Real-world Effectiveness of DTG + 3TC in People Living With HIV With Previous ART Experience but No Genotype Testing: The "AReTi" Study Results

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Key Takeaways

- **In real-world settings, baseline genotype testing is not always feasible due to logistical or financial constraints**
- **Results from the retrospective AReTi study support the use of DTG/3TC or DTG + 3TC as a switch option for carefully selected people with HIV who are virologically suppressed in clinical settings where genotype testing may not be feasible**

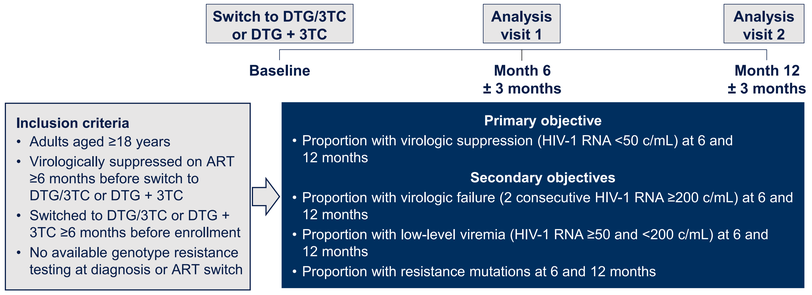
Purpose

- The 2-drug regimen dolutegravir/lamivudine (DTG/3TC) is recommended for people with HIV-1 both naive to antiretroviral therapy (ART) and with previous ART experience[1]
- Despite extensive data supporting the efficacy of DTG/3TC,[2,3] additional data are needed in settings where baseline genotype resistance testing is limited or unavailable
- From 2015 to 2021, genotype testing and viral load (VL) measurements were inconsistently conducted in Greece due to logistical and financial reasons
- In the AReTi study, we retrospectively evaluated the real-world effectiveness of DTG/3TC in people with HIV in Greece who had previous ART experience and no baseline genotype resistance testing at diagnosis and/or ART switch

Methods

- The retrospective AReTi study included people with HIV aged ≥18 years who were virologically suppressed and on ART for ≥6 months before switching to single-tablet, fixed-dose combination DTG/3TC or DTG + 3TC as 2 separate tablets (Figure 1)
- Participants did not have genotype resistance testing available at diagnosis or ART switch

Figure 1. AReTi Study Design



- Participants were recruited from 3 HIV centers in Greece that were treating almost 40% of all people with HIV in the country and lacked access to genotype testing at the time of diagnosis and/or ART switch
- The primary objective was to assess the proportion of people with HIV who were virologically suppressed (HIV-1 RNA <50 c/mL, Snapshot algorithm) at 6 ± 3 months and 12 ± 3 months after switch to DTG/3TC or DTG + 3TC
- Data collected between February 19, 2024, and December 24, 2024, during routine clinical practice, including complete medical and ART history, demographics, comorbidities, laboratory blood test results, and reason for ART switch, were obtained from clinical records
- All data were summarized descriptively
- In a supplementary analysis, least squares mean change in serum lipids after ART switch was estimated using mixed-effects model for repeated measurements

Results

Demographics and Baseline Characteristics

- The AReTi study included 141 people with HIV, 88% of whom were male; median (IQR) age was 51 (43-59) years, and median (IQR) ART duration was 10 (6-16) years (Table 1)
  - The most commonly used ART regimen before switch to DTG/3TC or DTG + 3TC was DTG/ABC/3TC (33% [46/141])
  - 48% (68/141) used ART regimens consisting of an INSTI + 2 NRTIs before switch
  - The majority of participants (69% [97/141]) had at least 1 comorbidity at baseline, with dyslipidemia being the most common (50% [70/141])

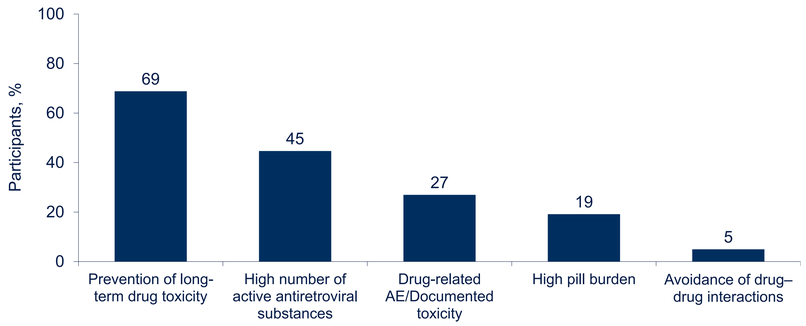
Table 1. Demographics and Baseline Characteristics

Parameter	AReTi study population (N=141)
Sex, male, n (%)	124 (88)
Age, median (IQR), years	51 (43-59)
Time from ART initiation to switch, median (IQR), years	10 (6-16)
ART regimen before switch, n (%)[a]	
INSTI + 2 NRTIs	68 (48)
INSTI + 2 NRTIs + pharmacokinetic boosters	26 (18)
NNRTI + 2 NRTIs	25 (18)
PI + 2 NRTIs + pharmacokinetic boosters	12 (9)
2 PIs + 2 NRTIs	6 (4)
INSTI + NRTI	1 (<1)
2 PIs + NNRTI + 2 NRTIs	1 (<1)
NNRTI + 2 NRTIs + pharmacokinetic boosters	1 (<1)
INSTI + 2 NRTIs + PI + pharmacokinetic boosters	1 (<1)
Past virologic failure(s) (2 consecutive HIV-1 RNA ≥200 c/mL) with no genotype resistance testing, n (%)	3 (2)
At least 1 comorbidity, n (%)	97 (69)
Most common comorbidities, n (%)	
Dyslipidemia	70 (50)
Hypertension	24 (17)
Depression	11 (8)
Asthma	11 (8)

ABC, abacavir; c, cobicistat; DRV, darunavir; EFV, efavirenz; EVG, elvitegravir; FTC, emtricitabine; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; NVP, nevirapine; PI, protease inhibitor; r, ritonavir; RAL, raltegravir; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; XTC, 3TC or FTC. [a]ART regimens before switch included DTG/ABC/3TC, EVG/c/TAF/FTC, DTG + TDF/XTC, NVP/ABC/3TC, EFV + TDF/FTC, DTG + TAF/FTC, DRV/c/TAF/FTC, RAL + TDF/XTC, RPV/TDF/FTC, EVG/c/TDF/FTC, DRV/c + TDF/XTC, DRV/c + ABC/3TC, NVP + TDF/FTC, RPV + TAF/FTC, and DRV/r + ABC/3TC.

- The main reasons for switching to DTG/3TC or DTG + 3TC were prevention of long-term drug toxicity (69% [97/141]) and high number of active antiretroviral substances (45% [63/141]; Figure 2)

Figure 2. Reasons for Switching to DTG/3TC or DTG + 3TC



Categories are not mutually exclusive. AE, adverse event.

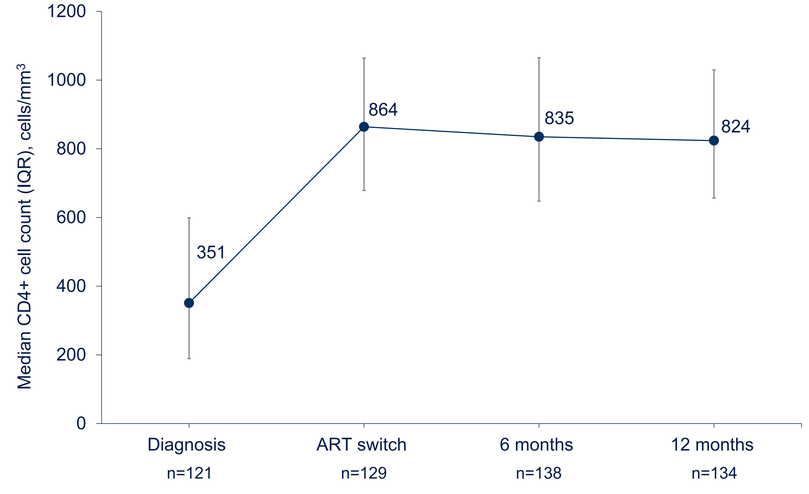
- 97% (134/138) of participants maintained virologic suppression at 6 months after switch to DTG/3TC or DTG + 3TC and 96% (130/135) maintained suppression at 12 months (Table 2)

Table 2. Virologic Outcomes (Snapshot Algorithm) in Participants With Available Data at Each Analysis Visit

Snapshot response, n (%)	At 6 ± 3 months (N=138)	At 12 ± 3 months (N=135)
Yes (HIV-1 RNA <50 c/mL)	134 (97)	130 (96)
No	4 (3)	5 (4)
HIV-1 RNA ≥50 c/mL	3 (2)	4 (3)
No virologic data	1 (<1)	1 (<1)

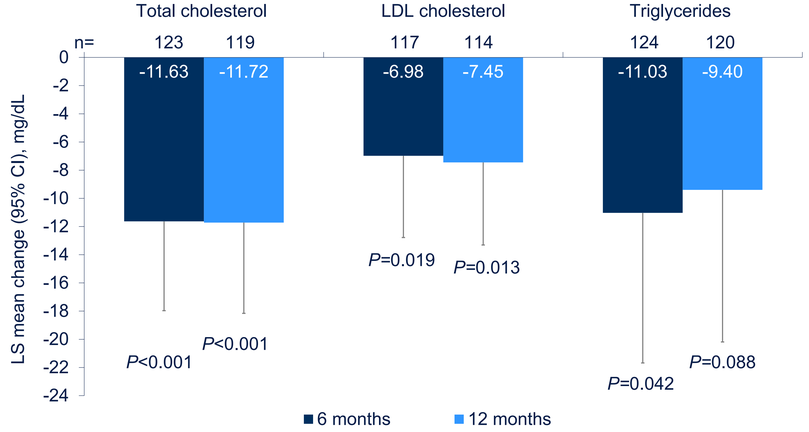
- No virologic failures (2 consecutive HIV-1 RNA ≥200 c/mL) occurred
- 7 individuals had viral blips (VL ≤100 c/mL) at 6 and 12 months
  - VLs decreased to <50 c/mL in 4 individuals; no subsequent tests were performed during the study period for the remaining 3 individuals
- Median CD4+ cell count remained stable at 6 and 12 months after ART switch (Figure 3)

Figure 3. CD4+ Cell Count at Key Time Points



- Serum levels of total cholesterol, low-density-lipoprotein cholesterol, and triglycerides decreased at 6 and 12 months after ART switch compared with baseline values (Figure 4)

Figure 4. Least Squares Mean Change From ART Switch in Serum Lipids at 6 and 12 Months After ART Switch



Estimated based on MMRM. LDL, low-density-lipoprotein; LS, least squares; MMRM, mixed-effects model for repeated measurements.

- No adverse events or serious adverse events were reported within 12 months after ART switch

Conclusions

- In real-world settings, logistical or financial constraints can limit access to baseline genotype testing
- In the AReTi study, we evaluated the effectiveness of DTG/3TC or DTG + 3TC in people with HIV who had previous ART experience but no resistance testing at the time of diagnosis or ART switch in routine clinical care in Greece
- 12 months after switch to DTG/3TC or DTG + 3TC, 96% of people maintained virologic suppression, there were no virologic failures, CD4+ cell count remained stable, and serum lipids decreased; no adverse events were reported
- In people with HIV who are virologically suppressed without available genotype resistance testing at diagnosis or ART switch in Greece, switching to DTG/3TC or DTG + 3TC was well tolerated and effective for maintenance of virologic suppression over 12 months

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References: 1. Panel on Antiretroviral Guidelines for Adults and Adolescents. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed August 18, 2025. **2.** Osiyemi et al. *Clin Infect Dis*. 2022;75:975-986. **3.** Llibre et al. *Clin Infect Dis*. 2023;76:720-729.

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