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Assessment of Treatment Outcomes for Patients Living with HIV/Aids on Tenofovir/Lamivudine/Dolutegravir in a Secondary Healthcare Facility in Niger State

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ABSTRACT

Introduction: The fixed dose combination of TLD was recommended as first-line antiretroviral therapy (ART) for the treatment of HIV/AIDS by the World Health Organization (WHO) and was adopted in Nigeria in 2019.This retrospective study assessed the outcomes of transitioning to and the effectiveness of Dolutegravir-Based regimen.

Objectives: To assess the efficacy of TLD on viral suppression among people leaving with HIV/AIDS in a secondary health care facility in Niger state, Nigeria.

Methods: This retrospective study analyzed records of adult HIV-Positive clients on first line ART at general hospital kutigi, Niger State, Nigeria over a period of six years (January 2018 to December 2023). Using appropriate statistical methods, we assessed clients' characteristics and treatment outcomes. Ethical approval was obtained (HMB/GHK/VOL.1/2) and data collected using adapted tool. All adult clients on first line regimen were included in the study with the exclusion of clients on second line and pediatric clients. Whole population (Census) was used for the study due to small population size and accuracy of data.

Results: A total of 265 client records were reviewed in 2023 to estimate the level of viral suppression in people living with HIV and on treatment with Tenofovir, Lamivudine and Dolutegravir (TLD) regimen and those transitioned from Tenofovir, Lamivudine and Efavirenz (TLE) in 2020, with male to female ratio of 1:2.4 with a mean age of 41.01±22.65 years. The study found a significant improvement in viral suppression from 85.1% to 99.6% three years post transitioning.

Conclusion: The findings indicate that the TLD regimen is highly effective in achieving viral suppression among people living with HIV/AIDS, these results support the continued use of TLD and may inform decisions by policymakers, researchers, and healthcare providers.

KEYWORDS: Antiretrovirals, Dolutegravir, Efavirenz-based, HIV Clients. And Nigeria.

ARTICLE DETAILS

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INTRODUC TION

HIV/AIDS pandemic has claimed over 35million lives with approximately 38million people living with HIV/AIDS worldwide in 2019 with 1.7 million new infections. (Ogbuagu, 2021). There was an increase in the global figure to 39.9 million people, with the WHO African region accounting for 25.6 million people (WHO 2023).

In 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) estimated the HIV prevalence among adults (15–49) years at 1.4%, about half of previous model-based estimates. NAIIS data showed that among adults aged 15–64 years, 96.4% self-reported being on ARV treatment or had detectable ARVs and 80.9% were virally suppressed. According to another study in 2023 by Onovo et. al. HIV prevalence was estimated at 2.1% (approximately 2,000,000) in Nigeria and 0.6% (22,468) in Niger State, Nigeria.

The backbone for Human immunodeficiency Virus treatment has been the combination of at least two Nucleoside/Nucleotide Reverse transcriptase inhibitors (NRTIs) and One from any of the following classes Non-

nucleoside reverse transcriptase inhibitor (NNRTIs), Protease Inhibitors (PIs), or Integrase Strand Transfer Inhibitor (INSTIs). Which has been the source of success in antiretroviral treatment. (Ojo *et. al.* 2023)

Tenofovir, Lamivudine and Dolutegravir (TLD) fixed dose combination used as first line regimen in the treatment of HIV/AIDS was recommended and supported by the President's Emergency Plan for AIDs Relief (PEPFAR) for use in priority countries including Nigeria. (Siberry, 2017). TLD has progressively replace TDF/3TC/EFV600 as first line regimen of choice, as recommended by World health organization (WHO) in 2015 with the introduction of a second-generation HIV-1 integrase strand transfer inhibitor Dolutegravir (DTG), has impacted on the treatment of HIV-infection in terms of efficacy and high barrier to resistance (Bollen, 2015).

According to world health organization (WHO) 2023 policy brief titled "the role of HIV viral suppression in improving individual health and reducing transmission" that Antiretroviral therapy has transformed the lives of people living with HIV. All over the world, people living with HIV that were early diagnosed, treated, and adhere to their medication as prescribed can now live longer and pursue as healthy a life as people who are HIV-negative. Further, people living with HIV who maintain an undetectable viral load by taking their antiretroviral therapy as prescribed have zero risk of transmitting HIV to their sexual partner(s) and minimal risk of transmitting HIV vertically to their children. Accurate, reliable testing for viral load is critical for realizing the benefits of antiretroviral therapy at both the individual and population levels.

HIV viral suppression is critical to improve individual health, prevent sexual transmission, and reduce perinatal transmission. There are three key categories for HIV viral load measurements:

1. Unsuppressed (>1000 copies/mL),
2. Suppressed (detected but ≤1000 copies/mL) and
3. Undetectable (viral load not detected by test used).

HIV viral load test results can be a motivation for adhering to treatment and achieving the goal of being undetectable (WHO 2023). Emphasizing and strengthening adherence counselling during antiretroviral therapy initiation and throughout treatment are essential, including communicating the prevention benefits of viral load suppression to all people living with HIV.

In addition to adherence, people living with HIV need regular health checks to ensure antiretroviral therapy is effective and devoid of adverse effect. These checks include a viral load test, carried out by collecting a blood sample and performing a test called polymerase chain reaction (PCR) to measure the amount of virus in the blood, which is reported in copies of virus per millilitre of blood. When a viral load is equal to or below 1000 copies/mL, the person is virally suppressed. When a viral load is so low the test cannot measure it, it is undetectable.

AIM OF THE STUDY

To assess the efficacy of TLD on viral suppression among people leaving with HIV/AIDS in a secondary health care facility in Niger state, Nigeria.

OBJECTIVES OF THE STUDY

1. To assess the proportion of patients who achieved viral suppression after transitioning.
2. To compare viral load suppression rates before and after transitioning.
3. To identify factors associated with viral suppression.
4. To assess the effect of TLD on viral suppression.

STATEMENT OF RESEARCH PROBLEM.

Despite the effectiveness of antiretroviral therapy (ART) in managing HIV/AIDS some patients may require a transition to a new regimen due to treatment failure, adverse drug reactions, availability of new regimen, or changes in treatment guidelines, WHO (2023). However, the impact of transitioning to a new ART regimen on viral suppression among people living with HIV/AIDS is not well understood. There is a need to determine the rate of viral suppression and identify predictors of successful viral suppression among patients transitioned from one ART regimen to another.

Key Issues are Treatment outcomes, predictors of success and Clinical implications.

The fixed dose combination of TLD was recommended as first-line antiretroviral therapy (ART) for the treatment of HIV/AIDS by the World Health Organization (WHO) and was adopted in Nigeria in 2019. Although there are limited data available on the use of TLD, some clinical studies revealed that TLD shows rapid viral suppression with a high barrier to resistance especially due to the inclusion of Dolutegravir, it is generally well tolerated, improved adherence and treatment outcomes with overall program efficiency.

RESEARCH GAP

There is a lack of comprehensive data on the outcomes of patients transitioned from one ART regimen to another, which poses a challenge to the development of evidence-based guidelines for managing treatment transitioned. This highlights the need for this study and provides a clear direction for the research investigation.

METHODOLOGY

STUDY DESIGN

The study is a retrospective study involving all HIV/AIDS adult clients on first line Antiretroviral therapy at general hospital kutigi, Niger State, Nigeria within the period six years (January 2018 to December 2023).

STUDY SETTING

General Hospital Kutigi is a Secondary healthcare facility located in Lavun Local Government Area of Niger State, North Central Nigeria. The facility offers a comprehensive care for HIV/AIDS patients. Ethical approval was obtained (HMB/GHK/VOL.1/2) AND the data was collecting from the health information management department of the hospital and analysis was done using the SPSS and Microsoft excel version 2017.

INCLUSION CRITERIA

All adult patients aged 15 years and above assessing care and treatment from the facility and on first line regimen of TLD and those transitioned from TLE to TLD.

EXCLUSION CRITERIA

All patients on second line regimen, patients with comorbidities associated with HIV and HIV non-reactive patients.

SAMPLE SIZE AND SAMPLING TECHNIQUE

Whole population was used for the study, with a total number of clients that met the inclusion criteria being 265 in 2023. The viral load results from PCR laboratory were reviewed after ethical clearance was obtained from the ethical committee of the Hospital and preliminary data collected.

Demographic variables such as sex, age was collected, data extracted using data extraction format was analyzed using Introstat and Statistical package foe Social Sciences (SPSS) version 23.0, descriptive data were presented as simple frequencies and percentages. The level of significance is set at $p \leq 0.05$.

RESULTS

Table 1 shows that of 265 clients reviewed in 2023 on the level of viral suppression in people living with HIV and on treatment with Tenofovir, Lamivudine and Dolutegravir (TLD) regimen and those transitioned from Tenofovir, Lamivudine and Efavirenz (TLE) in 2020, within the age range of 15 to 79 years. Female clients constituted 70.2% and 29.8% were Male with male to female ratio of 1:2.4 with a mean age of 41.01±22.65 years. Over 35% of the clients are between the ages of 35 to 45 years with only 1.1% falling between 75 to 84 years.

Only 5.3% are Christian and 94.7% being Muslims, having that the facility is in a Muslim dominated area.

Table 1: Showing Demographic Data

DEMOGRAPHIC	
AGE	15-79
15-24	20(7.5%)
25-34	53(20.1%)
35-44	95(35.8%)
45-54	67(25.3%)
55-64	17(6.4%)
65-74	10(3.8%)
75-84	3(1.1%)
MEAN±SD	41.01±22.65
GENDER, N (%)	265 (100)
MALE, N (%)	79 (29.8)
FEMALE, (%)	186 (70.2)
RELIGION	
MUSLIMS	94.7%
CHRISTIANS	5.3%

The result also revealed that clients with unsuppressed viral load before transitioning from TLE to TLD were suppressed as shown in Table 2. It was observed that in 2018, 20.9% 0f the Clients had an unsuppressed viral load, with 14.9% in 2019 pre transitioning period, while the unsuppressed clients increased to 18.4% largely due to newly initiated clients on TLD in 2020 and ineffectiveness of TLD in short term use as reported by Revocatus (2024), the percentage of non-suppression decrased to 4.2%, 1.1% and 0.4% in 2021, 2022 and 2023 respectively. The result showed the effectiveness of Dolutegravir based regimen as 99.6% of the clients on TLD who's samples were taken for viral load testing had viral suppression at the end of the study period.

Table 2: showing percentage of unsuppressed clients from 2018 to 2023.

	TENOFOVIR/LAMIVUDINE/EFFERVERENZ		TENOFOVIR/LAMIVUDINE/DOLUTEGRAVIR			
	2018	2019	2020	2021	2022	2023
MALE	7(21.2%)	10(50%)	11(23.4%)	7(63.6%)	0	0

FEMALE	26(78.8%)	10(50%)	36(76.6%)	4(36.4%)	3(100%)	1(100%)
TOTAL UNSUPPRESS	33(20.9%)	20(14.9%)	47(18.4%)	11(4.2%)	3(1.1%)	1(0.4%)
TOTAL CLIENTS	158	134	255	262	265	265

Table 3: showing viral load results from 2018 to 2023.

	2018	*2019*	*2020*	*2021*	*2022*	*2023*
Undetectable	29	0	0	0	0	0
≤1000 copies/mL (Suppressed)	44	93	148	143	245	220
>1000 copies/Ml (Unsuppressed)	32	33	45	11	2	2
LTFU	10	0	1	1	0	0
No Result	3	0	1	1	0	1
No Sample sent	40	8	59	106	18	42
Invalid	0	0	1	0	0	0
Total	158	134	255	262	265	265

DISCUSSION

There has been significant increase in number of patients on ART over the years in Nigeria with corresponding improvement in virological, immunological, and clinical outcomes especially with introduction of TLD fixed dose combination. (Ogbuagu, 2021). The viral suppression at the end of this study was 99.6%, the result obtained was close to 94.7% obtained in a study in Nigeria by Ojo *et. al.* (2023) but significantly higher than 75.4% obtain in a similar study conducted in Southeastern Nigeria and 78.95% to 92.86% obtain in a study in Nepal (Ogbuagu, 2021). The viral load was higher than the global UNAID report at the end of 2019, where 59% of the people living with HIV had viral suppression. (UNAID, 2021). The unsuppressed clients of 0.4% was significantly lower than that of a study conducted in Southeastern Nigeria (24.6%), China 12.1% and Nepal 9.94%. Although China and Nepal use AZV/3TC/NVP and TDF/3TC/EFV as first line treatment options.

The result generally revealed that the viral loads of clients with unsuppressed viral load before transitioning from TLE to TLD were suppressed. It was observed that in 2018, 20.9% 0f the Clients had an unsuppressed viral load, with 14.9% in 2019 pre transitioning period, while the unsuppressed clients increased to 18.4% after transitioning to TLD in 2020, and a marked decreased to 4.2%, 1.1% and 0.4% in 2021, 2022 and 2023 respectively. The result shows the effectiveness of Dolutegravir based regimen as 99.6% of the clients on TLD whose samples were taken for viral load testing had viral suppression.

CONCLUSION

The level of viral suppression among people leaving with HIV/AIDS in a secondary health care facility in Niger state was assessed and revealed that TLD was more effective in the management of HIV infection than previously administered regimens. This underscores the need for continuous monitoring and regular review of the outcome of Antiretroviral therapies amongst patients. The result of the study may be useful to policy makers, researchers, and healthcare practitioners.

There is therefore a need to continuously monitor regularly review the outcome of Antiretroviral therapies amongst patients.

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