Effectiveness of DTG/3TC Rapid Initiation in Treatment-Naïve People Living with HIV in Kuwait: a Real-World Cohort Study

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Key Takeaways

- In this real-world test-and-treat cohort, rapid initiation of dolutegravir/lamivudine (DTG/3TC) achieved 78.5% virologic suppression at Week 52 using the <50 copies/mL threshold (modified FDA Snapshot), and 93.1% at the <200 copies/mL threshold.
- Confirmed virologic failure was uncommon (4.3%), with no treatment-emergent resistance to DTG or 3TC was observed.
- Median CD4+ count increased by 276 cells/mm³, demonstrating substantial immune recovery.
- Treatment persistence was high, with 97.4% probability of remaining on treatment at Week 52.
- These findings support DTG/3TC as a practical first-line option for rapid ART initiation in routine clinical practice.

Plain Language Summary

- This real-world study evaluated the effectiveness of the two-drug regimen DTG/3TC when initiated rapidly after HIV diagnosis in Kuwait.
- Most participants started DTG/3TC within one week of diagnosis, even before complete baseline laboratory test results were available.
- After one year of treatment, most participants achieved viral suppression, experienced immunologic recovery, remained on treatment, with no treatment-emergent resistance or new safety concerns identified.

Introduction

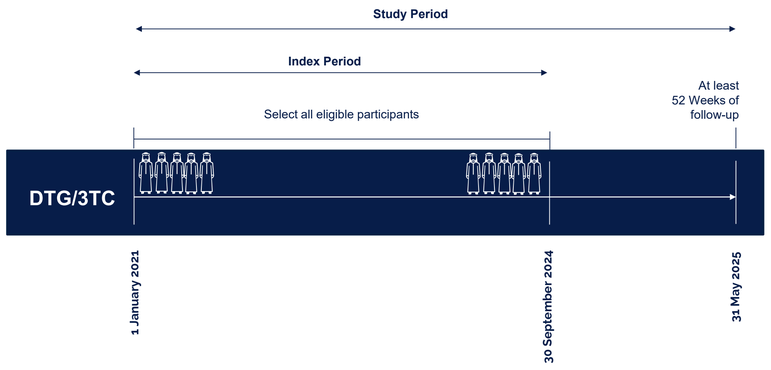
- Rapid antiretroviral therapy (ART) initiation is recommended to improve linkage to care, accelerate viral suppression, and reduce HIV transmission[1-4]. However, real-world evidence supporting rapid initiation of DTG/3TC remains limited, particularly in the Arabian Gulf region.
- RAPIDOLA study was designed to describe the effectiveness, treatment persistence, immunologic recovery, and resistance profile of DTG/3TC when initiated in a test-and-treat setting among treatment-naïve people living with HIV in Kuwait.

Methods

Study Design

Retrospective, single-centre observational cohort study conducted at Kuwait's national HIV treatment centre, between January 2021 and September 2024 (Figure 1).

Figure 1. Study Design Diagram



Population

Eligible participants were adults living with HIV-1 who were ART-naïve and initiated DTG/3TC on the same day or within 14 days of diagnosis, before complete baseline laboratory results (HIV-1 RNA, CD4+ cell count, HBV serology, or genotypic resistance testing) were available.

Primary Endpoint

- **Virologic suppression:** proportion of participants achieving HIV-1 RNA <50 copies/mL at Week 52 using a modified FDA Snapshot approach (missing data/discontinuations = failure).
- A sensitivity analysis was conducted using an alternative virologic suppression threshold of <200 copies/mL at Week 52.

Secondary Endpoints

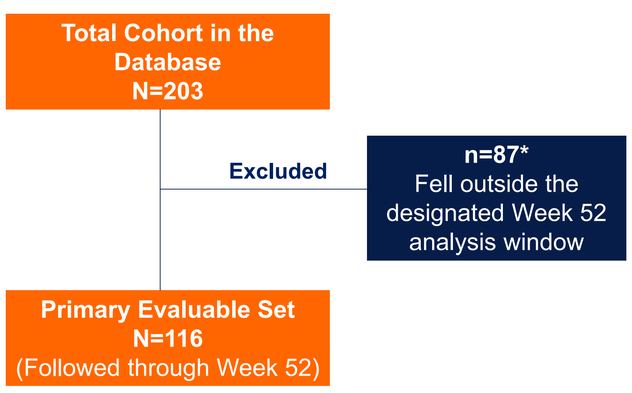
- **Confirmed virologic failure:** two consecutive HIV-1 RNA viral loads (VL) levels ≥200 copies/mL after suppression to <50 copies/mL.
- **Treatment-emergent resistance:** proportion of participants with confirmed acquired resistance to DTG or 3TC among those experiencing confirmed virologic failure.
- **Change in CD4+ cell count:** median change from baseline to Week 52.
- **Treatment persistence:** proportion of participants remaining on DTG/3TC through Week 52 without premature discontinuation.
- **Safety**

Results

Participants Disposition

- 116 participants were evaluable in the primary Week 52 dataset (Figure 2).

Figure 2. Participant Flow Diagram



*These 87 participants were excluded from the Week 52 analysis because they had not yet reached the predefined Week 52 follow-up window.

Participants Characteristics

- Participants demographics and baseline characteristics are shown in Table 1.
- Of the 116 participants, 28.4% had VL >100,000 copies/mL, and 10.7% had CD4+ cell count <200 cells/mm³.

Table 1. Demographic and Baseline Characteristics (N=116)

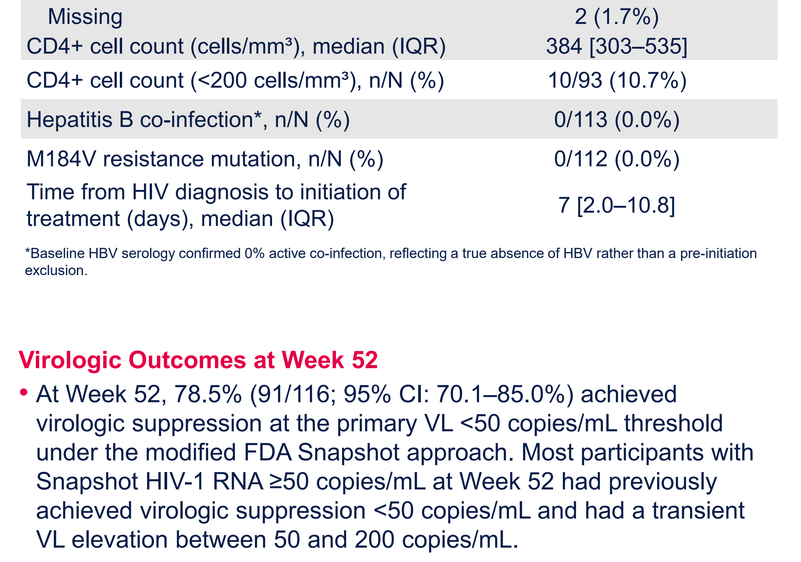
Characteristic	
Age (years), median (IQR)	33.6 [28.3–37.0]
Age group (≥50 years), n (%)	5 (4.3%)
Male, n (%)	105/116 (90.5%)
HIV-1 RNA (copies/mL), median (IQR)	46,575 [11,734–138,275]
HIV-1 RNA category (copies/mL), n (%)	
<100,000	81 (69.8%)
100,000–250,000	15 (12.9%)
250,000–400,000	3 (2.6%)
400,000–500,000	2 (1.7%)
>500,000	13 (11.2%)
Missing	2 (1.7%)
CD4+ cell count (cells/mm³), median (IQR)	384 [303–535]
CD4+ cell count (<200 cells/mm³), n/N (%)	10/93 (10.7%)
Hepatitis B co-infection*, n/N (%)	0/113 (0.0%)
M184V resistance mutation, n/N (%)	0/112 (0.0%)
Time from HIV diagnosis to initiation of treatment (days), median (IQR)	7 [2.0–10.8]

*Baseline HBV serology confirmed 0% active co-infection, reflecting a true absence of HBV rather than a pre-initiation exclusion.

Virologic Outcomes at Week 52

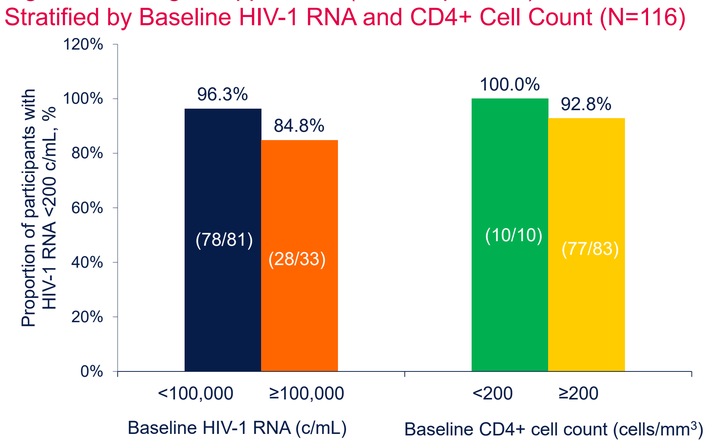
- At Week 52, 78.5% (91/116; 95% CI: 70.1–85.0%) achieved virologic suppression at the primary VL <50 copies/mL threshold under the modified FDA Snapshot approach. Most participants with Snapshot HIV-1 RNA ≥50 copies/mL at Week 52 had previously achieved virologic suppression <50 copies/mL and had a transient VL elevation between 50 and 200 copies/mL.
- Using the HIV-1 RNA <200 copies/mL sensitivity threshold, 93.1% of participants (108/116; 95% CI: 86.9–97.0%) achieved virologic suppression (Figure 3).
- Confirmed virological failure was recorded in only 5 (4.3%) participants (95% CI: 1.4–9.8%), with no treatment-emergent resistance to DTG or 3TC.

Figure 3. Virologic Outcomes at Week 52



*Virologic failure was defined as two consecutive HIV-1 RNA viral loads levels ≥200 copies/mL after suppression to <50 copies/mL.

Figure 4. Virologic Suppression (<200 copies/mL) at Week 52 Stratified by Baseline HIV-1 RNA and CD4+ Cell Count (N=116)

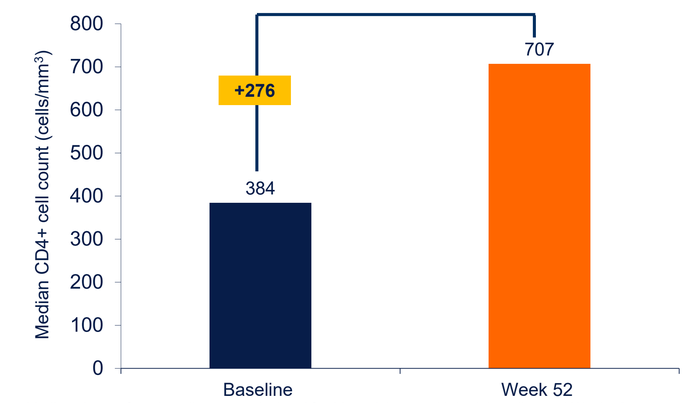


- High rates of virologic suppression (HIV-1 RNA <200 copies/mL) were achieved regardless of baseline VL and CD4+ cell count subgroups (Figure 4).

Immunological Outcomes at Week 52

- Median increase in CD4+ counts of 276 cells/mm³ from baseline through Week 52 (Figure 5).

Figure 5. Change from Baseline in CD4+ Cell Count Through Week 52 (N=93)



Median change from baseline was calculated for 93 participants with both baseline and Week 52 measurements available.

Treatment Persistence and Safety

- By Week 52, treatment discontinuation occurred in only 3 (2.6%) participants due to non-virologic reasons (weight gain, pregnancy, or participant's decision).
- Kaplan-Meier analysis showed a 97.4% probability of remaining on treatment at Week 52 (95% CI: 92.6–99.5%).
- Mean eGFR decreased by 9.95 mL/min/1.73 m², representing a modest renal change consistent with the known pharmacology of dolutegravir and its benign inhibition of tubular creatinine secretion.
- Clinically significant declines in renal function were uncommon, with eGFR reductions of ≥30% and ≥40% observed in only 4 (3.4%) and 2 (1.7%) participants, respectively.

Conclusions

- Rapid initiation of DTG/3TC demonstrated high levels of virologic suppression in treatment-naïve people living with HIV in Kuwait.
- Low rates of confirmed virologic failure were observed, with no treatment-emergent resistance and substantial immunologic recovery through Week 52.
- DTG/3TC was well tolerated, with high treatment persistence and low discontinuation rate.
- These findings reinforce DTG/3TC as an effective and practical option for rapid ART initiation in routine clinical practice.

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Abbreviations: ART, antiretroviral therapy; CD4+, cluster of differentiation 4; CI, confidence interval; DTG/3TC, Dolutegravir/Lamivudine; eGFR, estimated glomerular filtration rate; HBV, hepatitis B virus; HIV, human immunodeficiency virus; IQR, interquartile range; RNA, ribonucleic acid; VL, viral load.

References: 1. Bacon et al. *Clin Infect Dis.* 2021;73(1):e122-e128. **2.** Bacon et al. *Am J Prev Med.* 2021;61(5 Suppl 1):S47-S54. **3.** Rosen et al. *PLoS Med.* 2016;13(5):e1002015. Erratum in: *PLoS Med.* 2016;13(6):e1002050. **4.** Koenig et al. *PLoS Med.* 2017;14(7):e1002357.

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