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Comparative Clinical Effectiveness of TLD versus TLE Regimens in HIV/AIDS: A Systematic Review

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ABSTRACT

Antiretroviral therapy (ART) remains the cornerstone of Human Immunodeficiency Virus (HIV) management. The World Health Organization recommends Tenofovir–Lamivudine–Dolutegravir (TLD) as a preferred first-line regimen in many settings, replacing Tenofovir–Lamivudine–Efavirenz (TLE) because of its favorable virological efficacy, resistance barrier, and tolerability. However, comparative evidence across different patient populations remains heterogeneous. This systematic review aimed to compare the clinical effectiveness of TLD and TLE in patients with HIV/AIDS, focusing on virological suppression, immunological recovery, clinical outcomes, and safety. The review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 framework. Literature searches were conducted in PubMed, PubMed Central, ScienceDirect, and Google Scholar for studies published from January 2021 to May 2026. Eligible original studies were selected using predefined inclusion and exclusion criteria, and findings were synthesized narratively because of methodological and population heterogeneity. Of 50 records identified, 20 studies were included, covering adults, children, pregnant and lactating women, patients switching therapy, and patients with advanced AIDS. Sample sizes ranged from 102 to 2,599 participants, with follow-up periods of 6–24 months. Overall, most studies reported more favorable virological outcomes with dolutegravir-based regimens. For example, viral suppression at six months was 88.57% versus 55.71% in one adult study, while pediatric and advanced AIDS cohorts also showed higher suppression rates with DTG-based therapy. Several studies reported greater CD4+ recovery, improved clinical outcomes, better treatment durability, and fewer adverse-event-related regimen changes with TLD or DTG-based regimens. The findings indicate that TLD/DTG-based therapy is consistently associated with favorable virological and immunological outcomes compared with TLE/EFV-based therapy. Nevertheless, heterogeneity and the predominance of observational study designs limit causal interpretation. Prospective and randomized studies with longer follow-up are warranted to strengthen the evidence on long-term effectiveness and safety.
Keyword: *HIV, antiretroviral therapy, TLD, TLE.*

Introduction

Human Immunodeficiency Virus (HIV) is still a public health challenge in many countries despite the progress that has been made in its prevention and treatment efforts. The UNAIDS report shows that in 2023 there are around 39.9 million people living with HIV worldwide and around 630,000 deaths are still occurring due to AIDS-related diseases. The data confirms that HIV continues to place a great burden on the global health system, so an increasingly effective therapeutic strategy is needed to control the course of the disease (Joint United

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Nations Programme on HIV/AIDS (UNAIDS, 2024). HIV infection causes progressive damage to the immune system, especially through a decrease in the number of CD4+ T lymphocytes, thereby increasing susceptibility to opportunistic infections and various complications if not treated with optimal antiretroviral therapy (World Health Organization (World Health Organization, 2021).

Antiretroviral therapy (ARV) is a key component in HIV management because it is able to suppress viral replication to achieve virological suppression, maintain or increase the number of CD4 cells, improve immunological status, and reduce the rate of pain, death, and risk of HIV transmission. The success of therapy is not only influenced by patient adherence, but also by the effectiveness of the regimen, drug safety profile, and low potential for antiretroviral resistance (World Health Organization, 2021).

For more than a decade, the Tenofovir–Lamivudine–Efavirenz (TLE) combination has been a widely used first-line regimen in various countries because it is available in the form of a fixed-dose combination that facilitates patient adherence. However, the use of efavirenz has several limitations that can affect the success of therapy, including neuropsychiatric side effects, drug interactions through the cytochrome P450 enzyme system, and increased resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) group in some areas with high HIV prevalence. These conditions encourage the need to use regimens with better virological effectiveness and higher genetic barrier to resistance (World Health Organization, 2021).

The development of HIV therapy then presents Dolutegravir (DTG) as a second-generation integrase strand transfer inhibitor (INSTI) that has high antiviral potential, a good safety profile, and a higher genetic barrier to the emergence of resistance. These characteristics make DTG able to produce a faster decrease in viral load while maintaining the success of therapy in the long term. Therefore, the Tenofovir–Lamivudine–Dolutegravir (TLD) regimen is currently the main choice in most patients who start antiretroviral therapy (World Health Organization, 2021).

In recent years, more and more studies have compared the effectiveness of DTG-based regimens with EFV-based regimens. Mahale et al., (2023) reported that patients receiving TLD had a higher proportion of viral suppression after six months of therapy compared to the TLE group (88.57% versus 55.71%). These findings are reinforced by Mengistu et al., (2024) who showed that patients using DTG-based regimens had higher CD4 counts and lower viral loads than patients receiving EFV-based regimens. Longitudinal research in Tanzania also shows that the transition from TLE regimens to TLDs is related to improvements in virological and immunological outputs in long-term monitoring (Majula & Mweya, 2024). In addition, observational research in South Africa shows that although TLD regimens

provide better virological benefits, monitoring of metabolic side effects such as weight gain remains necessary in clinical practice (Sawry et al., 2024).

Although various studies have reported the superiority of TLD regimens over TLE, the available results still come from diverse populations, study designs, follow-up durations, and sample sizes, making the overall interpretation of the evidence less simple. These variations indicate the need for systematic synthesis of evidence in order to obtain a more comprehensive picture of the effectiveness of both regimens in improving virological and immunological outcomes in HIV/AIDS patients. Therefore, this study aims to compare the effectiveness of the Tenofovir–Lamivudine–Dolutegravir (TLD) and Tenofovir–Lamivudine–Efavirenz (TLE) regimens in HIV/AIDS patients through a systematic review approach based on scientific publications for the period 2021–2026. The year range was chosen to obtain the latest evidence after the widespread implementation of the dolutegravir-based regimen as a first-line therapy according to WHO guidelines.

Research Methods

This study uses the *Systematic Review* method which is compiled based on the *guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) 2020. Literature searches were conducted systematically on PubMed, PubMed Central (PMC), ScienceDirect and Google Scholar databases for articles published in the period January 2021 to May 2026. The keywords used were "HIV", "HIV/AIDS", "Dolutegravir", "DTG", "TLD", "Efavirenz", "EFV", "TLE", "viral suppression", "CD4", "clinical outcomes". Inclusion criteria are original research articles, published in 2021–2026, comparing TLD regimens with TLE or evaluating the effectiveness of TLDs, reporting virological, immunological, or clinical outputs, and articles available in full text in English or Indonesian. Meanwhile, exclusion criteria are review articles, editorials, case reports, or conference abstracts, articles without clear therapeutic output data, duplicate articles, and articles without full-text access.

The selection process was carried out following the PRISMA flowchart which included identification, screening, feasibility assessment, and article inclusion. The data extracted included authors, year of publication, country of study, research design, number of samples, ARV regimen used, virological, immunological, and clinical outcomes. The analysis was carried out descriptively by comparing the results between studies. The main outcomes analyzed included viral load suppression, increased CD4 count, therapy success, risk of therapy failure and other clinical outcomes.

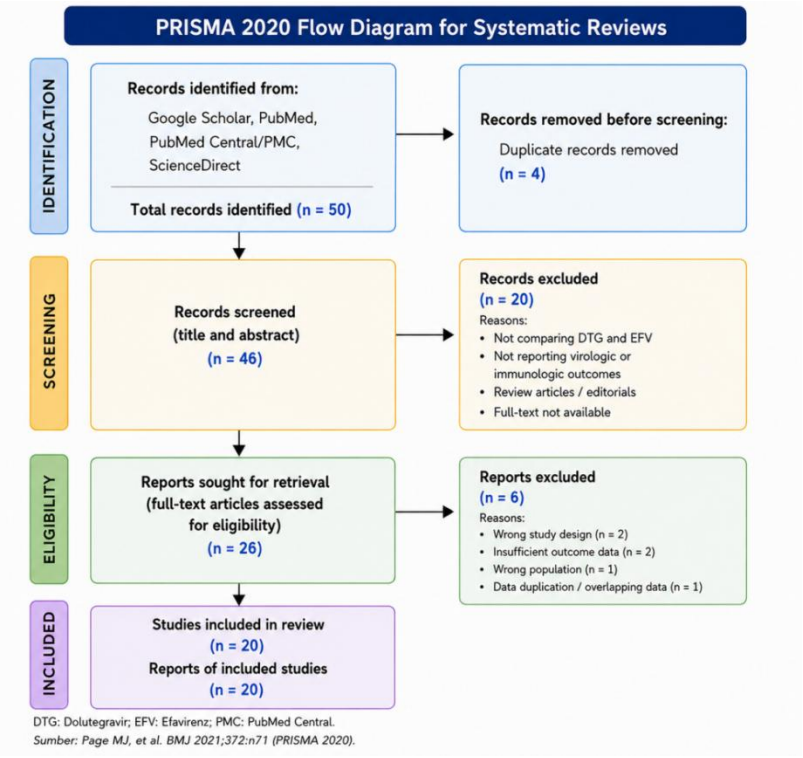


Figure 1. PRISMA Diagram 2020

Results and Discussion

A total of 50 articles were obtained from the initial search results through the Google Scholar, PubMed, ScienceDirect and PubMed Central (PMC) databases. After the process of identification, screening, full-text feasibility assessment, and selection based on inclusion and exclusion criteria using *the Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) guidelines, 20 articles were obtained that met the criteria to be analyzed in this systematic review.

The data extracted from each article includes the author's name, year of publication, title, research design, research subject and research results.

Table 1. Journal Review Extract

No	Author Year	Research Design	Research Subject	Key Results
1	Doke et al., (2024), India	comparative clinical observational study.	The number of samples of 261 HIV/AIDS patients receiving antiretroviral therapy at the research health service center.	The integration of dolutegravir into the conventional HIV regimen provides better clinical outcomes than previous regimens.

2.	Ramesh & Swathi (2025), India	observational clinical outcome study	The sample size was 261 people. 116 people who started TLD as a first-line therapy and 145 people who received TLE then switched to TLD	Dolutegravir is considered effective as part of first-line therapy and switching regimens in HIV patients.
3	Nwachukwu, Njelita, Eyisi, Ezenyeaku, Nwachukwu, Okechi, et al., (2023), South East Nigeria	Descriptive comparative observational study	110 HIV/AIDS patients received TLD therapy.	The TLD regimen is highly effective for HIV therapy and provides good virological and clinical outcomes in HIV patients in Southeast Nigeria
4	Mahale et al., (2023) India	Retrospective comparative study	The sample size was 140 patients, consisting of 70 patients in the DTG/TLD group and 70 patients in the EFV/TLE group.	The dolutegravir-based regimen provides better virologic suppression, better immunological response in the long term, and more optimal therapeutic outcome than the efavirenz regimen.
5	Mengistu et al., (2024), Ethiopia	Institution-based comparative cross-sectional study	106 adult HIV/AIDS patients, namely 53 patients using the DTG regimen and 53	The dolutegravir-based regimen had better effectiveness in increasing CD4+ and lowering viral load

			patients using the EFV regimen	than the efavirenz regimen, with a relatively similar hepatotoxicity profile.
6	Ayal & Berha (2023), Auckland	Hospital-based retrospective cohort study	The number of samples was 990 people who were HIV patients undergoing ART therapy (694 patients using the DTG regimen and 296 patients using the EFV regimen)	The dolutegravir-based regimen provides better viral suppression, CD4+ recovery, and safety profile than the efavirenz-based regimen in HIV patients.
7	Chiabi et al., (2025), Cameroon	Retrospective Hospital-Based Cohort Study	The total sample number was 207 children (139 children using EFV and 68 children using DTG.)	DTG-based regimens are more effective in achieving viral suppression in HIV children than EFV, providing faster viral suppression and showing better growth outcomes.
8	Brites et al., (2024), South Africa	Multicenter Ambispective Observational Cohort Study	Adult patients with advanced AIDS in Brazil totaled 184 patients (92 DTG patients and 92 EFV patients)	DTG-based regimens provide better viral suppression, better CD4 recovery, higher therapeutic durability, and better tolerability than EFV in patients with advanced AIDS.
9	Facha et al., (2024), Ethiopia	Uncontrolled Before-and-After Study	Pregnant and lactating women with HIV in Ethiopia. Total samples were 924 people (462 using EFV-based regimen	DTG-based regimen provides better viral suppression than EFV in women in the PMTCT program in Ethiopia

			and 462 using DTG-based regimen)	
10	Zuhdi et al., (2026), Indonesia	Retrospective Comparative Cohort Study	Adult patients with HIV undergoing antiretroviral therapy. The total sample was 175 people.	The dolutegravir-based regimen provides better clinical and immunological improvement than the efavirenz-based regimen in adult HIV patients
11	Kashyap et al., (2026), India	Retrospective observational before-and-after study	The subjects of the study were HIV-positive pregnant women and babies born to the mother. Number of samples: 67 HIV-positive pregnant women in the TLD group and 66 HIV-positive women in the TLE group	The results showed that the TLD regimen had a better tendency to prevent mother-to-child transmission of HIV than the TLE regimen.
12	Nwachukwu, Njelita, Eyisi, Ezenyeaku, Nwachukwu, & Agbata, (2023), Nigeria	Comparative analytical study.	The subjects of the study were 330 HIV-positive patients undergoing treatment at the ART Chukwuemeka Odumegwu Ojukwu University Teaching Hospital clinic.	All groups experienced improved WHO clinical staging after therapy. The TLD group showed the best outcomes.
13	Sari et al., (2025), Indonesia	Retrospective cohort study	The subjects of the study were 102 outpatient HIV/AIDS patients at the	Patients who use TLDs have about 3 times greater chance of achieving viral

			Umbulharjo 1 Health Center and the Gedongtengen Health Center	suppression than TLE patients.
14	Dumchev et al., (2022), Ukraine	Retrospective cohort study	The number of subjects studied was 1057 patients from various national HIV service centers in Ukraine.	Dolutegravir as a first-line ART shows better clinical effectiveness and supports the implementation of DTG scale-up in Ukraine's national HIV program.
15	Majula & Mweya (2024), Tanzania	Descriptive retrospective cohort study	The study subjects consisted of 250 adult HIV patients at Mbeya Zonal Referral Hospital, Tanzania	The transition from the efavirenz to dolutegravir regimen maintained a high level of viral suppression and demonstrated good tolerability
16	Silva et al., (2023), Brazil	Historical retrospective cohort study	The study subjects consisted of 2,599 adult HIV patients who started ART between 2015–2017 in Minas Gerais, Brazil.	Implementation of dolutegravir-based regimen increases HIV suppression success compared to efavirenz in first-line therapy
17	Zhong et al., (2023), China	Single-center retrospective cohort study	The study subjects consisted of 285 adult HIV patients with advanced HIV infection, 95 patients using the DTG regimen and 190 patients using the EFV regimen)	The dolutegravir-based regimen appears to be superior to efavirenz as an initial therapy in advanced HIV patients because it provides better immune recovery

				and faster virus suppression.
18	Njuguna et al., (2025), South Africa	Retrospective Cohort Study	The subject of the study was Adults with HIV in Mopani District, South Africa. Total sample of 1,416 patients (944 patients using TLD and 472 patients using TLE)	DTG-based regimen provides better viral suppression in the early phase of therapy (6 months)
19	Malaba et al., (2022), Africa Selatan from Uganda	Open-label, Randomised controlled trial.	268 pregnant women with HIV who had not received antiretroviral therapy, age ≥18 years, gestational age ≥28 weeks. A total of 135 were in the dolutegravir group and 133 were in the efavirenz group.	Dolutegravir shows a faster decrease in viral load than efavirenz. Dolutegravir is considered safe and tolerable by both mothers and babies.
20	Chan et al., (2023), Thailand	Retrospective cohort study	258 acute phase HIV (AHI) patients; 131 received EFV-based ART, 92 received DTG-based ART, and 35 received maraviroc-intensified DTG (DTG/MVC). The majority were males (99%) with a median age of 26 years.	After 96 weeks, the DTG group showed a greater increase in CD4+ and CD8+ than the EFV group. The improvement in cognitive function (NPZ-4) was also better in the DTG group than in the EFV.

Table 2. Synthesis of Research Findings

Aspects Studied	Number of Studies Supporting	Key Findings
Supresi Viral (Viral Suppression)	15/20 studies	DTG consistently results in a decrease in viral load and a higher rate of viral suppression than EFV.
CD4+ Enhancement	9/20 studies	DTG provides a greater increase in CD4+ counts thereby accelerating the recovery of the immune system of HIV patients.
Clinical Outcome Improvement	10/20 studies	DTG is associated with improvement of clinical stages, decreased disease progressivity, and increased therapeutic success.
Safety and Tolerability	5/20 studies	DTG has a good safety profile with a lower number of side effects and regimen changes compared to EFV.
Special Population (children, pregnant women, advanced AIDS)	5/20 studies	DTG still showed better effectiveness than EFV in specific populations.

A total of 20 studies were reviewed involving HIV/AIDS patients with diverse population characteristics, including adult patients, children, pregnant and lactating women, patients switching ARV therapy, and patients with advanced AIDS. The number of samples in each study varied from 102 to 2,599 HIV/AIDS patient respondents.

All studies compared the Tenofovir-Lamivudine-Dolutegravir (TLD) regimen with the Tenofovir-Lamivudine-Efavirenz (TLE) regimen. The duration of observation ranged from 6 months to 24 months. The most commonly used indicators of therapy success were viral load suppression, CD4+ count, changes in WHO clinical stage, and incidence of therapeutic side effects.

1.1 Virological Outcomes

Most of the studies reviewed showed that dolutegravir-based regimens provided better virological outcomes than efavirenz-based regimens. Mahale et al., (2023) reported that after six months of therapy, 88.57% of patients in the TLD group achieved virologic suppression compared to only 55.71% in the TLE group. Mengistu et al., (2024) found that patients who received the DTG regimen had a lower average viral load than the EFV group (783.83 ± 476.82 copies/mL vs 997.98

± 439.11 copies/mL; p=0.032). These results showed a better DTG ability to suppress HIV virus replication in line with the findings of Njuguna et al., (2025). Ayal & Berha (2023) reported that 69% of patients in the DTG group achieved a viral load of <50 copies/mL compared to 66% in the EFV group. In addition, the DTG group showed a faster time to achieve viral suppression than the EFV group. Research by Doke et al., (2024), Majula & Mweya (2024), and Ramesh & Swathi (2025) showed that the transition from the TLE to TLD regimen resulted in significant improvements in viral load control and maintained the target not detected (TND) status in most patients and Dumchev et al., (2022) reported that the dolutegravir-based regimen provided higher levels of viral suppression than the efavirenz-based regimen in HIV patients who had just started antiretroviral therapy. Nwachukwu et al., 2023) and Silva et al., (2023) reported a greater increase in virologic suppression rates in dolutegravir-based regimens compared to efavirenz-based regimens in the first year of antiretroviral therapy. These results demonstrate the effectiveness of dolutegravir-based regimens in maintaining long-term therapeutic success. Chiabi et al., (2025) reported that children using DTG had higher viral suppression rates than the EFV group at 6 months (63.2% vs 51.1%), 12th month (80.9% vs 64.7%), and 24th month (83.8% vs 70.5%). Brites et al., (2024) found that advanced AIDS patients receiving DTG had higher viral suppression rates at week 24 (67.4% vs 42.4%) and week 48 (65.2% vs 45.7%) compared to the EFV group, in line with the findings of Zhong et al., (2023) showed that a dolutegravir-based regimen resulted in better immunological recovery, a higher increase in $CD4^+$ cell count, and a better rate of virologic suppression compared to an efavirenz-based regimen in HIV patients with advanced HIV infection. Facha et al., (2024) reported that pregnant and lactating women who received the DTG regimen had a 30% lower risk of non-suppressing viral load than the EFV group. Overall, the study showed that DTG provides better virologic suppression capabilities than EFV in different population groups of HIV patients.

1.2 Immunological Outcomes

Most studies have shown that the use of dolutegravir-based regimens provides better immunological recovery than efavirenz-based regimens. Mengistu et al., (2024) reported that the average amount of CD4+ in the DTG group was higher than in the EFV group (589.40 ± 244.38 cells/mm^3 vs 450.64 ± 203.54 cells/mm^3; p=0.002). Mahale et al., (2023) and Zuhdi et al., (2026) that the increase in CD4+ count after 12 months of therapy was higher in the TLD group than in the TLE group. Ayal & Berha (2023) and Chan et al., (2023) also found that the DTG regimen provided better recovery of CD4+ counts than EFV, especially in patients with high initial viral load and low CD4+ counts. Doke et al., (2024) and Ramesh & Swathi (2025) reported a significant increase in CD4+ counts after patients switched from the TLE to TLD regimen. Most patients achieved CD4+ counts above 500

cells/mm³ after DTG use. Brites et al., (2024) found that the proportion of patients with CD4+ counts >200 cells/mm³ at week 48 was higher in the DTG group than in the EFV group (45% vs 29%). Sari et al., (2025) reported that the TLD regimen resulted in higher viral load suppression than TLE in HIV patients. These results show that the successful suppression of the virus achieved by DTG contributes to a more optimal immune system recovery.

1.3 Therapeutic Success and Clinical Outcomes

In addition to providing better virologic suppression and CD4+ enhancement, dolutegravir-based regimens also show higher therapeutic success than efavirenz-based regimens. Research by Doke et al., (2024) and Ramesh & Swathi (2025) shows that the integration of DTG into conventional antiretroviral regimens results in significant improvements in clinical outcomes, both in patients who have just started therapy and patients who have switched regimens. In patients with more severe conditions, such as advanced AIDS, Brites et al., (2024) also reported that DTG-based regimens resulted in higher rates of viral suppression, improved CD4 counts, and higher therapeutic durability compared to EFV-based regimens. These findings suggest that the effectiveness of DTG can still be maintained even in patients with severe immunodeficiency conditions and high viral load. Zuhdi et al., (2026) found that patients using DTG experienced better improvement in the WHO clinical stage than the EFV group after one year of therapy.

In the child population, Chiabi et al., (2025) reported that the use of DTG not only improves viral suppression but also provides better clinical outcomes than EFV. These findings suggest that the effectiveness of DTG is not only limited to the adult population but may also provide significant benefits to pediatric patients. In pregnant and lactating women, Facha et al., (2024) and *Kashyap et al.* (2026) suggest that the use of DTG has the potential to help achieve the target of elimination of mother-to-child HIV transmission. This condition is particularly important because optimal viral suppression during pregnancy and breastfeeding can lower the risk of mother-to-child transmission of HIV. Malaba et al., (2022) showed that the use of dolutegravir started at the end of pregnancy resulted in better maternal virologic suppression than efavirenz up to 72 weeks postpartum, without an increased risk of significant side effects in both mother and baby.

1.4 Safety and Tolerability

Several studies have also evaluated the safety aspects of dolutegravir use. Ayal & Berha (2023) found that the DTG group experienced fewer *adverse drug events* than the EFV group. In addition, patients taking DTG had better therapeutic tolerance. Mengistu et al., (2024) showed that despite a slight improvement in liver function parameters, no significant differences were found between the DTG and EFV groups related to hepatotoxicity. Brites et al., (2024) also reported that the rate

of regimen change due to side effects was lower in the DTG group than in the EFV group, indicating a better safety and tolerability profile.

The findings *of this systematic review* support the recommendations of the World Health Organization (WHO) that designate dolutegravir as a first-line therapy for HIV in various age groups and clinical conditions. The higher effectiveness in achieving viral suppression, improving immunological status, and a good safety profile make DTG a superior therapeutic option over EFV. However, most of the studies analyzed used observational and retrospective designs so that they still have the potential to cause selection bias and information bias. Therefore, further research with a randomized controlled trial design and longer follow-up periods is still needed to strengthen the evidence on the long-term effectiveness of dolutegravir-based regimens in various groups of HIV/AIDS patients.

Conclusion

Based on the results *of a systematic review* of 20 articles published in the period 2021–2026, despite methodological heterogeneity and variation in study quality, the consistency of results between studies shows that Dolutegravir-based antiretroviral regimens, particularly Tenofovir-Lamivudine-Dolutegravir (TLD) combinations, show better effectiveness than Efavirenz-based regimens, namely Tenofovir-Lamivudine-Efavirenz (TLE), in HIV/AIDS patients. The advantages of dolutegravir-based regimens are consistently found in various population groups, including adult patients, children, pregnant and lactating women, and patients with advanced AIDS.

Dolutegravir-based regimens show a tendency to provide higher virologic suppression rates, better immunological recovery through increased CD4+ cell count, have a good safety and tolerability profile, and improve clinical outcomes with a higher therapeutic success rate and a lower risk of therapy failure compared to efavirenz-based regimens. Thus, the use of TLDs can be considered as the primary choice in the management of HIV/AIDS to achieve optimal viral suppression targets and improve patient quality of life.

Recommendations

Further research is needed to conduct a prospective multicenter study with a larger sample size and a longer follow-up period to evaluate the effectiveness as well as long-term safety of dolutegravir-based regimens. Further research is also needed to assess the metabolic impact, weight change, patient quality of life, as well as the effectiveness of dolutegravir in specific populations such as children, pregnant women, the elderly, and patients with specific comorbidities.

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