TR-DOLA: Real-world Data on the Use of Dolutegravir (DTG) + Lamivudine (3TC) in Treatment-Experienced People Living With HIV in Türkiye

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Key Takeaways

- **At the time of this analysis, dolutegravir (DTG) + lamivudine (3TC) was only available as a 3-tablet regimen in Türkiye; therefore, we evaluated the effectiveness of DTG + 3TC as a multi-tablet regimen for HIV treatment in local real-world settings**
- **DTG + 3TC demonstrated high rates of effectiveness and improvements in CD4+ cell count and CD4+/CD8+ ratio in people with HIV who were virologically suppressed**
- **Virologic outcomes in this real-world population in Türkiye are consistent with those seen in other countries, further reinforcing DTG + 3TC as a highly effective treatment option among people with HIV suppression in real-world settings**

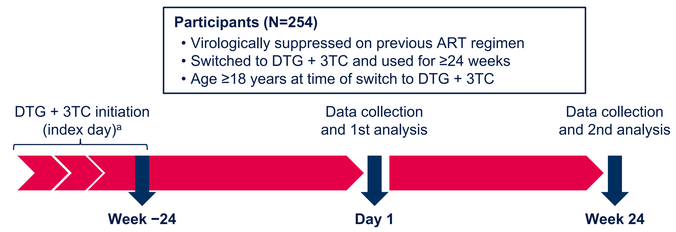
Purpose

- 2-drug antiretroviral therapy (ART) regimens may be preferable to 3-drug regimens for individuals with HIV to potentially decrease toxicities, drug−drug interactions, and costs, assuming virologic effectiveness is equivalent[1]
- The 2-drug regimen DTG + 3TC is recommended as initial therapy for people with HIV naive to ART and as a switch option for those with viral suppression and without hepatitis B co-infection or resistance to DTG or 3TC[2]
  - DTG + 3TC is available as a single-tablet, fixed-dose combination or as separate tablets
- In Türkiye, DTG + 3TC was only available as a 3-tablet regimen at the time of this analysis. In the absence of a single-tablet option, there was a need to evaluate the effectiveness of DTG + 3TC (multi-tablet regimen) for HIV treatment in local clinical practice in Türkiye
- In the TR-DOLA study, we assessed the effectiveness and safety of switching to multi-tablet DTG (one 50-mg tablet daily) + 3TC (two 150-mg tablets daily) in people with HIV who were ART-experienced and virologically suppressed in local clinical practice in Türkiye

Methods

- TR-DOLA was a multicenter, ambi-directional, single-arm, observational study of adults with HIV who switched to DTG + 3TC
- Data were collected from infectious disease clinics at 15 tertiary hospitals across Türkiye between January 2024 and February 2025
- The study included a ≥24-week retrospective data collection period followed by a 24-week prospective data collection period, for at least 48 weeks of DTG + 3TC treatment (Figure 1)
- Inclusion criteria were documented HIV-1 diagnosis, virologic suppression (HIV-1 RNA <50 c/mL) on prior ART regimen, age ≥18 years at DTG + 3TC initiation, DTG + 3TC use for ≥24 weeks per medical records, and prescribed DTG + 3TC independent of study
- Exclusion criteria were DTG + 3TC use for <24 weeks, documented INSTI and/or NRTI resistance mutations, hepatitis B co-infection, or participation in an interventional study
- Data were collected at DTG + 3TC initiation (retrospective), Day 1 (study enrollment), and Week 24 (prospective) and included demographic and clinical characteristics as well as virologic and immunologic outcomes (Figure 1)
  - Virologic failure (VF) was defined as 2 consecutive HIV-1 RNA values ≥50 c/mL before or at the evaluation time point or 1 HIV-1 RNA value ≥50 c/mL followed by DTG + 3TC discontinuation before or at the evaluation time point

Figure 1. TR-DOLA Study Design



[a]DTG + 3TC initiation could have been any day before Week −24.

- Change in HIV-1 RNA, CD4+ and CD8+ cell counts, CD4+/CD8+ ratio, liver and renal function tests, lipid levels, body mass index (BMI), and bone mineral density (BMD) from index date (DTG + 3TC initiation) are summarized descriptively

Results

Study Population

- Participant characteristics are shown in Table 1

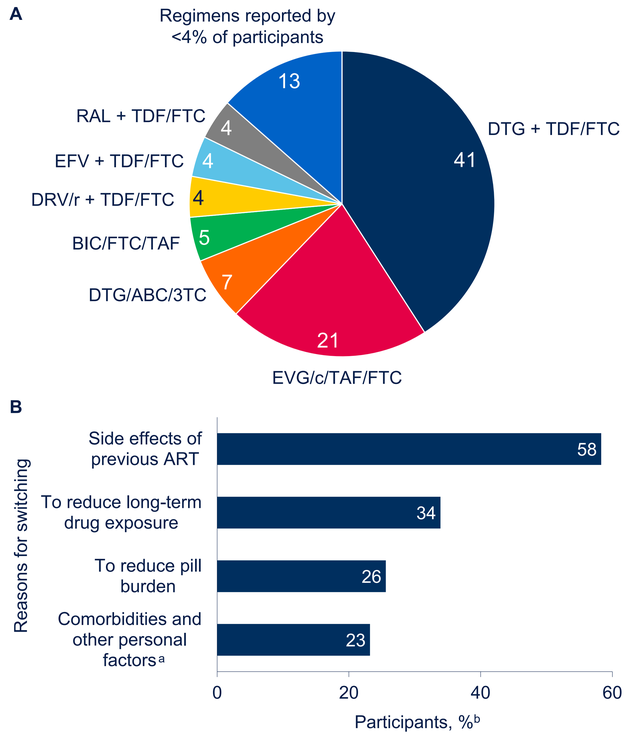
Table 1. Demographics and Clinical Characteristics

Characteristic	N=254
Sex, n (%)	
Male	208 (82)
Female	46 (18)
Age, mean ± SD, y	
At enrollment	50.2 ± 13.2
At diagnosis	40.1 ± 12.5
At DTG + 3TC initiation	46.3 ± 12.9
Time from diagnosis to DTG + 3TC initiation, mean ± SD, y	6.2 ± 4.7
Duration of DTG + 3TC use, mean ± SD, y	3.9 ± 1.9
BMI at DTG + 3TC initiation, mean ± SD, kg/m^2 (n=151)	27.2 ± 4.8
BMI category, n (%), kg/m^2	
<18.5	2 (1)
18.5 to <25.0	57 (38)
25.0 to <30.0	51 (34)
≥30.0	41 (27)
No. of previous ART regimens, n (%)	
1	124 (49)
>1	130 (51)
Comorbidities (>10%), n (%)	
Hyperlipidemia	92 (36)
Hypertension	85 (33)
Co-infections (eg, HCV, tuberculosis)	73 (29)
Osteoporosis	66 (26)
Coronary artery disease	54 (21)
Hepatic steatosis	51 (20)
Osteopenia	47 (19)
Diabetes mellitus	43 (17)
Major psychiatric disorder	30 (12)
Moderate-to-severe CKD (GFR ≤59 mL/min)	19 (7)
CD4+ cell count, mean ± SD, cells/mm^3 (n=198)	693.2 ± 343.4
CD4+ cell count, mean ± SD, % (n=196)	31.5 ± 9.4
CD8+ cell count, mean ± SD, cells/mm^3 (n=181)	816.8 ± 438.1
CD4+/CD8+ ratio, mean ± SD (n=179)	0.9 ± 0.5
HIV-1 RNA at DTG + 3TC initiation, mean ± SD, c/mL	6 ± 12.6

ART, antiretroviral therapy; BMI, body mass index; CKD, chronic kidney disease; DTG, dolutegravir; GFR, glomerular filtration rate; HCV, hepatitis C virus; SD, standard deviation; 3TC, lamivudine; y, year.

- Median (IQR) time from HIV diagnosis to DTG + 3TC initiation was 5.1 (3.0-8.5) years, and median duration of DTG + 3TC use was 3.0 (1.6-4.8) years
- The majority of participants switched to DTG + 3TC from DTG + TDF/FTC (41%) or EVG/c/TAF/FTC (21%)
- Most participants switched to DTG + 3TC due to side effects from their previous ART regimen (58%) and to reduce long-term drug exposure (34%; Figure 2)

Figure 2. (A) ART Regimen Before Switch to DTG + 3TC (>4% of Participants) and (B) Reasons for Switch to DTG + 3TC (>10% of Participants)

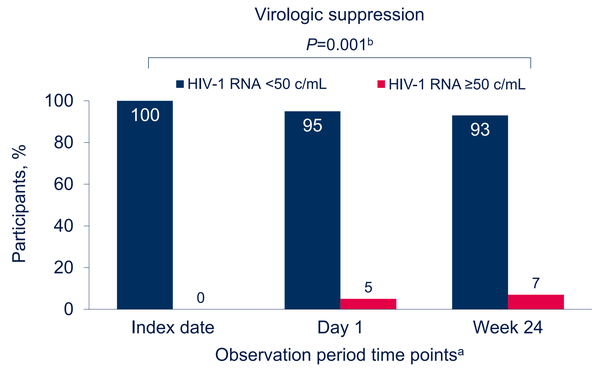


ABC, abacavir; ART, antiretroviral therapy; BIC, bictegravir; DRV/r, ritonavir-boosted darunavir; EFV, efavirenz; EVG/c, cobicistat-boosted elvitegravir; FTC, emtricitabine; RAL, raltegravir; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate. [a]For example, age or pregnancy. [b]Total percentage >100 because multiple responses were allowed.

Virologic Outcomes

- Per eligibility criteria, 100% of participants (N=254) had HIV-1 RNA <50 c/mL at the index date; this proportion decreased slightly to 94% (203/215) at Day 1 and was maintained through Week 24 (94%; 234/250)
- Among 211 individuals with HIV-1 RNA results available at all study time points, 93% (n=197) maintained virologic suppression (Figure 3)

Figure 3. Proportion of Participants Maintaining Viral Suppression (HIV-1 RNA <50 c/mL) During the Observation Period Among Those With HIV-1 RNA Results Available at All Study Time Points[a] (n=211)



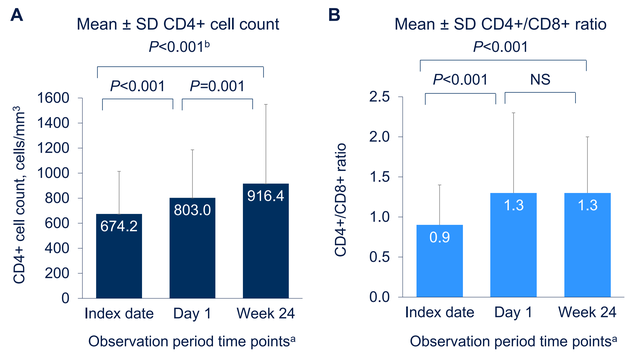
[a]Index date: DTG + 3TC initiation; Day 1: day of enrollment and initiation of prospective study period; Week 24: end of 24-week prospective follow-up period. [b]Cochran Q test.

- Further investigation is ongoing to establish whether individuals with unsuppressed viral load should be considered VF (ie, 2 consecutive HIV-1 RNA ≥50 c/mL before/at evaluation time point or 1 HIV-1 RNA ≥50 c/mL followed by DTG + 3TC discontinuation before/at evaluation time point)

Immunologic and Laboratory Parameters

- Over ≥48 weeks of DTG + 3TC treatment, CD4+ cell count and percentage and CD4+/CD8+ ratio (P≤0.001) progressively increased (Figure 4)
- Creatinine clearance (CrCl) significantly decreased (Table 2)
- No significant changes in liver function tests, lipid levels, BMI, or BMD were observed during the follow-up period (data not shown)

Figure 4. (A) Mean CD4+ Cell Count (n=142) and (B) Mean CD4+/CD8+ Ratio (n=133) During the Observation Period[a]



[a]Index date: DTG + 3TC initiation; Day 1: day of enrollment and initiation of prospective study period; Week 24: end of 24-week prospective follow-up period. [b]Wilcoxon test.

Table 2. Change in Key Immunologic and Laboratory Parameters During the Observation Period

Parameter, mean ± SD	n[a]	Time point[b]			*P* value
		Index date	Day 1	Week 24	
CD4+ cell count, %	151	31.3 ± 9.5	35.0 ± 9.9	36.6 ± 9.8	<0.001
CD8+ cell count, cells/mm^3	133	805.3 ± 379.5	717.8 ± 409.2	783.2 ± 415.2	0.307
CrCl, mL/min	203	88.6 ± 24.7	83.8 ± 21.1	82.7 ± 21.1	<0.001
Creatinine, mg/dL	203	1.0 ± 0.4	1.0 ± 0.2	1.1 ± 0.5	0.005

[a]Number of participants with data available at all time points. [b]Index date: DTG + 3TC initiation; Day 1: day of enrollment and initiation of prospective study period; Week 24: end of 24-week prospective follow-up period.

Conclusions

- Results from the TR-DOLA study reinforce the effectiveness of switching to DTG + 3TC for adults with HIV who are virologically suppressed in routine clinical practice in Türkiye
- DTG + 3TC offers a regimen with fewer drugs while maintaining high virologic effectiveness and improvements in immune parameters
- Results in this virologically suppressed population in Türkiye are in alignment with the data from real-world populations who switched to DTG + 3TC in other regions, including the Asia and Pacific region, South America, Europe, and Russia, which also showed high rates of effectiveness as well as few discontinuations[3,4]

Abbreviations: ABC, abacavir; ART, antiretroviral therapy; BIC, bictegravir; BMD, bone mineral density; BMI, body mass index; CKD, chronic kidney disease; CrCl, creatinine clearance; DRV/r, ritonavir-boosted darunavir; DTG, dolutegravir; EFV, efavirenz; EVG/c, cobicistat-boosted elvitegravir; FTC, emtricitabine; GFR, glomerular filtration rate; HCV, hepatitis C virus; RAL, raltegravir; TAF, tenofovir alafenamide; 3TC, lamivudine; TDF, tenofovir disoproxil fumarate; VF, virologic failure.

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References: 1. Gibas et al. *Lancet HIV*. 2022;9:e868-e883. **2.** Gandhi et al. *JAMA*. 2025;333:609-628. **3.** Doblado-Maldonado et al. *Medicine (Baltimore)*. 2025;104:e43558. **4.** Fraysse et al. *Infect Dis Ther*. 2025;14:357-383.

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