15-49 years) at 1.4%. With varying prevalence across the country, North West zone with least prevalence of 0.6%; Kaduna State 1% in which female having 1.4 and male 0.6 (UNAIDS, 2019).

Sub-Saharan Africa has remained among the hardest hit regions provided with one in every 25 adults living with HIV/AIDS. The region accounts for nearly two-thirds of the global total HIV cases (Kiros *et al.,* 2022). According to the UNAIDS report, strong domestic and international investment has stimulated steep declines in HIV infections and deaths from AIDS related illness in Nigeria. The 90-90-90 target by UNAIDS predicts that by 2020, 90% of PLWH will know their HIV status, 90% of people who know their HIV-positive status will be accessing treatment and 90% of people on treatment will have suppressed viral loads (UNAIDS., 2017). However, only 67% of PLWH in 2018 Nigeria knew their status, of which 53% were on High Active Antiretroviral Treatment (HAART) and only 42% were virally suppressed (Stafford *et al.,* 2019). The Northwest zone of Nigeria also reflects similar statistics as only 9 out of 20 PLWH on HAART achieved viral suppression (Abdullahi *et al.,* 2021).

People living with HIV infection require ongoing HIV care and access to medications to maintain continuous maximal virological suppression and allow immune reconstitution (Abdullahi *et al.,* 2021). Monitoring individuals receiving ART is important to ensure successful treatment, identify adherence problems, and determine whether and which ART regimens should be switched in case of treatment failure. Viral Load (VL) testing should be used aside from the routine testing schedule whenever there is clinical or immunologic suspicion of treatment failure. Plasma Viral load (VL) measurement is the gold standard for monitoring treatment improvement success. PLWH on HAART with unsuppressed viral load have a higher risk of resistance emergence HIV mutations virus progression, drug resistant transmission, HIV-related morbidity and mortality (Broyles *et al.,* 2023). Available statistics have shown that Nigeria is far behind the target of (UNAIDS 90-90-90 aspirations) despite the recent downward trend in prevalence and incidence. There was no research that has evaluated viral suppression among HIV patients longitudinally in the north-western part of Nigeria.

Moreover, factors associated with immunological, virological, and treatment may include several Socio-demographic variables, baseline data, and clinical characteristics. As a result, plasma viral load has been associated with diverse physiological and pathological functions. The aim of this study was to assess the plasma viral load of HIV infected naïve individuals and at six (6) months on treatment with the objective to determine the level of viral suppression and among HIV positive individuals attending Nasara HIV-treatment and Care Centre (NTCC) in Ahmadu Bello University (ABUTH) Zaria, Nigeria.

Materials and Methods

This study was conducted between June 2022 to April 2023 to determine the immune-virological status among HIV-infected individual on cART at Nasara HIV-treatment and Care Centre (NTCC) in Ahmadu Bello University (ABUTH) Zaria, Nigeria. The study area was chosen based on the high concentration of specialists (experts) in the field of HIV Medicine, with a multidisciplinary model of care, a molecular laboratory and Anti-Retroviral Therapy (ART) laboratory for HIV diagnosis and viral load assay.

Study participants and data collection

This research is a Quasi experimental design study that assessed the plasma viral load among HIV-infected treatment naive participants at baseline and at six months on treatment. Study participants age range of $\geq$ 18 to $\leq$ 50. A purposive non-probability sampling technique was used for HIV-infected treatment naive participants at NTCC. The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments in humans (Ballantyne and Eriksson, 2019). Their information was treated with utmost confidentiality. A semi structured interviewer questionnaire was administered to all consenting participants to obtain information on their socio-demographic and clinical history.

Hologic Panther Platform

The Hologic Panther Platform assay involves three main steps: Target Capture, Target amplification by Transcription Mediated Amplification (TMA) and detection of the amplification products that takes place in a single

tube on the Panther system. The HIV RNA were quantified using Hologic Panther Platform. The frozen specimens were thoroughly thawed and vortexed for 3 to 5 seconds to mix thoroughly. The specimens were allowed to attain 15^{O}C to 30^{O}C prior to processing. Seven hundred (700) uL of specimen was added into a 1200 uL collection tube. The samples were centrifuged at 1000 to 3000g for 10 minutes. Three (3) control levels were included for each rack of 94 samples. The samples were loaded and registered on the equipment.

Data analysis

The data were edited using Microsoft excel, missing values and outliers were identified and recorded appropriately. Normality and lognormality test, descriptive test and tests of significance were conducted using Graph Pad Prism version 8.0.1. The variables were summarized and presented using median and interquartile range. the plasma viral load of HIV-infected treatment naive, using Wilcoxon matched-pairs sign rank test.

Results

Thirty-eight (38) HIV infected individuals were recruited in this study. The mean ±SD age of the HIV-infected treatment naive participants was 36.16 (±8.5) years. Male participants constituted 31.6% (12/38) of the total number recruited while female participants constituted 68.4% (26/38) of total number recruited in the study. The age group of 31 - 40 years constituted the highest number of participants with 15 (39.5%), followed by 21 – 30 years group with 11(28.9%), then the 41-50 years age group with 10 (26.3%), and 18 – 20 years with 2 (5.3%). The median and interquartile range (IQR) of the viral load of HIV-infected treatment naive participants at baseline and on treatment were 761420 (240794-2704986) and 30 (30-30) respectively. The result shows a highest levels of plasma viral suppression in 6 months with viral load <30 copies/ml was 82% while ≥30 was 18%.

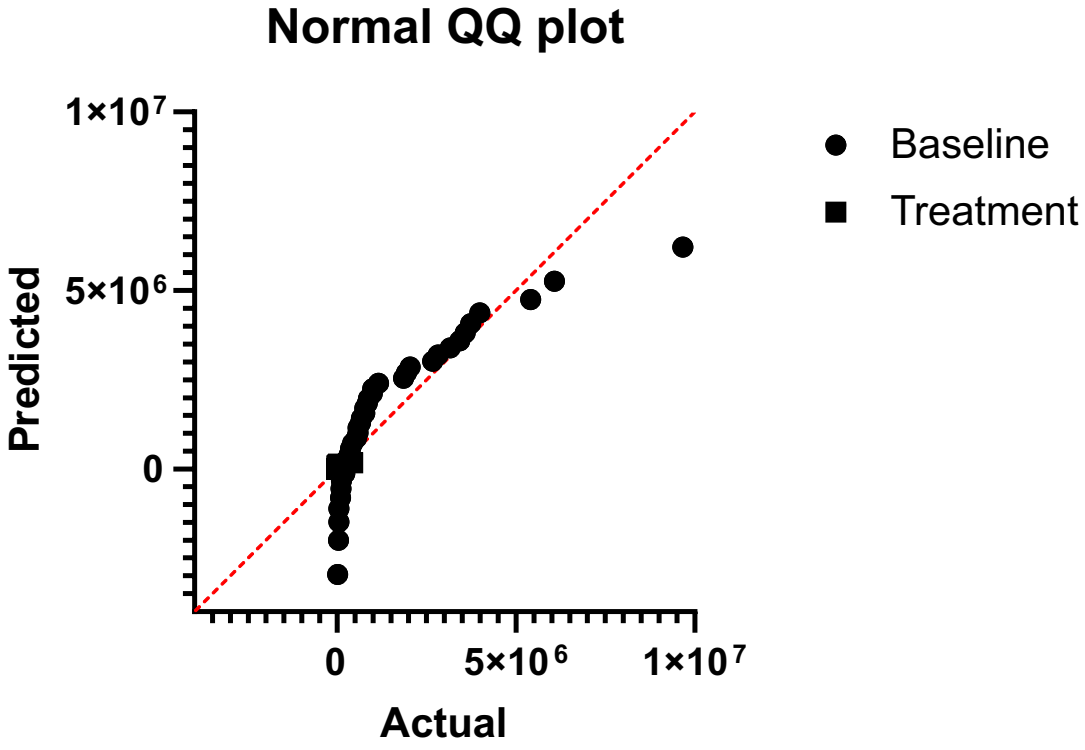

Figure 1: Normality and Lognormality test distribution of viral load in individual infected with HIV at Ahmadu Bello University Zaria.

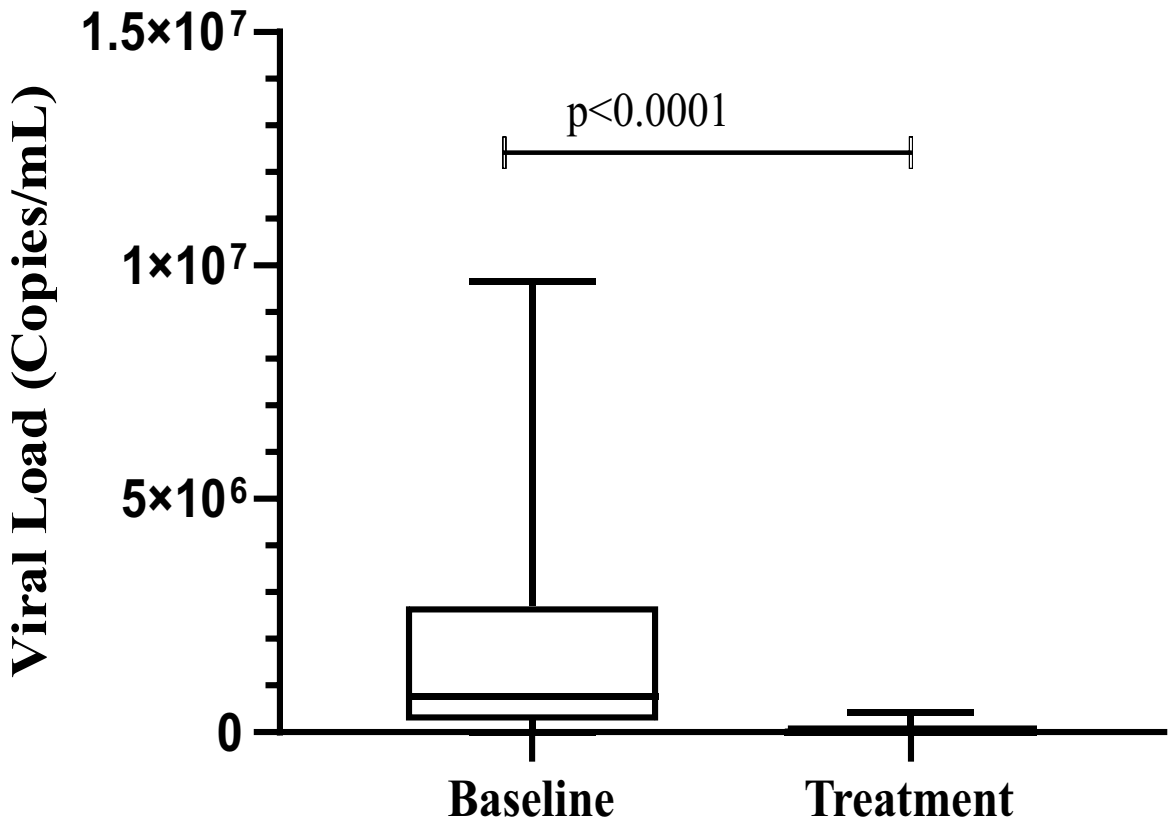

Figure 2: Plasma viral load quantification of HIV-infected treatment naive participants at baseline and at six (6) months on treatment. Significant difference obtained using Wilcoxon matched-pairs sign rank test.

Discussion

The Combine Antiretroviral Therapy (cART) is irrefutably effective at limiting HIV infectivity, replication, and prolonged treatment is not sufficient to eradicate the viral reservoir in people living with HIV (PLWH). This study showed that the level of viral suppression was in highest levels of plasma viral suppression in 6 months with viral load <30 copies/ml, that is 82% while ≥ 30 is 18%. The level of plasma viral suppression in this study was high which is in accordance within the global target of 90% viral suppression among people living with HIV (PLWH) on cART by UNAID (UNAIDS., 2017).

This research is in accordance with the study of viral suppression among HIV-positive patients on antiretroviral therapy in Northwest Nigeria with viral suppression of 90.4% (20-925copies/ml) (Abdullahi *et al.,* 2021). The level is higher compared with the national level of viral suppression of 44.4% in the north-western part of Nigeria (National Agency for the Control of AIDS, 2020); 79% reported in a multi-center Nigerian study (Stafford *et al.,* 2019); 81% in Borno state, North-eastern Nigeria (James *et al.,* 2020); and 69% in Ghana (Lokpo *et al.,* 2020) and 73% in Northern Ethiopia (Desta et al., 2020). High level of viral suppression in this study are comparable with the reports from Uganda where a level of 95% was observed for viral suppression after 12 months of cART among PLWH (Ssemwanga *et al.,* 2020). Likewise, the level of viral non-suppression obtained in this study is comparable to 9.0% and 7.0% reported in the African cohort study (Kiweewa *et al.,* 2019), and Vietnam (Rangarajan *et al.,* 2016) respectively. The high levels of viral suppression observed in this study compared to the other studies may be due to test and treat protocols (Stafford *et al.,* 2019) and after 6 months of initiation of first-line of HAART in a Moroccan study (Abebe *et al.,* 2019). In Mashonaland West province,

suppression increased from 68% in 2016 to 81% in 2018 in a population of economically marginalized children and adolescents in an impoverished rural community (Mapangisana *et al.,* 2021). Endalamaw et al. (2018) conducted various studies including a systematic review and meta-analysis (n = 5,899) in 13 studies at the University of Gondar referral hospital which reported 10.2% (95%CI 6.9-13.6), a study was done in Southern Ethiopia 11.5% (Yirdaw and Hattingh, 2015), Jimma 9.8% (Abdissa *et al.,* 2014), a study done in South Africa 11% (Edet *et al.,* 2019) and India 11% (Prabhakar *et al.,* 2011).

In contrast, the study in Borno State, north-eastern Nigeria found younger age group and marital status to be associated with poor viral suppression (James *et al.,* 2020); and in HIV virological non-suppression and factors associated with non-suppression among adolescents and adults on antiretroviral therapy in northern Ethiopia: a retrospective study revealed that 26.39% of them had viral non-suppression (Desta *et al.,* 2020), there is a slight agreement also with a report from Tigray region, Ethiopia which was 29.8% (National Agency for the Control of AIDS, 2020) Kenya 64.4% (Sang and Miruka, 2016), Tanzania 25% (Mgelea *et al.,* 2014), China 18.4% (Huang *et al.,* 2015), Colombia 14% (De La Hoz *et al.,* 2014), Thailand 33.5% (Khienprasit *et al.,* 2011), and Nepal 35% (Ojha *et al.,* 2016), a prospective observational and a study in England 47.6% (Cuzin *et al.,* 2007). These variations of the virological non suppression rate might be due to study design differences which were based on self-report of the patients on ART care (Hailu *et al.,* 2018; Ravikumar *et al.,* 2022) or differences in the quality of care in service delivery like counseling and adherence support activities among the different study settings (Mageda *et al.,* 2023).

A South African study also identified low CD4 count to be associated with poor viral load suppression (Lilian *et al.,* 2019). The CD4 cells are one of the prime targets of HIV, hence its fall corresponds to increasing viral loads. Although not the main marker of monitoring HIV, low CD4 counts at the beginning of treatment calls for closer monitoring of the PLWH as they have a higher chance of having poor viral suppression(Gaebler *et al.,* 2022).

Conclusion and Recommendation

The study of Immune-virological status among HIV-positive patients has been instrumental virological suppression in six months on treatment by improving the quality of individuals infected with HIV. Moreover, the demographic, economic and clinical data employed for this study increase the chances of close monitoring of patients and regular follow up on patients by intensified patients' adherence support for repeat testers after suspected failure of the drug. Counselling should also focus on encouraging spouses of married patients to act as treatment supported for their partners.

Limitation

In this study, we analyze thirty-eight PLWH. The sample size should be increased by using many tertiary base hospitals across the geopolitical zones. This will give wider coverage and give more inside on patient management.

Consent

Written informed consent was sought and obtained from each participant prior to enrollment into the study as all participants were adults. The participants were adequately informed of their right to choose to or not to participate or withdraw at any point so wished.

Conflict of interest

There is no any conflict of interest about study, in the collection, analysis, or interpretation of data, in the writing of the manuscript, or in the decision to publish the results.

Ethical approval

The Ethical approval/certificate dated 4th March, 2022; ABUTH Ethics Committee assigned number: ABUTHZ/HREC/A12/2022 with reference number (NHREC/10/12/2015; D-U-N-S NUMBER:954524802) was obtained from the Health Research Ethics Committee (HREC) of ABUTH, Zaria Nigeria before commencement of sample collection.

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