P-1037

Dolutegravir + Lamivudine in People With HIV-1 Who Are Naive to Antiretroviral Therapy With Baseline Viral Load ≥500,000 c/mL: Systematic Literature Review and Meta-Analysis of Real-World Evidence

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Key Takeaways

- **8 independent, real-world cohorts provided outcomes for 372 people with HIV who were naive to treatment and initiating DTG + 3TC with baseline VL ≥500,000 c/mL**
- **Among people with available virologic data, 87% (235/271) at Week 48 and 92% (113/123) at Week 96 had study-defined VS in the descriptive analysis**
- **In a pooled meta-analysis of these real-world studies, the estimated proportion of people with VS was high at Week 48 (≥85%) and Week 96 (93%) in both fixed- and random-effects models**
- **These findings help address residual clinical uncertainty about initiating DTG + 3TC in people with baseline VL ≥500,000 c/mL**

Plain Language Summary

- DTG + 3TC can be used by people starting HIV treatment without a viral load restriction per the US product label and guidance from the US Department of Health and Human Services; however, there remains limited clinical trial data focused specifically on people with HIV and high viral loads at diagnosis
- We identified and assessed results from real-world studies of people who started DTG + 3TC with very high viral loads
- Among people with available virologic results, most had viral loads below the suppression thresholds evaluated at Years 1 and 2, where available
- These findings add real-world information for clinicians considering DTG + 3TC for people starting treatment with very high viral loads

Introduction

- Dolutegravir + lamivudine (DTG + 3TC) is an approved 2-drug regimen (2DR) for initial antiretroviral therapy (ART) without baseline viral load (VL) restrictions in product labeling[1]
  - Updated US Department of Health and Human Services guidelines now state that DTG + 3TC may be considered as an initial regimen regardless of baseline VL in appropriately selected individuals[2]
- A recent meta-analysis of the GEMINI-1/-2, STAT, D2ARLING, and DOLCE clinical trials demonstrated that in people naive to ART with baseline VL ≥500,000 c/mL, the 2DR DTG + 3TC achieves comparable virologic efficacy to DTG-based 3-drug regimens (3DRs) at Week 48[3]
- Individuals with baseline VL ≥500,000 c/mL represent one of the most clinically challenging populations among people naive to ART; therefore, real-world evidence (RWE) is important to complement clinical trial data in this population
- We conducted a systematic literature review (SLR) and meta-analysis of RWE to characterize outcomes with DTG + 3TC in people naive to ART with baseline VL ≥500,000 c/mL

Methods

Systematic Literature Review

- An SLR was conducted to identify RWE on the use of DTG + 3TC in people with HIV naive to ART and with very high baseline VL (≥500,000 c/mL) using PRISMA guidelines
- Data from RWE studies published between January 2013 and March 2026 reporting DTG + 3TC use in people with HIV naive to ART were identified from structured searches of Embase, PubMed, Cochrane Library, gray literature, and relevant international conference proceedings
- Studies were included if they reported effectiveness (virologic), safety, or tolerability outcomes at Weeks 48 and/or 96 among ≥10 individuals with HIV naive to ART with very high baseline VL to minimize small-study bias
- To minimize the risk of double-counting individuals, data from the publication with the largest or most up-to-date cohort for each population were considered; however, when these "lead publications" did not report the outcome of interest, secondary publications were leveraged to fill data gaps and avoid double counting
- Rates of study-defined virologic suppression (VS) were summarized using descriptive statistics
  - Analyses used the study-reported population with available virologic data at each time point; missing outcomes were not imputed

Meta-Analysis

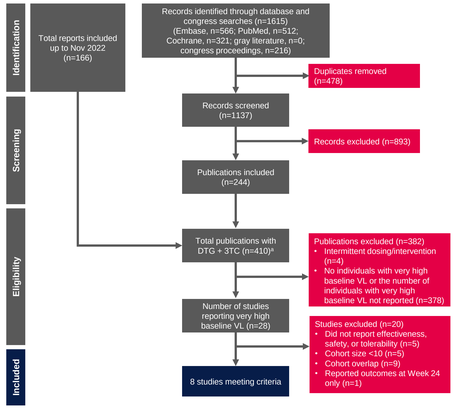
- The SLR-included studies were screened to identify all studies reporting VS at Weeks 48 or 96 for inclusion in the meta-analysis
- A single-arm meta-analysis produced point estimates from fixed- and random-effects models for proportions of individuals with VS at Weeks 48 and 96; random-effects models were used to account for between-study heterogeneity
- Clopper-Pearson CIs were calculated for individual studies; the DerSimonian-Laird estimator was used for tau^2 calculation; and statistical heterogeneity between studies was assessed using the I^2 equation
- Sensitivity analyses were conducted to account for variability in VS definitions, in which studies using a VS definition threshold of <50 and <200 c/mL were pooled

Results

Studies Included in SLR and Descriptive Analyses

- The SLR identified 410 real-world publications published between January 2013 and March 2026, representing 125 cohorts and 75,927 individuals with HIV using DTG + 3TC (Figure 1)
  - Of these, 89 studies included DTG + 3TC use in people naive to ART (n=5144), spanning the full range of baseline VL; of these 89 studies, 28 specifically reported outcomes among people with baseline VL ≥500,000 c/mL (n=745); and of these 28 studies, 23 reported effectiveness, safety, or tolerability outcomes (n=614)
- Of the 23 studies, 8 reported VS outcomes at Week 48 and/or Week 96 in cohorts of ≥10 people with baseline VL ≥500,000 c/mL (total baseline n=372); 7 studies reported Week 48 outcomes (baseline n=319; available virologic data n=271), and 3 reported Week 96 outcomes (baseline n=257; available virologic data n=123)[4-11]
  - Cohorts were represented across China or Taiwan (4 studies), Spain (3 studies), and Turkey (1 study)
- Across these 8 studies, 87% (235/271) and 92% (113/123) of individuals had VS (VL <50 c/mL [7 studies] or <200 c/mL [1 study]) at Weeks 48 and 96, respectively

Figure 1. PRISMA Flow Chart of SLR-Identified RWE Studies



[a]Of these, 89 studies included people naive to ART.

Studies Included in Meta-Analysis

- Meta-analysis feasibility was assessed and confirmed for VS outcomes at Weeks 48 and 96
- In the SLR, 23 of 28 studies reported effectiveness, safety, or tolerability outcomes for people naive to ART initiating DTG + 3TC with baseline VL ≥500,000 c/mL
  - Of these 23 studies, 5 were excluded due to cohort size (N<10), 9 were excluded due to cohort overlap with other studies, and 1 was excluded due to only reporting outcomes at Week 24
- A total of 8 studies were included across analyses at Weeks 48 and 96 (Table)

Table. Proportion of People With Baseline VL ≥500,000 c/mL Who Had VS With DTG + 3TC at Weeks 48 and 96 in Studies Included in Meta-Analysis

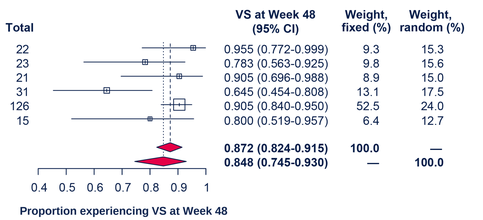
Study, year[a]	Country	People with VL ≥500,000 c/mL using DTG + 3TC/ Total DTG + 3TC users, baseline, n/N (%)	Meta-analysis time points, weeks	VS definition, VL, c/mL	VS, n/N (%)[b]
Zhao et al, 2022[4]	China	22/42 (52)	48	<50	21/22 (96)
Dou et al, 2024[5]	China	26/26 (100)	48	<50	18/23 (78)
Martin-Torres et al, 2025 (REDOLA)[6]	Spain	21/21 (100)	48	<50	19/21 (90)
Wang et al, 2025 (Guiyang Public Health Clinical Center)[7]	China	31/176 (18)	48	<50	20/31 (65)[c]
Inan et al, 2025 (DOLAM-500)[8]	Turkey	155/155 (100)	48; 96	<50	114/126 (90); 76/83 (92)
Yang et al, 2026 (DRAGON)[9,d]	Taiwan and China	49/406 (12)	48; 96	<200	31/33 (94); 15/15 (100)
Suárez-García et al, 2024 (CoRIS)[10]	Spain	53/472 (11)	96	<50	22/25 (88)
Hernandez et al, 2025 (Hospital Universitario de La Princesa)[11]	Spain	15/15 (100)	48	<50	12/15 (80)

[a]Cohort names included where applicable. Data are based on 8 real-world studies that included ≥10 people who were naive to ART and initiated DTG + 3TC with baseline VL ≥500,000 c/mL. [b]Percentages represent number of individuals with study-defined VS at time point (n) among all individuals with available data at each time point (N). [c]2 individuals who achieved VS at Week 24 subsequently discontinued treatment and experienced viral rebound at Week 48, contributing to suboptimal VS. [d]Included in sensitivity analysis only due to VS outcome definition being inconsistent with other studies.

Meta-Analysis Effectiveness Estimates at Week 48

- Of the 8 studies identified, 6 reported consistent VS data (VL <50 c/mL) at Week 48 and were included in meta-analysis estimates
- Pooling these studies, the estimated proportion (95% CI) of people with VS was 0.848 (0.745-0.930) using the random-effects model (Figure 2)
- Additionally, 1 study also reported VS outcomes at Week 48 but used a different definition of VS (VL <200 c/mL)[8]
  - Using a sensitivity analysis pooling studies regardless of the VS outcome definition, the estimated proportion (95% CI) of people with VS was 0.865 (0.779-0.934) using the random-effects model

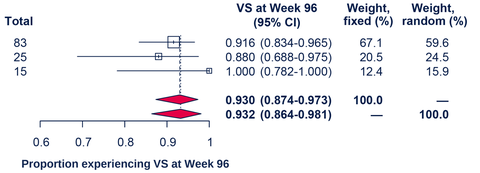
Figure 2. Meta-Analysis–Estimated Proportions of People With VS (VL <50 c/mL) Using DTG + 3TC at Week 48



Meta-Analysis Effectiveness Estimates at Week 96

- 3 of the 8 studies presented VS data at Week 96 and were included in meta-analysis estimates
  - Although VS definitions varied slightly (VL <200 c/mL [1 study] vs VL <50 c/mL [2 studies]), all 3 studies were pooled given the limited number available at Week 96
- When pooling studies reporting VS data at Week 96, regardless of the VS definition, the estimated proportion (95% CI) of people with VS was 0.932 (0.864-0.981) using the random-effects model (Figure 3)

Figure 3. Meta-Analysis–Estimated Proportions of People With VS (VL <50 or <200 c/mL) Using DTG + 3TC at Week 96[a]



[a]Findings should be interpreted with caution given the small number of available studies and inconsistent definitions of VS across studies.

Conclusions

- In this meta-analysis of RWE, high proportions of people naive to ART and initiating DTG + 3TC with baseline VL ≥500,000 c/mL achieved VS at Weeks 48 and 96
- The high VS proportions observed in this real-world analysis are consistent with findings from a recent meta-analysis of clinical trials comparing DTG + 3TC with DTG-based 3DRs at Week 48[3]
- Several limitations should be considered when interpreting these findings. The Week 96 estimate was based on only 3 studies and a smaller population than the Week 48 analysis. Differences between time points may reflect variation in study availability, cohort composition, available case reporting, and VS definitions rather than changes in treatment effectiveness over time
- Together with clinical trial evidence, these real-world findings may add to the evidence base informing contemporary treatment guidance for people with baseline VL ≥500,000 c/mL

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