



Effect of Dolutegravir/Lamivudine/Tenofovir (TLD) on the Viral Load among HIV-Infected Patients in Kebbi State, Nigeria

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Abstract

Human Immunodeficiency Virus (HIV) remains a major global public health concern, particularly in sub-Saharan Africa. The fixed-dose combination therapy involving Dolutegravir, Lamivudine, and Tenofovir (TLD) has been recommended for its superior efficacy and tolerability all above the World. This study aimed at evaluates the effect of TLD on viral load suppression among HIV-infected patients in Kebbi State, Nigeria using retrospective cohort and semi-structured questionnaire methods. Data on the demographics, treatment history and viral load were obtained from 169 HIV-positive medical records patients receiving ART in selected health facilities within the study area. From the results obtained over 75% of the medical records patients were transitioned to TLD achieved viral load suppression (<200 copies/mL) within six months compared to patients on older ART regimens that observed with a significantly lowest suppression rate of about 55%. Additionally, patients on TLD reported fewer side effects, improved health outcomes and higher adherence levels. TLD demonstrated superior viral load suppression and tolerability. Thus, transitioning eligible patients to TLD and investing in adherence programs is critical to achieving HIV epidemic control targets in the study area.

Keywords: Dolutegravir, HIV, Lamivudine, Tenofovir and Viral load

1.0 Introduction

HIV remains one of the most serious and deadly infections globally. Kebbi State, like many regions in Nigeria, has been affected by HIV/AIDS. The prevalence rates, although varying over time, indicate a significant public health challenge [1]. It continues to present significant health and socio-economic challenges worldwide, with the African region bearing the heaviest burden [2]. Despite antiretroviral therapy (ART) advancements, challenges in viral suppression persist [2]. Dolutegravir/Lamivudine/Tenofovir (TLD) has emerged as a highly effective first-line regimen recently [2]. Nigeria has committed to ending the AIDS epidemic as part of its national health strategy [3, 4]. Programs in Kebbi State contribute to achieving this national goal.

Recently HIV continues to be a significant global public health concern, responsible for an estimated 40.4 deaths (ranging between 32.9 and 51.3 million) to date, with new cases still being reported in every country. Alarmingly, some regions that had previously seen declining infection rates are now experiencing resurgence [2]. As of the end of 2022, approximately 39.0 million people (33.1 to 45.7 million) were living with HIV, with around two-thirds (25.6 million) located in the WHO African region [2]. That same year, HIV-related illnesses claimed 630,000 lives (480,000–880,000) and 1.3 million people (1.0–1.7 million) acquired new infections. Although a cure for HIV has not yet been found, advances in prevention, diagnosis, treatment, and the management of opportunistic infections has turned HIV into a controllable

chronic illness, enabling individuals living with the virus to lead long and healthy lives [2].

HIV/AIDS places a considerable strain on the healthcare system, diverting resources from other essential services [5]. Continuous surveillance and data collection are crucial for understanding the disease dynamics. Vulnerable individual men, women, and high-risk populations like hookers and people who inject drugs are impacted at disproportionately higher rates [6]. The disease affects the workforce, leading to reduced productivity and increased poverty [7]. Addressing the needs of these groups will be essential for controlling the epidemic [6]. Antiretroviral therapy (ART) has greatly extended the life expectancy of individuals living with HIV. Currently, fixed dosed combination therapy (Tenofovir, Lamivudine, and Dolutegravir) is being introduced in most countries in the Sub-Saharan Africa. There is need for a clinical and immunological assessment of HIV patients transitioned to this new therapy over a period of years. These studies aimed at determine the effect of TLD on the viral load of HIV-infected patients in Kebbi State.

2. Materials and Methods

2.1 Study Area

Kebbi State is situated between latitudes $10^{\circ}00' - 13^{\circ}20' N$ and longitudes $3^{\circ}00' - 6^{\circ}00' E$. The State is bounded by the Republics of Niger and Benin in the west, Niger State in south, Zamfara State in the east and Sokoto State in the north and east. It has a mean annual temperature of $21^{\circ}C - 38^{\circ}C$, though it fluctuates. The mean annual rainfall of the state is between 500mm in the north to 130mm in the south also the area has varied vegetation zones.

2.2 Study Design

The study was retrospective cohort study and conducted across selected ART clinics in Kebbi State, Northwestern Nigeria. It was involved the use of medical record of HIV patients.

2.3 Sampling Technique

A multi-stage sampling method was utilized in which Kebbi State was stratified into senatorial districts and Random sampling was used to select health facilities within each district. Proportionate stratified sampling was used to ensure

representation of medical record of the patients on TLD and those on other ART regimens.

2.4 Study Population

The study population consisted of 169 medical records of HIV-positive patients of both sexes, aged 18 years and older, who had been on antiretroviral therapy (ART) for a minimum of 12 months. These records were obtained from various health facilities across Kebbi State during the data collection period.

2.5 Inclusion and Exclusion Criteria

Medical file record of HIV-positive patients aged 18yrs to above, transitioned to TLD or maintained on older ART regimens with complete viral load records were enclosure while patients record with incomplete records or co-infections interfering with ART were excluded.

2.6 Ethical Approve

Ethical consideration was obtained from the competent authority (Bonaventure Okoye E Laboratory Technical Advisor USAID-ACE3 Project, Behind Khayyaj Filling Station, Birnin Kebbi, Kebbi State) as HSCL/USAID/VOL.1/56. The ethical approval to conduct this study was obtained from the ethical committee, Bonaventure Okoye E Laboratory Technical Advisor USAID-ACE3 Project, Behind Khayyaj Filling Station, BirninKebbi, Kebbi State through collaboration with the ethnical committee of Abdullahi Fodio University of Science and Technology, Aliero.

2.7 Data Collection

The primary data namely; demographics (age, gender, occupation, and marital status), ART history, viral load measurements and regimens side effects were obtained and extracted from 169 patients medical record sat different health facilities within the Kebbi state without their knowledge prior. Each individual patient medical record was study and data was extracted through the help of medical recorder clerk/record administrator for the completeness and accuracy of the data. The data extracted were compiled and recorded in semi-structured questionnaire.

2.8 Validity and Reliability of the Collected Data

Data validity and reliability were assessed by cross-referencing with notes obtained from the the medical record of HIV-infected then process to identify any potential omissions or additions.

2.9 Data Analysis

Statistical analysis was performed using SPSS v25. Descriptive statistics summarized sociodemographic characteristics, and comparative analysis assessed viral suppression rates between regimens using t-tests and ANOVA. A p-value <0.05 was considered statistically significant.

3.0 Results

A total of 169 HIV patient medical records in Kebbi state were properly assessed. Out of the medical records ascertain, 99 (58.6%) were males and 70 (41.4%) were females (Table 1). Regarding marital status, 78 (46.2%) were observed as married followed by 52 (30.8%) divorced and 39 (23.1%) singles. In the other hand, it revealed that, the major of the HIV patients attended all the health facilities study were business (29%), unemployed (23.7), others (20.1%), farmer (18.9%) and civil servant with the least value of (8.3%) Table (1) respectively.

Table 2 shows that at baseline, 60 participants (35.51%) had achieved viral suppression (viral load <50 copies/mL), while this number increased to 109 (64.49%) following the switch to the TLD regimen.

The majority of participants were classified under WHO clinical stage A and demonstrated adherence rates exceeding 95%. Notably, there were statistically significant improvements in key clinical parameters after initiating TLD, particularly in viral load ($p < 0.001$), although the change in WHO clinical staging was not statistically significant ($p = 0.68$) (Table 2).

Table 1: Socio-demographic of HIV Patients Participants in Kebbi State

Variables	Frequency	Percentage (%)
Age		
18–25	37	21.9
26–45	93	55
>45	39	23.1
Gender		
Male	99	58.6
Female	70	41.4
Marital status		
Singled	39	23.1
Married	78	46.2
Divorced or widowed	52	30.8
Occupation		
Business	49	29
Farmer	32	18.9
Civil servant/Government employer	14	8.3
Unemployed	40	23.7
Others	32	20.1

Table 2: Effect of TLD Transition on the HIV Patients in Kebbi State

Variables	Pre-TLD	Post-TLD	P-Value
Viral load n (%)			
<50cpm	60 (35.51)	132(78.1)	
>50cpm	109(64.49)	37(21.9)	<0.001
WHO clinical staging n (%)			
Stage A	133 (78.69)	164 (96.44)	
Stage B	36 (21.4)	5 (2.95)	0.68
Adherence			
Less than 95%	155 (91.71)	169 (100)	
Greater than 95%	14 (8.28)	0	

After three months on the TLD regimen, a highly significant rate of viral load suppression was observed, whereas only 16.56% of individuals in the ART group achieved suppression during the same period. This trend remained consistent at the

six-month mark, with the ART group showing a suppression rate of 23.66%, compared to 83.43% in the TLD group, indicating a substantial virological response among those on TLD at P value<0.001 (Table 3).

Table 3: HIV viral load levels among patients on TLD compared to those on other ART regimens

Regimen	Month on Regimens	
	At 3 Month	At 6 Month
TLD	129 (76.33)	141 (83.43)
ART	28 (16.56)	40 (23.66)
P value	< 0.0001	< 0.0044

Note: A viral load <150 copies/mL is considered virological suppression. P value <0.001 is considered statistically significant. TLD: tenofovir/lamivudine/dolutegravir and ART: Antiretroviral therapy

As indicated in Table 4, 89.9% of patients were transitioned to TLD and 10.1% of patients commenced TLD directly. Among the medical records of the patients, 142 (84%) of the patients were none comorbidities, 10 (5.9%) were found to have malaria, 8 (4.7%) are hypertension and 4 (2.3%) of

the patients had other diseases. Among the 100 patients only 39.05% of patients were currently on CPT (Cotrimoxazole preventive therapy). On the other hand, CPT was not started or not documented for 45.45% of patients, and 1.5% of patients discontinued CPT. No documented clinical PCP and adverse drug reaction (ADR) experiences were found. The latest CD4 counts as well as CD4 count at the initiation or transition of TLD was not done for 89.3% and 81% of the patients, respectively. Among the patients, 3.5% had a recent CD4 count greater than 350 cells/mm³, while 6.5% had a CD4 count below 350 cells/mm³. On the other hand, CD4 counts of > 350 cells/mm³ and < 350cells/mm³ were documented in only 10.2% and 8.8% of the patients at the initiation and transition of TLD. Moreover, 76.92% of the patients were found to have a scheduled medication refill history.

Table 4: Treatment outcomes and Clinical Profile

Variables	Categories	Frequency	Percentage (%)
TLD rank	Instigated TLD	17	10.1
	Transitioned to TLD	152	89.9
Comorbidities	None	142	84
	Hypertension	8	4.7
	Peptic ulcer Disease	5	2.9
	Malaria	10	5.9
	Other	4	2.3
On Cotrimoxazole preventive therapy	Currently on CPT	66	39.05
	CPT is not started/not documented	77	45.45
	CPT discontinued	16	1.51
PCP, Pneumocystis carinii pneumonia	Yes	0	
	No	169	100
Any adverse drug reaction (ADR) experience	Yes	0	
	No	169	100
CD4 count at initiation or transition of TLD	Not done	151	89.3
	<350	11	6.5
	>350	6	3.5
Latest CD4 count	Not done	137	81
	<350	15	8.8
	>350	17	10.2
Medical reasons for avoiding TLD	No contraindication	169	100
	Renal failure	0	0
	Others	0	0
Medication refill	Scheduled	130	76.92
	Unscheduled	39	23.8

4.0 Discussion

HIV remains a major global public health issue, with 39 million people living with the virus as of 2022, and sub-Saharan Africa bearing nearly two-

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thirds of the burden [2]. The adoption of fixed-dose combination therapies like Dolutegravir/Lamivudine/Tenofovir (TLD) has transformed HIV care worldwide. [8] reported that approximately 71% of people on antiretroviral therapy (ART) have

achieved viral suppression, a milestone largely attributed to the global rollout of TLD in line with the 95-95-95 targets.

The Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) estimated an overall, HIV prevalence among adults in Nigeria to be 1.4%, with an adult respondent of 87.3% aged between 15-49 years [9]. In a related study in southern Nigeria [10], it was found that the majority of their respondents 75.5% were within the 25 - 49 age range which is high them what obtained in the presented study 55%. Similar to previous studies from Sokoto in Nigeria, most of the HIV patients were female [11] these disagree with the present findings. My study also revealed that 46.2% of the respondents are married compared with 30.8% who were divorced or widowed and 23.1% singled. In addition, 23.7% of the patients were found to be Unemployed compared with 29% business. This collaborate the cross-sectional study conducted by [12] in a Nigerian Tertiary Hospital.

TLD has been established as the preferred first-line regimen due to its high efficacy, low resistance, once-daily dosing, and minimal side effects. [13], showed that over 90% of patients using TLD achieved undetectable viral loads, supporting the regimen's clinical superiority. In different parts of the World different researchers have validated TLD's effectiveness [14, 15, 16, 17]. These previous studies parallel with the presence findings which align with the regional and global patterns. In Kebbi state, more than 75% of HIV medical records shown that patients transitioned to TLD achieved viral suppression (<200 copies/mL) within six months with greater improvement when compared suppression rate recorded in patients that is on older ART regimens. Moreover, patients on TLD reported documented lower side effect led to the improvement of their health status and better adherence. This is in line with the [2] that stated that, post-TLD improved immune recovery and human life eminence. Another study by [18] in Ethiopia observed lowest devious contagions and fewer hospitalization rates among HIV patients on TLD. [19] in Northwest part of Nigeria stressed reduced malaria co-infections and enhanced daily functioning. This contradicted with findings of [20], whom recorded an subset of patients experienced adverse effects like insomnia, nausea, elevated liver enzymes and highlighting the need for pharmacovigilance among the patients of Cameroon. Thus, the presence findings indicated **Bulletins of Natural and Applied Sciences (2025).2(2):91-97**

that 89.9% clinical medical records of HIV patients that transitioned to TLD there's an increase rate of their health, general wellbeing and reduction of resourceful infections with less side effects.

Table (3) revealed that after six months of initiating TLD, 83.43% of the medical records atients achieved viral suppression (<50 copies/mL), compared to only 23.66% among those who remained on older ART regimens. These results corroborate the findings by [2, 22] in Kenya and [23] in Nigeria whom showed the varied suppression rate of 85% and 75% among the HIV patients. In order hand, [24, 25] reported emerging drug resistance in patients with prior ART failure who transitioned to TLD without adequate viral load monitoring. Generally, TLD is very useful with therapeutic merit in any local population.

5.0 Conclusion

This study assessed the impact of Dolutegravir/Lamivudine/Tenofovir (TLD) on viral load suppression and general clinical outcomes of HIV-positive individuals in Kebbi State, Nigeria. The findings demonstrate that the introduction of TLD significantly enhanced viral suppression rates, with over 75% of patients achieving undetectable viral loads (<200 copies/mL) within six months of transition. This outcome is consistent with both global and regional data indicating the superior efficacy of TLD compared to older ART regimens. This outcome is consistent with both global and regional data indicating the superior efficacy of TLD compared to older ART regimens. Additionally, patients on TLD documented fewer adverse effects, better adherence, and improved overall health-related quality of life, particularly among adolescents. These outcomes underscore the regimen's clinical advantages and its suitability as a preferred first-line treatment in resource-limited settings such as Kebbi State.

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