ORIGINAL ARTICLE

Safety and Tolerability of Tenofovir, Lamivudine, and Dolutegravir Regimen in South Indian Adult Human Immunodeficiency Virus-1 Patients

Pathan Amanulla Khan, Mahadevamma Lingaih

Department of Pharmacy Practice, College of Pharmaceutical Sciences, School of Health Sciences, Dayananda Sagar University, Bengaluru, Karnataka, India

Abstract

Background: The fixed-dose combination of tenofovir, lamivudine, and dolutegravir (TLD) is the World Health Organization's recommended first-line regimen for human immunodeficiency virus (HIV) treatment due to its potent virologic suppression and high tolerability. However, concerns remain regarding its long-term safety, especially in diverse populations. **Objective:** The objective of this study was to assess the safety, tolerability, and adverse effects of the TLD regimen among HIV-positive individuals in a real-world South Indian patient. **Methods:** An ambispective study was conducted on 1021 HIV-1-positive patients aged 19–75 years receiving the TLD regimen at a district ART center. Adverse drug reactions (ADRs), laboratory parameters, opportunistic infections (OIs), and treatment tolerability were analyzed. Data were collected from medical records and patient reports. Statistical analysis included Chi-square tests and binary logistic regression. **Results:** Among the participants, 659 ADRs were reported, with nausea (18.06%), headache (16.23%), and rash (14.87%) being the most common. Older age (40–59 and 60–75 years) and male gender were associated with increased ADR risk. Hepatitis B co-infection showed a near-significant association with higher ADR (odds ratio = 2.788, $P = 0.057$). OIs were reported in 15.7%, predominantly pulmonary tuberculosis (9.6%). Tolerability was high, with 87.3% of patients rating their experience as "Excellent." Laboratory abnormalities included anemia (59.3%) and dysglycemia (24.0%), with minimal hepatic or renal toxicity. **Conclusion:** The TLD regimen demonstrates excellent tolerability and efficacy with a manageable safety profile. Monitoring for anemia, metabolic changes, and age-related ADR risks is recommended to optimize treatment outcomes in HIV care programs.

Key words: Adverse drug reactions, dolutegravir, tenofovir, lamivudine, and dolutegravir regimen, human immunodeficiency virus treatment, opportunistic infections, tolerability

INTRODUCTION

The human immunodeficiency virus (HIV) is the infectious agent that causes sexually transmitted disease HIV,[1] mostly from people or patients unaware of their HIV-positive status.[2] There are two primary subtypes of immunodeficiency virus: HIV type 1 (HIV-1) and HIV type 2 (HIV-2).[3] HIV-1 breaks down into subgroups M, N, O, and P, with the M Group further having subtypes A-D, F-H, and J-K.[1,4] In recent years, the global scale-up of antiretroviral therapy (ART) has dramatically reduced HIV-related mortality and morbidity.[5] To strengthen it further, the WHO has recommended a transition to dolutegravir (DTG)-based regimens as first-line therapy, specifically the fixed-dose combination of tenofovir, lamivudine, and dolutegravir (TLD) regimen.[6] This recommendation arose from its potent virologic suppression, high resistance threshold, once-daily dosing convenience, fewer drug-drug interactions and overall good safety profile.[7] However, some recent studies have raised concerns regarding weight gain, neuropsychiatric adverse effects, including insomnia and anxiety in a subset

Address for correspondence:
Mahadevamma Lingaiah, Department of Pharmacy Practice, College of Pharmaceutical Sciences, School of Health Sciences, Dayananda Sagar University, Bengaluru, Karnataka, India. Phone: +91-9035733812.
E-mail: mahadevammalingaiah11@gmail.com

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of patients, along with nephrotoxicity and reductions in bone mineral density, especially with prolonged use of the TLD regimen.[8-10] Despite these safety concerns, the overall tolerability of the TLD regimen remains high, and its public health benefits have led to its widespread adoption in HIV treatment programs globally.[11-13] Owing to the above-mentioned reasons, continuous pharmacovigilance and cohort studies are essential to monitor long-term outcomes and identify patient populations that may require regimen adjustments.

MATERIALS AND METHODS

An ambispective study was carried out at a South Indian district ART center for a period of 2 years, from March 2023 to March 2025on patients living with HIV and AIDS aged between 19 and 75 years who are receiving the TLD regimen as their treatment. The inclusion criteria involved patients with positive HIV-1 infection who are on therapy with the TLD regimen for a minimum of 24 weeks. The exclusion criterion includes subjects who had negative HIV Infection and are on other HAART regimens with severe renal or hepatic impairment. Along with these subjects, who were hypersensitive/allergic to the TLD regimen, were also excluded.

Data collection

The study was conducted with the institutional ethics committee ref number (IEC/03/17) for the collection of data through patient medical records. Patient's history/data includes when they have been diagnosed with HIV, treatment they have been receiving and their response to that treatment were collected by obtaining informed consent. All the eligible patients on one tablet each of DTG (50 mg) and TDF and 3TC (300/300 mg) fixed dose combination once daily were taken in to the study. Study specific tolerability questionnaire was developed, incorporating the use of Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events to assess tolerance based on the scoring algorithm that has co-occurrence of two or more ADRs and the patient's degree of adherence to the medication regimen, providing a comprehensive assessment of treatment tolerability. Following the above criteria, two categories, good tolerability: <3 ADRs with adherence more than 95% and excellent tolerability with <2 ADRs with adherence more than 95%, were considered, as almost all patients fell under these two categories.

Sample size and statistical plan

According to the quoted study, "Dravid A, Morkar D *et al*., the sample size calculated and the resulting sample were 1013. The data collection and compilation were done in Microsoft Excel. The data analysis was performed using the Statistical Package for the Social Sciences version 27. The frequency and proportion were used to describe the demographic and clinical factors. Mean and Standard deviation were used to estimate the virological and immunological outcomes. Chi-square test was used to perform the univariate analysis. Binary logistic regression analysis was used to find the odds of the risk factors associated with efficacy. Statistical significance was considered at 5% level of significance ($P < 0.05$).

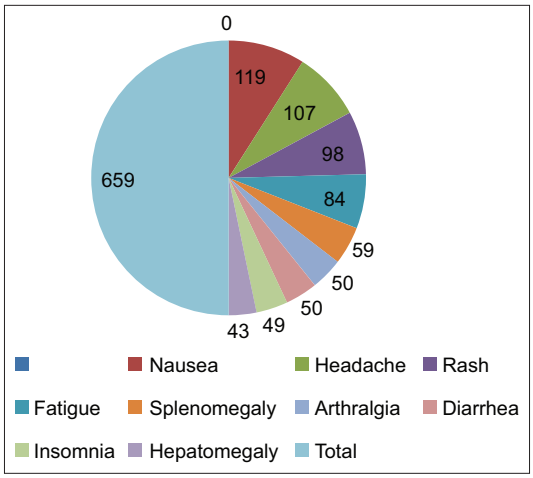

Figure 1: Side effects and frequency based on patients' treatment

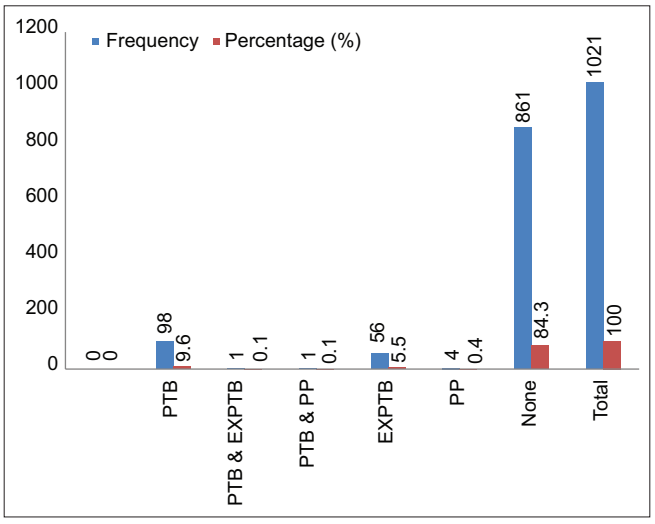

Figure 2: Opportunistic infections associated with the tenofovir, lamivudine, and dolutegravir regimen

RESULTS

Demographics and family history of patients showed young adults (19–39) dominate the sample, accounting for two-thirds of participants, while coming to gender, male participants (524) slightly outnumber females (475), with a very small representation of TG individuals. On the other hand, family history showed that more than half have spouses who are positive for the studied condition. In contrast, a sizable one-third have spouses who are negative, along with

Table 1: The odds ratio related to patient characteristics associated with adverse drug reactions

Patient characteristics	Odds ratio for (ADR)	*P*-value	95% confidence interval for OD	
			Lower	Upper
Age				
19–39	1.000			
40–59	1.444	0.011	1.089	1.914
60–75	1.674	0.002	0.000	1.6779
Gender				
Female	1.000			
Male	1.313	0.050	1.000	1.722
TG	0.332	0.164	0.071	1.565
Family history				
Spouse (+)	1.000			
Spouse (–)	1.059	0.687	0.800	1.403
Children (+)	0.000	1.000	0.000	
Spouse-expired	0.844	0.615	0.437	1.631
Unmarried	1.825	0.174	0.767	4.341
Family not tested	0.552	0.059	0.298	1.023
Medication adherence				
Poor ADR (<80%)	1.000			
Fair ADR (81–95%)	0.663	0.692	0.087	5.066
Good ADR (>95%)	0.515	0.487	0.079	3.346
Comorbidities				
HTN	1.000			
Thyroid disease	1.103	0.824	0.467	2.603
Diabetes mellitus	0.998	0.996	0.512	1.947
Hep-B	2.788	0.057	0.971	8.006
None	1.018	0.952	0.576	1.798
HTN and DM	0.933	0.886	0.360	2.417

ADR: Adverse drug reactions, HTN: Hypertension, DM: Diabetes mellitus

Table 2: The proportion of tolerance level among the participants

Tolerability level	Frequency	Percentage
Good	130	12.7
Excellent	891	87.3
Total	1021	100.0

a small fraction of either unmarried, report deceased spouses, or have not had family testing for HIV.

A total of 659 adverse drug reactions (ADRs) from Figure 1were reported across nine different symptoms. Nausea was the most frequently reported side effect, accounting for 18.06% of all ADRs, followed closely by headache (16.23%) and rash (14.87%). Fatigue was also common, representing 12.75% of the ADRs. Less frequently observed were splenomegaly (8.95%), arthralgia and diarrhea (both at 7.59%), insomnia (7.43%), and hepatomegaly, which was the least reported at 6.52%.

The odds ratio (OR) estimates of table 1 for study factors associated with ADR suggest around 1.444 times the risk of ADR is higher in the age interval 40–59 years in comparison with 19–30 years and 1.67 times higher in the 60–75 years age group. While coming to the gender male group has a risk of ADR 1.313 times higher than females, and in the TG group, the risk is lower compared to female but statistically it is not significant. The results also suggest that the risk of ADR is found 2.788 times higher in hepatitis-B patients, and in the rest of the comorbidities, the risk remains almost the same.

The distribution of various opportunistic infections (OI) among a total of 1021 individuals showed that most individuals from the Figure 2 showed that most individuals, accounting for 84.3%, had no recorded OI infection. Pulmonary tuberculosis (PTB) was the most reported OI, accounting for 98 individuals, representing 9.6% of the total. Extrapulmonary TB (EXPTB) was observed in 56 individuals (5.5%), whereas Pneumocystis pneumonia (PP) appeared in only 4 cases (0.4%). A small number of individuals presented with multiple conditions: One case each of PTB combined with EXPTB and PTB combined with PP, each constituting just 0.1% of the population. Overall, while PTB and EXPTB were the most frequent infections, most individuals had no infection, highlighting a relatively low rate of infections and better tolerability.

The tolerability levels among 1021 participants from table 2 revealed that the majority rated their experience as highly tolerable. Specifically, 87.3% (891 individuals) reported an "Excellent" level of tolerance. In contrast, only 12.7% (130 participants) rated their tolerability as "Good." These findings indicate a strong overall tolerability of the treatment or intervention, with nearly nine out of ten participants reporting top-tier satisfaction.

The laboratory data analysis of the table 3 reveals that abnormalities in hemoglobin levels are the most common finding, affecting 59.3% of the population. This includes cases of severe, moderate, and mild anemia as well as some instances of elevated hemoglobin, suggesting a significant prevalence of anemia and polycythemia among the patients. Random blood sugar abnormalities were also notable, with 24% of individuals showing either hypoglycemia or hyperglycemia, indicating a considerable burden of glucose metabolism disorders such as diabetes. Abnormal alkaline phosphatase levels were present in 8.7% of cases,

Table 3: Objective variables related to patients' treatments

Parameters	Normal range	Abnormal range	Abnormal frequency	Abnormal percentage
Hemoglobin (g%)	13.1–17	<13.1 or>17	605 (55+100+357+93)	59.3
Serum creatinine	0.7–1.3 mg/dL	>1.3 mg/dL	70	6.9
Serum bilirubin	0.1–1.2 mg/dL	>1.2 mg/dL	22	2.2
SGOT (IU/L)	5–40 IU/L	>40 IU/L	43	4.2
SGPT (IU/L)	5–35 IU/L	>35 IU/L	54	5.3
Alkaline phosphatase (IU/L)	30–120 IU/L	<30 or>120 IU/L	89 (2+87)	8.7
Random blood sugar (mg/dL)	70–140 mg/dL	140–199 mg/dL	245 (24+221)	24.0

SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamate pyruvate transaminase

which could reflect bone disease, liver dysfunction, or biliary obstruction. Mild elevations in liver enzymes (serum glutamic oxaloacetic transaminase [SGOT] and serum glutamate pyruvate transaminase [SGPT]) were observed in a smaller percentage of patients (4.2% and 5.3%, respectively), pointing to potential liver injury from various causes. Elevated serum creatinine levels were seen in 6.9% of the population, suggesting impaired kidney function or dehydration in some cases. Finally, serum bilirubin abnormalities were the least common, present in only 2.2% of patients, and may indicate mild liver dysfunction or other benign conditions.

DISCUSSION

The TLD regimen is widely utilized in clinical practice for treating HIV infection. Its benefits include once-daily dosing, which can be taken with food or on an empty stomach at a low dose within a fixed-dose combination, reduced cross-resistance, and a broader barrier to resistance.[14,15] Upon examination of the data on adverse effects associated with the TLD regimen, both expected and relatively uncommon side effects were revealed among patients undergoing ART. Among the total of 659 reported adverse events, the most frequent were nausea (18.06%), rash (14.87%), fatigue (12.75%), and headache (16.23%), consistent with findings from previous clinical trials and real-world studies involving DTG-based therapy.[8,16,17] Notably, rash (14.87%) and nausea (18.06%) were prominent among the side effects. Although DTG is generally well tolerated, skin reactions have been reported, albeit less frequently than with older Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)-based regimens such as efavirenz.[18] The relatively higher incidence of rash observed here may suggest possible coadministration with other drugs, hypersensitivity reactions, or local factors, which require further investigation. Similarly, arthralgia and splenomegaly (8.95%), while not commonly associated with TLD, could reflect immune reconstitution inflammatory syndrome or unrelated opportunistic infections (OIs), particularly in newly initiated patients.[19] On the other hand, hepatomegaly (6.52%) and splenomegaly may indicate subclinical liver involvement, chronic HBV co-infection, or other systemic conditions. Although DTG is considered hepatologically safe, tenofovir and lamivudine have known activity against hepatitis B, and hepatic flares can occur in patients co-infected with HBV during ART initiation.[20] Several demographic and clinical factors were evaluated for their association with ADRs. The analysis found a statistically significant relationship between age and ADR incidence. Individuals aged 40–59 years had 1.44 times higher odds of experiencing an ADR compared to those aged 19–39 (OR = 1.444, $P = 0.011$, 95% confidence interval [CI]: 1.089–1.914). This aligns with previous literature suggesting that age-related physiological changes and polypharmacy may increase the risk of ADRs in middle-aged and older populations.[21] Gender was a borderline significant factor, with males exhibiting a 31% higher risk of ADRs compared to females (OR = 1.313, $P = 0.050$). While the confidence interval was narrow (95% CI: 1.000–1.722), this matches some studies that report gender-based differences in drug metabolism and immune response.[23] However, the borderline *P*-value indicates that further research is needed to confirm this trend. Among comorbidities, hepatitis B infection was linked to a nearly threefold increase in the odds of ADRs (OR = 2.788, $P = 0.057$), though this did not reach traditional statistical significance. Nonetheless, the clinical importance of this finding cannot be overlooked, especially considering that liver dysfunction may impair drug metabolism, increasing the risk of ADRs.[23] Future studies with larger sample sizes may help clarify this relationship.

Of 1021 individuals on TLD, the majority (84.3%) had no documented OIs, reflecting the high effectiveness of early ART initiation in reducing OI burden. Tuberculosis (TB) remained the most common OI, with PTB diagnosed in 9.6% and EXPTB in 5.5% of participants. Co-occurrence of PTB with EXPTB (0.1%) or PP (0.1%) was rare. Isolated PP was observed in only 0.4% of the study population. These findings are consistent with global evidence that TB remains the leading OI in people living with HIV, particularly in high-burden countries, despite ART rollout.[24,25] The observed prevalence of TB in our study is lower than historical pre-ART rates, which often exceeded 30–40% in similar populations,[26] underscoring the impact of DTG-based regimens in achieving rapid viral suppression and immune recovery.[8] The relatively low frequency of PP in this study may reflect improved immune status due to early ART initiation and effective cotrimoxazole preventive therapy,

as recommended by national and WHO guidelines.[27] The reduced OI burden overall is in line with studies demonstrating that early use of potent integrase inhibitors, such as DTG, facilitates faster CD4 recovery, thereby lowering OI risk compared to NNRTI-based regimens.[7,28] The tolerability profile demonstrated that the TLD regimen was highly tolerated among study participants, with 87.2% rating tolerability as excellent and the remaining 12.7% rating it as good. Importantly, no participants reported tolerability below "Good," indicating that adverse effects were minimal or non-disruptive to daily living. These findings align with global data on the safety and tolerability of DTG-based regimens. The WHO's 2018 recommendation of TLD as the preferred first-line ART was based in part on evidence from randomized controlled trials and programmatic studies demonstrating a favorable tolerability profile and low discontinuation rates.[29] In the ADVANCE and NAMSAL trials, TLD showed excellent safety with very low rates of treatment-limiting adverse events, further supporting its widespread use and tolerability.[8,17] The laboratory safety profile observed in this study indicates that most participants maintained parameters within the normal range during TLD therapy, with relatively few clinically significant abnormalities. The most frequent abnormality was anemia, observed in 59.3% of participants. Although DTG-based regimens are generally associated with a lower risk of hematologic toxicity compared to zidovudine-containing regimens,[8,29] the high anemia prevalence here may reflect underlying HIV-related disease burden, nutritional deficiencies, or comorbid conditions rather than direct TLD toxicity. Renal function, as assessed by serum creatinine, was elevated in 6.9% of participants. This finding is consistent with known benign increases in serum creatinine caused by DTG's inhibition of renal tubular creatinine secretion without affecting actual glomerular filtration rate.[16] Only a small proportion (2.2%) exhibited hyperbilirubinemia, and mild transaminase elevations (SGOT 4.2%, SGPT 5.3%) were infrequent, aligning with previous evidence that TLD has a low incidence of hepatotoxicity compared with older NNRTI-based regimens.[7,17]

Elevations in alkaline phosphatase were detected in 8.7% of participants, which may reflect hepatic or bone turnover processes and should be interpreted in the clinical context. Notably, dysglycemia (hypoglycemia or hyperglycemia) occurred in 24.0% of participants – an observation requiring careful evaluation given emerging reports of metabolic changes, including weight gain and altered glucose metabolism, in some individuals initiating DTG.[30]

CONCLUSION

The TLD regimen shows strong efficacy, safety, and tolerability in treating HIV, with most patients experiencing few and manageable side effects. While some adverse events, such as rash, anemia, and metabolic issues, require ongoing monitoring, the overall low rate of OIs and high patient-reported tolerability underline the regimen's safety and effectiveness in real-world settings. These findings support continued use of TLD as a preferred first-line therapy, with attention to individual risk factors such as age, hepatitis B co-infection, and tuberculosis to improve patient outcomes.

AUTHOR CONTRIBUTIONS

PAK and ML worked on the conceptualization and methodology of the topic. PAK did a literature review, collected data and analyzed it for the study. PAK is responsible and accountable for the drafting of the manuscript. ML reviewed the whole manuscript and approved it for submission.

Limitations

The study was conducted in a single geographic region (South India), which may limit the generalizability of the findings to other populations. Because of its single-centered nature, the results may not reflect outcomes across different healthcare settings. Another limitation was the sample size, which was relatively small, potentially limiting the detection of rare ADRs. Apart from this follow-up duration was limited, which may not adequately capture long-term safety outcomes such as metabolic, renal, or bone-related adverse effects.

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