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REAL-WORLD EFFICACY OF DOLUTEGRAVIR: A REVIEW OF VIROLOGICAL SUPPRESSION AND CD4+ RECOVERY TRENDS

G. NAGA YASHWANTH [1], C. MYTHILI [1], M. MAYURI [1], E. BHAVANA [1], Y. SRI BHARATHI [2], M. Bhargavi [3], Y. PRAPURNACHANDRA [4]

[1]*Vth Year Pharm D students, Ratnam Institute of Pharmacy, SPSR Nellore, Andhra Pradesh*
[2]*Assistant Professor, Department of Pharmacy Practice, Ratnam Institute of Pharmacy, SPSR Nellore, Andhra Pradesh.*
[3]*Associate Professor, Department of Pharmacy Practice, Ratnam Institute of Pharmacy, Pidathapolur (V&P), Muthukur (M), SPSR Nellore 524346*
[4]*Principal of Ratnam Institute of Pharmacy, SPSR Nellore, Andhra Pradesh*.

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***Corresponding author**
Y. Sribharathi

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ABSTRACT

Background: Because of its strong genetic barrier to resistance and exceptional tolerability, dolutegravir (DTG) has revolutionized HIV care since the World Health Organization recommended it as a preferred first-line medication. Although its effectiveness has been demonstrated in clinical studies, practical confirmation of its effect on key clinical parameters in the early phases of therapy is desperately needed. The impact of DTG-based antiretroviral treatment (ART) on immunological recovery and virological outcomes during the first six months after commencement is assessed in this analysis.

Methods: A thorough analysis of both prospective and retrospective clinical data was carried out, with an emphasis on HIV-1-positive individuals (≥18 years) starting DTG-based regimens. The mean change in CD4+ T-cell count from baseline to month 6 and the rate of virological suppression (defined as HIV-1 RNA <50 or <200 copies/mL) were the main outcomes evaluated. Treatment compliance and early warning indicators like weight increase were secondary factors.

Results: The majority of patients get viral suppression after 24 weeks of starting a DTG treatment, demonstrating its quick effectiveness. Significant immunological reconstitution follows, with CD4+ increases of 100–150 cells/mm³ being usual. Despite its great effectiveness, physicians need to keep an eye out for any early metabolic abnormalities, such weight gain. Conclusion: Superior viral clearance and a strong immunological recovery throughout the first six months of DTG-based ART justify its usage as a powerful first-line therapy.

Keywords: Dolutegravir, HIV-1, Viral Suppression, CD4+ Recovery, 6-Month Outcomes.

1. INTRODUCTION

In order to achieve 95% virology suppression, the World Health Organization (WHO) recommended including highly effective antiretroviral therapy (ART) into HIV treatment regimens. This ART has been shown to be effective across a variety of populations and has lesser toxicity and resistance.7. Following that, it was recommended that DTG be used as the preferred first-line regimen in combination with either FTC or TDF with 3TC, which is an optimized NRTI backbone. Furthermore, DTG is recommended as the preferable ARV drug for second-line ART in adults,

adolescents, and children who have not responded to a non-DTG-based first-line regimen. Effective prescription, administration, and usage, as well as ongoing availability and adherence, are crucial for maintaining the advantages of ART. Despite the undeniable effectiveness of ART, several problems still exist. Patients will have to take the medications for the rest of their lives since they are unable to totally eliminate the virus, which puts them at risk for harmful side effects, drug interactions, and drug resistance [1].

The development of antiretroviral treatment (ART) has radically changed the field of HIV/AIDS management. Achieving long-lasting virological suppression and promoting a strong immune recovery have been the major objectives of treatment since the development of highly active antiretroviral therapy (HAART). These indicators are the gold standard for evaluating the effectiveness of therapy and forecasting long-term morbidity and death. They are mainly determined by plasma HIV-1 RNA (viral load) and CD4+ T-cell counts [2].

Efavirenz and other Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-based regimens were the mainstay of first-line treatment for more than ten years. However, a worldwide change in treatment procedures was brought about by the increase in medication resistance prior to therapy and worries about neuropsychiatric adverse effects. Dolutegravir (DTG), a second-generation Integrate Strand Transfer Inhibitor (INSTI), was recommended by the World Health Organization (WHO) as the recommended first-line treatment for all populations in 2018 [3].

Dolutegravir differs from its predecessors due to its distinct pharmacological profile. It works by binding to the HIV integrate enzyme with high affinity, therefore preventing the strand transfer process required for the integration of viral DNA into the host genome. As a result, virus replication rapidly decreases. A once-daily dosage frequency that improves patient adherence-a crucial component in actual clinical settings-as well as a superior genetic barrier to resistance are clinical characteristics of DTG.

Significant clinical trials (such the SINGLE and ADVANCE investigations) have shown that DTG-based ART is more effective than Efavirenz-based regimens, with greater rates of virological suppression and fewer treatment-emergent resistance mutations. However, assessing DTG's efficacy in "real-world" programming contexts becomes crucial as healthcare systems throughout the world shift millions of patients to it. According to recent research, the first six months of treatment are a crucial time as this is when the biggest trajectory of viral load decrease and CD4+ count increase takes place [4].

Although DTG's immunological advantages are widely known, new research has also sparked concerns about metabolic health, especially in light of the notable weight gain that some populations saw within the first 24 to 48 weeks of therapy. It is critical for comprehensive patient care to comprehend the relationship between these metabolic changes and CD4+ recovery and virological success [5].

With an emphasis on its effects on virological suppression and CD4+ T-cell dynamics in HIV-infected patients, this review attempts to compile the most recent data on the clinical results of DTG-based ART. This research aims to evaluate the clinical transition to DTG and provide a standard for tracking treatment success in several international cohorts by examining early treatment responses.

2. EPIDEMOLOGY

1. Global Adoption and Utilization

By late 2025, Dolutegravir has become the most widely utilized antiretroviral agent in the world.

- Scale-up: Over 118 of 128 countries (approximately 92%) have adopted DTG-based regimens as the preferred first-line therapy.[6]
- Population Coverage: In Low- and Middle-Income Countries (LMICs), DTG-containing regimens (specifically the TLD fixed-dose combination) account for over 90% of all ART prescriptions for adults and adolescents.
- Demographics: Current epidemiological data highlights a shift in usage patterns, with women of childbearing age now representing a significant majority of DTG users following the resolution of early safety concerns regarding neural tube defects.

2. Virological Suppression Trends (The "Third 95")

The "Third 95" refers to the objective of achieving viral suppression in 95% of patients receiving therapy. The main force for advancement in this field is DTG.[7]

- 6-Month Success Rates: In real-world cohorts (e.g., studies from South Africa, Uganda, and Vietnam), 83% to 92% of patients achieve a viral load of <50 copies/mL within just 24 weeks (6 months) of starting DTG-based ART.[8]
- Late Presenters: Among patients with "late presentation" (starting ART with high viral loads or CD4 <350 cells/μL), suppression rates remain high, reaching approximately 83% at 6 months and increasing to 90%+ by one year.
- Impact of Switching: For patients switching from older NNRTI regimens (like Efavirenz) due to failure or side effects, the population-level viral suppression often increases by 10-15% within the first year of the DTG transition.

3. IMMUNOLOGICAL RECOVERY STATISTICS

Epidemiological studies track the restoration of cellular immunity across large populations to gauge public health success.

- Mean CD4+ Increase: The average immunological gain across global cohorts is consistently reported between +100 and +150 cells/mm³ during the first 6 months of therapy.

- CD4/CD8 Ratio: A key epidemiological marker in 2025 is the CD4/CD8 ratio, which has been shown to improve significantly (mean increase of ~0.2) within the first year on DTG, signalling a reduction in chronic immune activation.
- Non-responders: Approximately 5-10% of patients are classified as "immunological non-responders" (failing to gain >50 cells/mm³ despite viral suppression). Epidemiology shows this is more common in older patients (>50 years) and those starting with a baseline CD4 <100 cells/mm³.

4. Resistance and Public Health Threats

The "genetic barrier" of DTG is its most important epidemiological asset.

- Pre-treatment Resistance: Surveys in 2024-2025 show that pre-treatment resistance to DTG is virtually non-existent (<0.5%) in most countries.
- Acquired Resistance: Among the small percentage of patients who experience virological failure on DTG, only about 2% to 6% develop intermediate or high-level integrate inhibitor resistance. However, this rate can be higher (up to 19%) in treatment-experienced patients who transition to DTG while already having high viral loads.

Mechanism of Action

1. Molecular Interaction: The "Magnesium Bridge"

The catalytic core domain, which houses the highly conserved D, D, E motif (Asp64, Asp116, and Glu152), lies in the centre of the HIV-1 integrate enzyme. Two divalent magnesium ions (Mg^{2+}) that are necessary for the enzyme's function are coordinated by this motif [9].

- Chelation**:** DTG features a polycyclic planar moiety that functions as a "chelating trap." It positions its oxygen atoms to bind directly to these Mg^{2+} ions in the active site [10].
- Sequestration: By "locking" onto these metal cofactors, DTG effectively prevents the enzyme from interacting with the host cell's chromosomal DNA.

2. Inhibition of Strand Transfer

The actual stitching of the viral DNA into the host's genome is necessary for the HIV replication cycle. Strand transfer and 3'-processing are the two phases involved in this procedure. DTG focuses on the second, more crucial step [11].

- The Blockade: Once DTG is bound to the integrate-viral DNA complex (the intasome), it physically obstructs the binding pocket.
- Halting Integration: It prevents the processed 3' ends of the viral DNA from attacking the host DNA. Because the viral DNA cannot integrate, it remains "episomal" and is eventually degraded, effectively halting the production of new visions.

3. Why It Works So Fast: Dissociation Kinetics

- The speed of viral suppression is largely due to DTG's extraordinarily slow dissociation rate (off-rate) [12].
- Binding Half-Life: DTG remains attached to the integrate-DNA complex for much longer than first-generation inhibitors (like Raltegravir) [13]. Its dissociative half-life is approximately 71 hours, compared to just a few hours for older drugs.
  - **Sustained Potency:** This "long-lasting grip" means the enzyme is inhibited almost continuously, leading to the rapid drop in viral load (often seen within 4 weeks) that characterizes DTG therapy.

4. Comparison: Efficiency over Older Classes

- DTG is often more efficient than Protease Inhibitors (PIs) or NNRTIs for several structural and biological reasons**:**

Table 01: Efficient than Protease Inhibitors.

Feature	Dolutegravir (INSTIs)	NNRTIs (e.g., Efavirenz)	Protease Inhibitors (PIs)
Target Step	Integration (Final step of entry)	Reverse Transcription (Early)	Viral Assembly (Late)
Speed of Action	Very Fast (Rapidly stops new DNA)	Moderate	Slower (Produces non-infectious virus)
Genetic Barrier	High (Hard for virus to mutate)	Low (Single mutation can fail)	High
Molecular Fit	Flexible (Adjusts to mutations)	Rigid	Complex

- INSTIs vs. PIs: While Protease Inhibitors allow the virus to be "born" but make it non-infectious, INSTIs stop the virus from ever taking over the cell's "machinery." This leads to a cleaner and faster reduction in plasma viral load.
- INSTIs vs. NNRTIs: NNRTIs bind to a "pocket" that is prone to easy mutations. DTG's flexible structure allows it to "readjust" its position within the binding pocket, maintaining its grip even if the virus attempts to mutate [11].

4. VIROLOGICAL OUTCOMES

Dolutegravir (DTG) was chosen as the recommended first-line medication worldwide primarily because to its virological effectiveness. Its clinical profile is characterized by strong suppression and quick clearance in a variety of patient populations.

1. Time to Suppression: The "Rapid Clearance" Advantage

DTG's capacity to lower viral load (VL) to undetectable levels more quickly than more established medication classes like NNRTIs (e.g., Efavirenz) is one of its biggest benefits.

- Median Time to Suppression: In non-pregnant adults, the median time to reach <50 copies/mL is approximately 28 days (4 weeks).

- Comparison: Landmark trials such as DolPHIN-2 have shown that DTG achieves viral suppression in a median of 28 days, compared to 84 days for Efavirenz-based regimens. This speed is clinically vital for reducing the "window of transmissibility" and is especially critical for pregnant women presenting late in gestation to prevent vertical transmission [14,15].

2. Suppression Rates at 6 Months: Real-World Evidence

Real-world programming evidence confirms that DTG retains high efficacy even in difficult circumstances with adherence difficulties, despite the fact that clinical studies frequently provide "perfect" outcomes.

- On-Treatment Success: Recent meta-analyses (2025) of programmatic evidence show a pooled viral suppression rate of 95% at 6 months among patients retained in care.
- Intention-to-Treat (ITT) Results: In studies that include all patients who started the drug (regardless of whether they stayed on it), the success rates typically range between 85% and 92%.
- Transitioning Success: Patients switching from an older regimen (like EFV) to DTG often show even higher 6-month suppression rates-up to 98%-compared to those starting ART for the first time [4,16].

3. Baseline Viral Load Influence: Efficacy in High-Vermin Patients

A critical question in HIV care is whether DTG is effective for patients starting with very high viral loads (defined as >100,000 copies/mL).

- High-Viremia Performance: Data from the GEMINI and STAT studies demonstrate that DTG-based therapy remains highly effective for patients with high baseline loads.
- Very High Loads (>500,000 copies/mL): Even at extreme viral levels, 81% to 85% of patients achieve viral suppression within the first 6–12 months. While these patients may take slightly longer (closer to 8–12 weeks) to reach "undetectable" status, their final outcomes are comparable to those with lower baseline loads [17].
- Clinical Resilience: The high genetic barrier of DTG means that even in the presence of massive viral replication, the drug rarely leads to treatment-emergent resistance.

Table 02: Baseline Viral Load Influence: Efficacy in High-Vermin Patients.

Metric	DTG Performance (24 Weeks)	Clinical Significance
Median Time to <50 c/mL	~28 Days	Fastest clearance of current drug classes.
Suppression Rate (Real-World)	85% – 95%	Highly reliable for programmatic use.
Success at VL >100k c/mL	Robust (>85%)	Safe for "test and treat" without waiting for VL labs.
Resistance at Failure	<1\%	Extremely high barrier to drug resistance.

5. IMMUNOLOGICAL OUTCOMES

1. CD4+ Count Recovery: The First 6 Months

The recovery of CD4+ T-cells, which are the main targets of HIV, represents the "rebuilding" of the immune system. Regimens based on DTG are known to promote a strong biphasic rise in these cells.

Average Increase: Clinical studies and real-world cohorts report a mean CD4+ count increase of +100 to +167 cells/mm³ within the first 6 months of therapy.

Rapid Initial Gain: The most dramatic rise typically occurs in the first month (approximately +97 cells/mm³), followed by a more gradual but steady increase.

Baseline Influence: Interestingly, patients who start with very low counts (<200 cells/mm³) often experience the largest absolute gains in the first 6 months, though they may still remain below the "normal" threshold of 500 cells/mm [3,18].

2. CD4/CD8 Ratio: A Marker of Inflammation

The ratio of CD4 to CD8 cells in a healthy immune system is 1.0 to 3.0. HIV reverses this ratio by over stimulating CD8s and killing CD4s.

- Importance: The CD4/CD8 ratio is a critical biomarker for chronic immune activation and immunosenescence (premature aging of the immune system). Even if the CD4 count is high, a low ratio (e.g., <0.5) indicates that the body is still in a state of "inflammatory stress."
- Clinical Risk: A persistent low ratio is associated with a higher risk of non-AIDS co morbidities, including cardiovascular disease, liver damage, and certain cancers.
- DTG Advantage: Evidence suggests that Integrate Inhibitors (INSTIs) like DTG promote faster normalization of this ratio compared to older drug classes (NNRTIs or PIs), helping to "cool down" the immune system more effectively [19].

3. Immunological Non-Responders (INRs)

A difficult subgroup of patients attains "virological success" (meaning their viral load is undetectable) but falls short of "immunological success."

Definition: INRs are characterized as patients who continue to have viral suppression but do not see a notable increase in CD4 counts, which is usually indicated by a count of 200 within a year or a gain of >50 cells/mm³.

Prevalence: Approximately 11% to 14% of patients starting ART at very low baseline counts fall into this category.

Risk Factors: Major predictors for this poor response include:

Advanced Age: Patients >50 years old often have reduced thymus function.

Late Diagnosis: Starting treatment only after the immune system is severely damaged (AIDS stage).

- Chronic Inflammation: Co-infections like Hepatitis C or TB can hinder the recovery of CD4 cells [20].

Table 03: Immunological Non-Responders.

Metric	Target Outcome (6 Months)	Clinical Significance
CD4+ Count Increase	>100 cells/mm³	Reduced risk of opportunistic infections.
Absolute CD4+ Count	Targeting >350-500	Goal for "immune reconstitution."
CD4/CD8 Ratio	Trending toward >0.5-1.0	Reduced chronic inflammation and cancer risk.

6. SAFETY AND TOLERABILITY

1. Common Side Effects

During the first few weeks of treatment, the majority of DTG side effects are minor and temporary.

• Gastrointestinal (GI) Issues: Nausea and diarrhoea are reported by approximately 3–7% of patients but rarely lead to drug discontinuation.

• Headache and Dizziness: These are the most frequently reported physical symptoms, affecting roughly 1–10% of users. They typically resolve without medical intervention within the first month.

2. The "Weight Gain Phenomenon"

Weight gain has become the most talked-about adverse consequence of DTG by 2026. According to recent research, DTG could disrupt the operation of adiposities, or fat cells, or it might lower natural weight as an effect of older medications like Efavirenz.

- Metabolic Shifts: Patients starting DTG-based ART often experience significant increases in Body Mass Index (BMI) [21]. In the landmark ADVANCE trial, participants on DTG/TDF/3TC saw a mean weight gain of +4.3 kg to +9.4 kg over 192 weeks.
- Clinical Obesity: The incidence of clinical obesity (BMI \age 30) can rise from ~7% to nearly 28% in some cohorts within two years of initiating DTG [22].
- Risk Factors: Weight gain is most pronounced in women, individuals of African descent, and those starting therapy with a low baseline CD4 count (the "return-to-health" effect).

3. Neuropsychiatric Effects.

Although they are not common, adverse effects of the central nervous system (CNS) constitute a major reason for therapy switching.

- Insomnia and Sleep Disturbances: Insomnia is the most common CNS complaint, reported in ~17% of patients in some trials (compared to ~11% for other drugs). Taking the dose in the morning can often mitigate this.
- Mood Changes: Anxiety and depression have been reported in 5–8% of patients. These effects are observed more frequently in women and patients over 60 years of age.
- Discontinuation Rates: Despite these symptoms, fewer than 3% of patients actually stop the drug due to neuropsychiatric events, indicating that most cases are manageable.

Table 04: Neuropsychiatric Effects.

Adverse Event	Prevalence	Clinical Management
Weight Gain / BMI increase	High (25–30%)	Lifestyle counselling; monitor blood pressure & glucose.
Insomnia	Moderate (~15%)	Switch to morning dosing.
GI Distress	Low (<5%)	Take with food; usually self-limiting.
Headache	Low (~7%)	Over-the-counter analgesics; usually resolves in 2 weeks.

7. DISCUSSION

1. Clinical Trials vs. Real-World Programmatic Data

There is frequently a "gap" between the outcomes of closely watched studies and those observed in crowded public health clinics.

- Controlled Trials (e.g., SINGLE, GEMINI, ADVANCE): These pivotal studies reported viral suppression rates often exceeding 90–95% [23]. These trials benefit from "perfect" patients with high adherence and frequent laboratory monitoring.
- Real-World Programmatic Data: Large-scale observational studies (such as those from South Africa and Brazil) confirm that DTG is robust, though suppression rates may be slightly lower (typically 85–92%) due to social determinants of health, such as drug stock-outs or co-infections. However, DTG has shown a 14-percentage point increase in viral suppression compared to Efavirenz in real-world "target trial" simulations [24].

2. Adherence and "Forgiveness" (The Genetic Barrier)

A drug's "forgiveness" refers to its ability to maintain viral suppression even when a patient occasionally misses a dose [25].

- High Genetic Barrier: DTG is considered to have one of the highest genetic barriers to resistance. It binds so tightly to the integrate enzyme (with a 71-hour half-life on the intasome) that it continues to work even if blood levels dip slightly.
- Adherence Thresholds: While older drugs required >95\% adherence for success, real-world data suggest that DTG-based regimens can maintain suppression with adherence as low as 80%. This "forgiveness" is a

major safety net for patients with busy lifestyles or mental health challenges [26].

3. Immune Reconstitution Inflammatory Syndrome (IRIS)

A pre-existing infection might paradoxically get worse during IRIS as the immune system "wakes up" and starts to fight back.

- The Risk Factor: Patients with very advanced HIV (baseline CD4 <200 cells/mm³) are at the highest risk. Because DTG lowers viral load so rapidly, the immune system can "reconstitute" too quickly, leading to an over-exaggerated inflammatory response.
- Incidence: Studies indicate that IRIS is roughly three times more likely in patients starting Integrate Inhibitors (like DTG) compared to NNRTIs or PIs, precisely because of the speed of the drug. Common IRIS-associated triggers include Tuberculosis (TB), Cryptococcus, and Pneumocystis pneumonia [27].
- Management: Clinicians must monitor late presenters closely during the first 3–6 months. In some cases, steroids are used to manage the inflammation without stopping the life-saving ART [28].

Table 05: Immune Reconstitution Inflammatory Syndrome.

Feature	Clinical Observation	Practical Implication
Real-World Efficacy	High (85–92% suppression)	Validates the global transition to DTG.
Genetic Barrier	Very High	Reduces the risk of resistance from missed doses.
IRIS Risk	Higher in late presenters	Requires careful monitoring of CD4 <200 patients.

8. CONCLUSION AND FUTURE DIRECTIONS

1. Summary: A New Clinical Gold Standard

According to the synthesis of available data, dolutegravir (DTG)-based antiretroviral therapy (ART) will continue to be the gold standard of treatment for HIV management in 2026.

- Superior Suppression: DTG consistently outperforms older drug classes (NNRTIs and PIs) by achieving significantly faster and more durable virological suppression. Real-world data reinforces that nearly 90–95% of patients retained in care reach undetectable status within 6 months [29].
- Robust Recovery: Immunological gains are reliable and potent, with average CD4+ increases of +100 to +150 cells/mm³ in the first 24 weeks. This rapid immune reconstitution is pivotal in reducing the incidence of opportunistic infections and AIDS-defining illnesses.[30]
- Durable Success: Due to its high genetic barrier, DTG provides a critical "safety net" for patients with suboptimal adherence, making it a resilient tool for global public health [4, 21].

2. Gaps in Knowledge: The Road Ahead

Even while the short- to medium-term advantages are obvious, as we pass the first ten years of extensive DTG usage, there are a few "blind spots" that urgently need to be investigated:

- Long-Term Metabolic Health: There is a critical need for 5–10 year longitudinal data on the "Weight Gain Phenomenon." While we know DTG causes early BMI increases (up to 27% obesity incidence in some trials), we do not yet fully understand if this weight gain plateaus or continues to increase over a decade [31].
- Cardiovascular Risk: As the HIV population ages, the link between DTG-associated weight gain and Major Adverse Cardiovascular Events (MACE) remains a key gap. We need more research to determine if DTG directly increases the risk of heart disease or if the risk is secondary to metabolic shifts [32].
- Resistance in Programmatic Settings: While resistance is rare (<1\%), emergent mutations (like G118R or N155H) are being reported in patients failing treatment in real-world settings. Continued surveillance is necessary to prevent a silent rise in integrate inhibitor resistance.
- Special Populations: More robust sex-specific data is needed to guide long-term care for women of childbearing age, who experience the most significant metabolic changes on DTG [33].

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