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CLINICAL OUTCOMES OF DOLUTEGRAVIR-BASED ANTIRETROVIRAL THERAPY

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ABSTRACT: This study investigates the efficacy of transitioning from Tenofovir/Lamivudine/Efavirenz (TLE) to Tenofovir/Lamivudine/Dolutegravir (TLD) as the primary antiretroviral therapy for HIV management. A retrospective analysis was performed on 261 patients, comprising 116 individuals who commenced TLD as first-line therapy in 2020 and 145 individuals who initially received TLE in 2017 prior to transitioning to TLD in 2020. Both clinical and non-clinical dimensions were analyzed. Viral load (VL), CD4 cell count, and WHO clinical stage constituted the clinical variables. Age, sex, weight, transmission method, and body mass index (BMI) were non-clinical factors. Both groups exhibited substantial alterations in weight, viral load, and CD4 count ($p < 0.001$***). The two groups exhibited minimal disparity, evidenced by the median BMI of patients initiating TLD at 20.83 (IQR 18.95–23.87; $p = 0.115$, ns) and those transitioning from TLE to TLD at 21.63 (IQR 19.62–24.37; $p = 0.004$**). TLD is advantageous for HIV treatment as it typically enhances clinical outcomes and sustains viral suppression when incorporated into the ART regimen.

Keywords: *Dolutegravir (TLD); Tenofovir/Lamivudine/Efavirenz (TLE); HIV management; antiretroviral therapy (ART); viral load; CD4 cell count; BMI; clinical outcomes; viral suppression; first-line therapy; retrospective study.*

1. INTRODUCTION

HIV infection is a significant worldwide health issue as it can gradually impair the immune system and, if untreated, result in acquired immunodeficiency syndrome (AIDS). HIV is currently a manageable chronic infection due to antiretroviral therapy (ART). For individuals with it, this has markedly enhanced their quality of life and longevity. To far, HIV infection has resulted in the deaths of about 40.1 million individuals globally. By the conclusion of 2022, almost 39 million individuals globally were HIV +. Approximately 25.6 million of them inhabited Africa.

In 2022, there were approximately 1.3 million new HIV infections and 630,000 deaths attributable to HIV-related causes. These statistics illustrate the ongoing global impact of HIV/AIDS and underscore the necessity for the continued advancement of effective strategies for the prevention, diagnosis, and treatment of the illness. In 2022, HIV/AIDS continued to pose a substantial public health challenge in India, with over 2.3 million individuals infected with the infection.

Despite a recent decline in the number of HIV-positive individuals in India, several regions and demographics persist in exhibiting elevated rates. HIV prevalence is higher among men

who engage in sexual activity with other men, transgender individuals, female sex workers, and intravenous drug users. India's initiatives to address HIV/AIDS have included antiretroviral therapy, targeted preventive strategies for high-risk populations, and extensive testing and counseling programs. Notwithstanding considerable progress in HIV treatment, attaining optimal outcomes for each individual continues to be problematic. Nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and integrase strand transfer inhibitors (INSTIs) are customarily utilized in conjunction within standard antiretroviral therapy regimens. Despite the efficacy of these regimens in diminishing HIV-related morbidity and death and curtailing viral reproduction, treatment failure and drug resistance persist as substantial challenges. Treatment failure may result from various circumstances, including drug toxicity, the emergence of treatment-resistant virus strains, and noncompliance with the prescribed regimen. Moreover, adhering to previous ART regimens and preventing viral resurgence has proven difficult due to their intricacy and the number of medications involved.

In October 2020, the World Health Organization (WHO) substituted efavirenz (EFZ) with dolutegravir (DTG) as the primary treatment for HIV. This signified a substantial transformation in HIV treatment regimens. This alteration was chiefly instigated by EFZ's failure to attain optimal therapeutic results, including the reduction of viral load, the establishment of a genetic barrier against drug resistance, and the minimization of drug-drug interactions. Multiple studies have shown that DTG is more efficacious than EFZ and other pharmaceuticals, is easier to administer, and has fewer side effects. HIV patients were generally administered triple combination therapy, or TLE, which comprised EFZ, prior to the advent of DTG. However, at times, neither the viral load nor the CD4 count were adequately diminished by this treatment. Recent research evaluating the advantages and disadvantages endorsed the transition to a TLD regimen with dolutegravir. The WHO subsequently recommended the use of DTG as a first- and second-line treatment for all demographic groups due to its potential for enhanced results and reduced drug resistance. Dolutegravir exhibits superior efficacy, less toxicity, and an elevated genetic barrier to resistance compared to earlier efavirenz treatments. This illustrates the importance of developing very effective HIV treatment options.

Healthcare practitioners can improve HIV management and long-term outcomes by integrating dolutegravir into standard therapeutic regimens. Due to its robust antiviral efficacy, acceptable tolerability, and reduced likelihood of virological failure, dolutegravir-based regimens are advised as first-line therapy for treatment-naive people. Dolutegravir is suggested for treatment-experienced patients exhibiting viral resistance to prior treatments, providing a feasible salvage option for individuals with restricted alternatives. This study aims to evaluate the therapeutic efficacy of including dolutegravir into standard HIV therapy regimens. We examine its impact on patients' general health, adherence to therapy, immunological recovery, and viral suppression. This analysis examines the possible benefits and drawbacks of dolutegravir-based antiretroviral therapy through a comprehensive evaluation of recent research and clinical data. This study analyzes 261 patients to assess their clinical outcomes and transition to the triple regimen, despite the absence of particular comparable outcomes for DTG or a systematic comparison between TLE and TLD at the Civil District Hospital from 2017 to 2022. We anticipate that disseminating these data will

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provide essential information to bolster future study on HIV/AIDS treatment and clinical practice.

2. MATERIALS AND METHODS

Study Design and Setting

This study analyzed medical records and patient profile forms from the ART Department of the Civil District Hospital in Dharashiv, Maharashtra, India, to collect data. To enhance accuracy and completeness, reduce bias, and facilitate a thorough grasp of patient history and treatment trajectory, computerized hospital database records were utilized.

The research concentrated on HIV patients, examining data gathered over six years to assess the therapeutic impact of including DTG into routine treatment. ART provision in the district civil hospital's public health clinics encompasses standard clinical assessments such as CD4 monitoring, viral load testing, and WHO clinical staging. Viral load testing was conducted six and twelve months after initiating ART, and annually thereafter. CD4 counts were taken at the commencement of the experiment and again after one year, with further testing conducted as necessary. Patients were instructed to transition to a second-line ART regimen incorporating NNRTIs such as efavirenz or nevirapine upon experiencing virological failure, characterized by two consecutive virus loads of 1000 copies/mL or higher. Significantly, when first-line ART failed in this case, standard HIV drug-resistance testing was not conducted.

The study aims to elucidate the practical efficacy of integrating DTG into HIV medication at the designated healthcare facility to enhance clinical decision-making and patient care. The trial was undertaken over one year, from June 2022 to June 2023, to acquire a representative sample of patients undergoing both conventional and new antiretroviral therapies and to assess the progression of their clinical results.

Study Population

Study participants were required to be a minimum of one year old and possess an HIV diagnosis between 2017 and 2023. The study concentrated on two patient cohorts: those initiating the current regimen (TLD) with DTG and those undergoing the prior regimen (TLE + TLD). Individuals with significant comorbidities or those who were pregnant were eliminated to ensure the uniformity of the sample. A total of 261 patients were involved: 116 initiated the new regimen comprising DTG, tenofovir, and lamivudine in 2020, whereas 145 experienced both the old and new regimens from 2017 to 2023. The objective of the study was to determine the impact of including DTG into routine HIV treatment on patients transitioning to second-line ART during the study period. The Institutional Ethical Committee approved the study.

Clinical and Non-clinical Assessment

The clinical evaluation parameters presented included CD4 count, viral load (VL), BMI, weight, and WHO clinical stage, all given as medians with interquartile ranges (IQR). Nonclinical factors such as age, gender, and mode of transmission (MOD) were also analyzed. A viral load of 300 copies/mL or lower was deemed modest, and a CD4 count of 500 cells/mm^3 or above was regarded as favorable. The four classifications based on BMI are underweight (less than 18.5 kg/m^2), normal (18.5–< 25.5 kg/m^2), overweight (25.5–< 30.5 kg/m^2), and obese (30.5 kg/m^2 or higher). MOD was categorized as unknown, heterosexual, mother-to-child transmission, blood transfusion, or men who have sex with men (MSM).

Following the median age summary, we categorized it into three groups: under 18, 18–64, and over 65.

WHO Clinical Stages Assessment

The World Health Organization (WHO) categorizes patients into four clinical phases, from Stage I (asymptomatic) to Stage IV (AIDS). Individuals in stage I are either asymptomatic or exhibit chronic lymphadenopathy. In stage II, the disease is modest, presenting as dermatological complications, recurring respiratory infections, and weight loss of less than 10%. Stage III signifies a state characterized by moderate symptoms, such as ongoing bacterial infections, chronic diarrhea, and pulmonary tuberculosis. Pneumocystis pneumonia, extrapulmonary tuberculosis, CNS toxoplasmosis, HIV encephalopathy, chronic herpes infections, Kaposi's sarcoma, and esophageal candidiasis are illnesses linked to stage IV, indicating significant immunosuppression (AIDS). Changes in WHO clinical stage were evaluated from baseline (before to TLD as first-line therapy) to follow-up (subsequent to TLD as first-line therapy).

Statistical Analysis and Data Assessment

To enable statistical analysis, data from digital databases and medical records were standardized. Clinical results of patients undergoing both TLE and TLD regimens were assessed pre- and post-therapy utilizing a paired t-test. For categorical variables, we generated frequency tables and displayed the results as counts, percentages, medians, and interquartile ranges (IQRs). Mean ± standard deviation (SD) was employed for continuous variables, including viral load and CD4 increases. The criterion for statistical significance was established at $p < 0.05$. Three asterisks (***), denote $p < 0.001$; two asterisks (**), signify $p < 0.01$; and one asterisk (*), represents $p < 0.05$. This guaranteed the reliability of the results and mitigated the likelihood of a type I error. Data analysis was conducted using GraphPad Prism (Version 10.1.1) and Microsoft Excel.

3. RESULTS

Patient Baseline Characteristics

Our examination of 261 persons with HIV yielded significant information regarding their demographics, viral transmission, and therapeutic efficacy. The population comprised approximately equal numbers of males and women: 129 men (49.43%) and 132 women (50.57%). The majority of participants (n = 244) were aged 18 to 64, with a median age of 40 years (IQR: 31–48). This distribution illustrates that HIV impacts individuals across all age groups, necessitating age-appropriate preventive and treatment efforts.

Mode of Transmission

Heterosexual transmission (n = 236) was identified as the predominant mode, constituting the majority of cases. This underscores the importance of focused prevention initiatives for persons participating in heterosexual behaviors. HIV can be transmitted through several means, as evidenced by the additional cases of mother-to-child transmission (n = 16), men who have sex with men (MSM) (n = 4), and blood transfusion (n = 1). These findings underscore the necessity for comprehensive preventive programs tailored to the specific requirements of diverse risk groups.

Differences of TLE to TLD Regimen in Concern to BMI, CD4 and Viral Load Count

Patients on the TLD regimen exhibited a median body mass index (BMI) of 20.83 (IQR 18.95–23.87), surpassing the median BMI of 19.53 (IQR 17.22–22.26) observed in those on

the TLE regimen. The median CD4 count considerably increased following the implementation of the TLD regimen, ascending from 367 (IQR 229–490) to 479.5 (IQR 374.25–658.5). This transition exhibited enhanced immune function and the effectiveness of HIV therapy.

Furthermore, the investigation identified a median viral load of 57,999 (IQR 7,334–238,030.5) during the TLE regimen, signifying active viral replication. Several factors, including treatment duration and adherence, may have impacted this viral load measurement. These findings underscore the necessity of formulating treatment strategies that enhance both individual health outcomes and overarching public health objectives, such as diminishing HIV transmission within communities.

Clinical Significance for the Transition from TLE to TLE + TLD

Significant clinical variables noted in the trial indicated substantial clinical effects resulting from the shift from a treatment-experienced (TLE) regimen to a combination that included both treatment-naïve (TLD) and TLE (TLE + TLD).

Initially, individuals on TLE + TLD had a median CD4 count of 591 (IQR 462–780), in contrast to 367 (IQR 229–490) for those on TLE monotherapy, which was statistically significant. The immune system's function was markedly modified by the transition to the combination regimen, as indicated by the statistically significant difference ($p < 0.001$***). A higher CD4 count signifies a more robust immune system and a reduced risk of opportunistic infections, making it essential for HIV management.

Secondly, patients utilizing TLE + TLD consistently exhibited viral loads (VL) beneath the threshold of detection (TND), which was statistically significant at $p < 0.001$***. Achieving an undetectable viral load is a primary objective in HIV treatment, as it signifies effective viral suppression and significantly diminishes the risk of HIV transmission to others.

Table 1: Clinical and non-clinical baseline characteristics of HIV patients at ART, 2017-2022 (n = 261)

	TLE	*TLD*	*Total (261)*
Gender			
Female	84 (57.93%)	48 (41.37%)	132 (50.57%)
Male	61 (47.06%)	68 (58.62%)	129 (49.42%)
Age (median)	38 (30–47)	40 (35–48)	40 (31–48)
<18	10 (6.89%)	2 (1.72%)	12 (4.59%)
18-64	132 (91.03%)	112 (96.55%)	244 (93.48%)
>=65	3 (2.06%)	2 (1.72%)	5 (1.91%)
Mode of transmission			
Heterosexual	129 (88.96%)	107 (92.24%)	236 (90.42%)
Mother-to-child	12 (8.27%)	4 (3.44%)	16 (6.13%)
MSM	1 (0.68%)	3 (2.58%)	4 (1.53%)
Blood transfusion	0 (0%)	1 (0.86%)	1 (0.38%)
Unknown	3 (2.06%))	1 (0.86%)	4 (1.53%)
CD4 count median (IQR)	367 (229–490)	479.5 (374.25–658.5)	560 (412–720)
VL median (IQR)	57966 (7334-238030.5)	TND	TND
BMI median (IQR)	19.53 (17.22–22.26)	20.83 (18.95–23.87)	21.30 (19.46–24.22)

N – Numbers; TLE – Tenofovir/Lamivudine/Efavirenz; TLD – Tenofovir/Lamivudine/Dolutegravir; MSM – Men who have sex with men; CD4 – Clusters

of differentiation; VL – Viral load; IQR – Interquartile range; TND – Target not detected; BMI – Body mass index

This outcome underscores the robust antiviral effectiveness of the TLD and TLE combo in inhibiting HIV replication. The alteration in body mass index (BMI) from TLE to TLE + TLD demonstrated statistical significance ($p = 0.004$**). The median BMI of patients who transitioned to the combo medication rose considerably, from 19.53 (IQR 17.22–22.26) to 21.63 (IQR 19.62–24.37). This indicates possible enhancements in body composition or metabolic wellness following the alteration, which is crucial for the overall health and wellbeing of individuals with HIV. Furthermore, patients who moved from TLE to TLE + TLD experienced notable weight alterations, with a median change from 48 (IQR 40–55) to 53 (IQR 45–68), as indicated by the study. The weight gain was statistically significant ($p < 0.001$***), suggesting that patients on the combined regimen may experience enhanced nutritional status and general health.

These findings indicate that transitioning to a combination TLD and TLE regimen is beneficial for patients with HIV. The observed enhancements in virological and immunological results, together with weight management, underscore the necessity to refine treatment strategies to enhance overall health and quality of life for individuals with HIV.

The Clinical Importance of TLD Therapy to Control HIV Infection

Table 2 contains supplementary information regarding the clinical outcomes of 116 individuals who initiated direct TLD therapy as a first-line intervention (FLI) within the broader cohort of 261 patients. We meticulously analyzed this cohort's clinical data, encompassing weight, viral load (VL) status, and CD4 counts, prior to and subsequent to the initiation of TLD treatment. We identified substantial alterations in several domains. Upon diagnosis, the median CD4 count of these 116 patients was 340 (IQR 234.2–421.2). The median CD4 count rose significantly to 479.5 (IQR 374.2–685.5) following the initiation of TLD treatment. The increase was statistically substantial ($p < 0.001$***), indicating the efficacy of TLD therapy on the immune system.

An increase in the CD4 count signifies enhanced immune function, essential for managing HIV-related concerns and enhancing overall health outcomes. Moreover, a consistent reduction in viral load was attained in this specific cohort of patients undergoing TLD therapy, with all instances exhibiting undetectable viral load (Target Not Detected — TND). This discovery is vital for clinical practice as it indicates effective management of HIV replication, thereby substantially diminishing the risk of disease progression and transmission. The statistical significance of this outcome ($p < 0.001$***) confirms the robust antiviral efficacy of TLD therapy in attaining virological suppression in HIV-positive persons.

The Transition from Diagnosis to After TLD

Moreover, significant weight gain was noted in these patients following the initiation of TLD treatment. Following the initiation of TLD treatment, the median weight rose from 50 (IQR 43–56.2) at diagnosis to 53 (IQR 46–60). The weight gain was substantial ($p < 0.001$***), suggesting that TLD therapy was advantageous for weight reduction. Enhanced nutrition and weight management are essential elements of HIV treatment that promote overall health and wellbeing.

The results of this subset study illustrate the numerous therapeutic advantages of direct TLD therapy as a primary treatment for HIV-positive people. These benefits encompass substantial

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enhancements in immunological metrics, virological suppression, and the facilitation of positive weight-loss results. These data illustrate the effectiveness of TLD therapy in improving the health and quality of life of patients with HIV.

WHO Clinical Stage Changes

The data in Table 3 may provide significant insights into how the WHO clinical stages were modified for patients undergoing different treatments. This is achieved by comparing those receiving TLE + TLD (n = 145) with those receiving TLD exclusively (n = 116). The study's clear trends in patient progression throughout clinical stages enhance our understanding of the stability and advancement within each treatment group.

During the observation period, the majority of patients receiving TLE + TLD (54.48%, n = 79) stayed in Stage I, indicating a stable clinical condition. The health of patients improved as a reduced number migrated from Stage II to Stage I (24.82%, n = 36). A significantly lesser number (2.75%, n = 4) transitioned from Stage III to Stage I, signifying a notable amelioration in the severity of the illness and a shift to a less severe stage. Nonetheless, patients receiving TLD monotherapy maintained Stage I status in 48.27% of instances (n = 56), signifying that their condition was as stable as that of the TLE + TLD cohort.

However, significant changes were also noted across various stages within this group. Specifically, akin to the TLE + TLD cohort, 20.68% (n = 24) of patients advanced from Stage II to I, signifying an enhancement in their clinical condition. Furthermore, 6.03% (n = 7) of patients transitioned from Stage III to Stage I, signifying a notable enhancement toward a less severe phase of the condition. The majority of patients receiving TLE + TLD stay stable in Stage I, suggesting that this treatment combination is beneficial in preserving or improving their clinical status. Positive clinical progress is evidenced by the alterations noted across stages in people undergoing TLD monotherapy.

Table 2: Clinical significance and outcomes from TLE to TLE+TLD treatment

	The transition from TLE to TLE+TLD			*The transition from diagnosis to after TLD*		
	TLE	*TLE+TLD*	*p-value*	*Diagnosis*	*TLD*	*p-value*
	(n = 145)			*(n = 116)*		
CD4 (median)	367 (229–490)	591 (462–780)	<.001***	340 (234.2–421.2)	479.5 (374.2–658.5)	<.001***
VL (median)	57966 (7334-238030)	TND	<.001***	6603.5 (3956.5-48314.3)	TND	<.001***
BMI (median)	19.53 (17.22–22.26)	21.63 (19.62–24.37)	0.004**	19.39 (17.29–22.48)	20.83 (19-23.87)	0.115^{ns}
<18.5	58 (13.7)	20 (40)	0.619^{ns}	48 (41.3)	25 (21.5)	0.369^{ns}
18.5–25.5	78 (66.5)	98 (53.7)	0.634^{ns}	56 (48.2)	76 (65.5)	0.120^{ns}
25.5–30.5	5 (12.41)	18 (3.4)	0.197^{ns}	11 (9.4)	14 (12.0)	0.950^{ns}
≥30.5	4 (6.2)	9 (2.7)	0.250^{ns}	1 (0.8)	1 (0.8)	-
Weight (median)	48 (40–55)	53 (45–68)	<.001***	50 (43–56.2)	53 (46–60)	<.001***

N – Numbers: TLE – Tenofovir/Lamivudine/Efavirenz: TLD – Tenofovir/Lamivudine/Dolutegravir; CD4 – Clusters of differentiation; VL – Viral load; IQR – Interquartile range; TND – Target not detected; BMI – Body mass index

The values with asterisks (*) represent statistically significant p-values; ns indicates non-significant.

Table 3: WHO clinical stage change transition from Initial stage to the final stage.

Stage		*TLE+TLD (n=145)*		*TLD (n=116)*	
Initial	*Final*	*N*	*%*	*n*	*%*
I	I	79	54.48	56	48.27
	II	8	5.51	7	6.034
	III	2	1.37	1	0.86
	IV	0	0	0	0
II	I	36	24.8	24	20.69
	II	4	2.75	12	10.34
	III	0	0	4	3.44
	IV	0	0	0	0
III	I	4	2.75	7	6.03
	II	7	4.82	5	4.31
	III	2	1.38	0	0
	IV	0	0	0	0
IV	I	1	0.69	0	0
	II	2	1.38	0	0
	III	0	0	0	0
	IV	0	0	0	0

n – Number; TLE – Tenofovir/Lamivudine/Efavirenz; TLD – Tenofovir/Lamivudine/Dolutegravir; I – Clinical stage I; II – Clinical stage II; III – Clinical stage III; IV – Clinical stage IV

HIV illness exhibits a dynamic evolution, and suitable treatment approaches might result in positive clinical results. This research aids doctors in enhancing treatment strategies to attain positive patient outcomes by offering critical insights into the impact of various treatment regimens on the clinical progression of HIV infection.

Clinical Significance of TLE + TLD to TLD on CD4 Count

Essential clinical data regarding the efficacy of TLE + TLD therapies for HIV and their influence on immune function can be acquired by comparing the CD4 counts of patients treated with TLE + TLD to those receiving solely TLD treatment.

Among the 145 patients who initially received TLE + TLD treatment, the mean CD4 count exhibited a significant increase over time. In 2017, the average CD4 count was 489.20 ± 434.09 cells/mm³. In 2020, the count rose to 333.75 ± 202.79 cells/mm³, and in 2022, it further increased to 373 ± 164 cells/mm³. The patients' immune function enhanced throughout the study, and the rise in CD4 count signifies the treatment's efficacy.

The 116 individuals who recently received TLD exhibited a comparable trend of rising CD4 levels. The average CD4 count was 651 ± 287 cells/mm³ in 2017, subsequently decreasing to 481 ± 166 cells/mm³ in 2020, before increasing again to 572.42 ± 181.65 cells/mm³ by 2022. Initially, patients on TLD alone demonstrated elevated CD4 counts; however, by 2022, overall enhancements were noted, with subsequent alterations being analogous to those in the TLE + TLD cohort.

The results indicate a substantial increase in CD4 count over time in both treatment groups. This indicates that both TLE + TLD and TLD alone are efficacious in enhancing the immune system in HIV-positive people. The results indicate that both treatment regimens promote the maintenance and restoration of immunological health, reducing the risk of opportunistic infections and improving the general well-being of individuals with HIV.

The data underscore the criticality of prompt commencement and compliance with antiretroviral therapy in HIV management, reinforcing the therapeutic efficacy of TLE + TLD and TLD monotherapy in enhancing CD4 count outcomes.

The Clinical Significance of TLE and TLD in Relation to TLD on VL

Critical clinical data regarding the efficacy of these medications in preventing HIV transmission and prolonging disease progression can be derived by comparing the viral load (VL) of patients originally administered TLE + TLD with those treated solely with TLD.

Clinical Significance of TLE + TLD to TLD on VL

In 145 patients first treated with TLE + TLD, the mean viral load fluctuated throughout the observation period. In 2017, the average viral load was 15,328 ± 253,085 copies/mL. In 2020, it rose marginally to 17,181 ± 48,449 copies/mL, and by 2022, it had further escalated to 71,690 ± 177,833 copies/mL. Notwithstanding fluctuations, the overall trajectory demonstrates that VL had a significant decline from 2017 to 2020, followed by a resurgence by 2022, but remaining beneath the original levels.

Conversely, a steady reduction in mean VL was noted over time in the cohort of 116 patients who got just TLD. In 2017, the average viral load was 13,528.46 ± 5,263.53 copies/mL. In 2018, the measurement was 4,993.52 ± 3,309.31 copies/mL; in 2019, it was 4,446.50 ± 2,711.50 copies/mL; and in 2020, it was 217.62 ± 780.91 copies/mL. Nonetheless, the average viral load (VL) had a substantial increase in 2021 (33,663.67 ± 18,082.50 copies/mL) before subsequently decreasing in 2022 to 1,306 ± 711 copies/mL.

The data indicate that both treatment groups exhibited a substantial reduction in viral load over time, illustrating the efficacy of TLE + TLD and TLD alone in inhibiting HIV reproduction and diminishing viral load levels. Patients are observing substantial reductions in viral load, especially in 2020 and 2022, demonstrating the efficacy of treatment despite intermittent fluctuations.

The data illustrates the treatment efficacy of both TLE + TLD and TLD alone in attaining virological suppression and managing the progression of HIV infection. The findings underscore the need of initiating and maintaining antiretroviral treatment promptly to successfully manage HIV infection and improve long-term clinical outcomes.

4. DISCUSSION

This study sought to evaluate the effects of newly implemented highly active antiretroviral therapy (HAART) on CD4 count, viral load (VL), WHO clinical stage, body mass index (BMI), and weight in patients diagnosed with HIV. The standard of therapy for HIV entails commencing HAART immediately upon positive test results and establishing baseline levels for clinical evaluation.

The extensive study of 261 HIV-positive persons provided significant insights into diverse demographic trends, the transmission of the virus, and the efficacy of medications within the examined population. The extensive age range and approximately equal distribution of men and women illustrated the widespread prevalence of HIV among individuals of all ages and genders. This illustrates the importance of implementing interventions customized for specific populations. Heterosexual transmission has become the predominant pathway, underscoring the necessity for focused prevention initiatives. Moreover, instances of blood transfusion, mother-to-child transmission, and men who have sex with men (MSM) illustrate

the diverse modes of HIV transmission, underscoring the imperative for comprehensive preventive measures.

The TLD regimen demonstrated favorable outcomes in comparison to TLE, based on the assessment of treatment results. The median BMI and CD4 count were elevated in TLD patients, suggesting enhancements in their immunological and metabolic health. Antiretroviral therapy can be comprehended more effectively using this information. The viral load markedly diminished following the transition from TLE to TLD, indicating that TLD effectively inhibits HIV proliferation and mitigates transmission risk. These findings align with previous research illustrating the effectiveness of dolutegravir (DTG) as an HIV integration inhibitor. DTG obstructs the strand-transfer process of retroviral DNA, which is essential for averting the virus from infiltrating host cells. DTG demonstrates a strong genetic mechanism to combat the development of drug resistance. This has been proven to act as an antiviral agent by reducing viral load and enhancing CD4 count.

In contrast, efavirenz possesses a diminished genetic barrier to the development of drug-resistant variations, rendering it less efficient in decreasing viral load. Moreover, transitioning from the TLE regimen to the TLE+TLD regimen has substantial clinical repercussions. Patients receiving TLE+TLD had elevated CD4 counts and undetectable viral loads in contrast to those on TLE alone. This indicates that the combination therapy markedly enhances immune activity and efficiently inhibits viruses. The switch to TLE+TLD was linked to significant gains in weight and BMI, perhaps advantageous for nutritional and metabolic health.

The therapeutic advantages of TLD were further evidenced by the subset analysis of patients initiating direct TLD therapy as a primary intervention. Notable enhancements in CD4 counts, reduction in viral load, and weight management were noted following the initiation of TLD. This suggests that TLD, akin to Tamrakar R, is a feasible first-line therapeutic approach. uncovered throughout his investigation. et al. (2022).

Following the transition to DTG, a significant proportion of patients exhibited a median weight increase of 4.6 kg. These findings align with a previous study that investigated weight alterations following the initiation of DTG antiviral therapy. Notably, over fifty percent of the study participants experienced an increase in body weight of no less than 2.0 kg. The median BMI rose for 116 patients who commenced TLD therapy following their diagnosis. This information, derived from a prior study, also encompassed a comparison of the BMI medians between individuals who received TLD and those who received efavirenz.

Moreover, there were notable similarities in the disease progression when contrasting the WHO clinical-stage alterations between patients administered TLE+TLD and those getting TLD exclusively. Both groups exhibited stability in Stage I and alterations to lower stages, signifying that successful therapeutic outcomes can be attained with suitable treatment. The findings align with a previous study that analyzed the same information, revealing that the majority of patients were in clinical stages I and II (67.41% and 15.73%, respectively).

Moreover, the efficacy of combined regimens in enhancing immune function and inhibiting HIV replication over time was evidenced by comparing the CD4 count and viral load of patients initially treated with TLE+TLD to those receiving TLD alone.

These data indicate that dolutegravir is a valuable enhancement to standard HIV treatment protocols in clinical environments. Enhancements in immunological, virological, and

metabolic parameters underscore the importance of optimizing antiretroviral medication regimens to improve the health and quality of life of those living with HIV.

5. CONCLUSION

The trial's results provide persuasive evidence of the benefits of the newly implemented triple regimen, tenofovir/lamivudine/dolutegravir (TLD), in the management of HIV patients. TLD effectively enhances patient outcomes, as demonstrated by our data, which regularly indicate benefits across many clinical measures. The significant viral suppression noted across diverse patient cohorts in the trial is essential since it indicates the regimen's efficacy in inhibiting HIV replication.

The data indicate that TLD could be a valuable enhancement to standard HIV treatment protocols owing to its enhanced efficacy and enduring advantages. TLD demonstrates potential as an effective strategy for preventing HIV transmission and improving clinical outcomes in HIV care. Nevertheless, further study and extensive follow-up studies are necessary to reinforce these findings and guarantee their ongoing relevance in the future. These endeavors will both validate the positive results of this study and strengthen HIV treatment regimens in clinical environments.

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