

Switch for a Long-Term Success

OC 68

Clinical outcomes in PWH switching from oral combinations with dolutegravir (DTG) + lamivudine (3TC) or rilpivirine (RPV) to bicitegravir/emtricitabine/tenofovir alafenamide (B/F/TAF): data from the Italian ICONA Foundation Cohort (OPTIMIZE-BIC Analysis)

Authors

A. De Vito¹, A. Tavelli^{2,3}, A. Giacomelli^{4,5}, V. Mazzotta⁶, G. Orofino⁷, R. Serraino⁸, R. Marocco⁹, R. Rossotti¹⁰, S. Nozza¹¹, L. Albinì¹², G. Forcina¹², A. Vergori¹³, A. Di Biagio^{14,15}, A. d'Arminio Monforte², G. Madeddu¹

Affiliation

¹Unit of Infectious Diseases, Department of Medicine, Surgery and Pharmacy, University of Sassari, Sassari, Italy, ²Fondazione ICONA, Milan, Italy, ³National PhD Programme in One Health Approaches to Infectious Diseases and Life Science Research, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy, ⁴Department of Infectious Diseases, Luigi Sacco University Hospital, ASST Fatebenefratelli Sacco, Milan, Italy, ⁵Department of Biomedical and Clinical Sciences, University of Milan, Milan, Italy, ⁶U.O.C. Immunodeficienze Virali e IST, INMI "L. Spallanzani" IRCCS – Roma, Italy, ⁷Unit of Infectious Diseases, "Divisione A", ASL "Città di Torino", Torino, Italy, ⁸Dipartimento di Sicurezza e Bioetica - Sezione di Malattie Infettive, Università Cattolica del Sacro Cuore, Rome, Italy, ⁹Infectious Diseases Unit, SM Goretti Hospital, Latina, Italy, ¹⁰S.C. Malattie Infettive – ASST Grande Ospedale Metropolitano Niguarda – Milano, Italy, ¹¹Clinica Malattie Infettive - Ospedale San Raffaele, Università Vita-Salute – Milano, Italy, ¹²Gilead Sciences Srl, Italy, ¹³Infectious Diseases Unit, Department of Medical and Surgical Sciences, University of Foggia, Foggia, Italy, ¹⁴Department of Health Sciences, University of Genoa, Genoa, Italy, ¹⁵Infectious Disease Unit, IRCCS Ospedale Policlinico San Martino, Genoa, Italy

ABSTRACT

Background: Data on the effectiveness and durability of B/F/TAF in people with HIV (PWH) switching from DTG-based two-drug oral regimens (2DR) are limited. We aimed to characterize treatment-experienced PWH switching from DTG-based 2DR to B/F/TAF and to evaluate virological, immunological, and metabolic outcomes.

Methods: OPTIMIZE-BIC (GS-IT-380-7670) is a retrospective analysis including PWH from the ICONA cohort who switched from DTG+3TC or DTG+RPV (single- or multi-tablet regimens) to B/F/TAF, between Jul-2019 and Apr-2025, regardless of HIV-RNA at switch. We included only PWH with ≥ 1 HIV-RNA measurement post-switch. Participants were stratified by HIV-RNA at switch: < 50 copies/ml (uVL) or ≥ 50 copies/ml (dVL). The primary endpoint was virological suppression (HIV-RNA < 50 copies/ml) at the last follow-up. Secondary endpoints included time to: -virological failure (VF, 2 consecutive HIV-RNA > 50 or single > 1000 copies/ml followed by ART-change) among uVL; -virological suppression (VS) among dVL; -treatment discontinuation (TD) for any reason and for toxicity. Changes in CD4 count, CD4/CD8 ratio, liver enzymes, and lipid profile were assessed. Kaplan–Meier methods and

mixed linear regression models were used.

Results: Eighty-three PWH were included; median age 48 years (IQR 38–58), 69.9% male, and median ART exposure of 7.7 years (IQR 3.6–11.4). At switch, 47 (56.6%) were in the uVL group and 36 (43.4%) in the dVL group (Table 1). After a median follow-up of 1.4 years (IQR 0.6–2.6), overall 74/83 PWH (89.2%, 95%CI 80.4–94.9) had HIV-RNA <50 copies/mL at last observation.

In the dVL group, 83.3% (95%CI 67.2–93.6) had HIV-RNA <50 cps/ml at last assessment. Median time to suppression was 3.5 months (95%CI 2.8–5.3), with 81.8% (95%CI 67.2–92.6) of PWH reaching VS by 1-year (Figure 1A).

In the uVL group, HIV-RNA was <50 cps/ml at last measurement in 93.6% (95%CI 82.5–98.7). Only 1 VF occurred with a probability of 3.1% at 1 year (95%CI 0.45–20.2, Figure 1B).

17 PWH discontinued B/F/TAF during follow-up. The cumulative probability of TD for any reason was 10.1% (95% CI 5.0–20.2, Figure 1C) at 1 year, with no significant differences between dVL and uVL (p=0.498). Discontinuations were mainly driven by treatment simplification (n=7, 6.4%), lack of virological control (n=3, 3.6%) and toxicity (n=3, 3.6%). At 1-year the probability of TD for toxicity was 3.2% (95%CI 0.8–11.6, Figure 1D).

The CD4/CD8 ratio significantly increased in both groups. Among dVL, CD4 counts increased significantly at 12 months (Figure 2). Liver enzymes and lipid parameters remained stable, with a modest increase in HDL cholesterol (Figure 3).

Conclusions: In this real-world cohort, switching from DTG-based 2DR to B/F/TAF resulted in high rates of virological suppression, rapid viral control in viremic PWH, low virological failure, and good treatment durability, with favorable immunological trends and a neutral metabolic profile.

Table 1. Baseline epidemiological and clinical characteristics.

Variables	People with HIV (n=83)
Age (years), median (IQR)	48.0 (38.0–58.0)
<40 years, (%)	23 (27.7%)
40–49 years, (%)	23 (27.7%)
50–64 years, (%)	20 (24.1%)
≥65 years, (%)	17 (20.5%)
Assigned male at birth, n(%)	58 (69.9%)
Assigned female at birth, n(%)	25 (30.1%)
Risk factors for HIV transmission	
Heterosexual intercourse, n (%)	38 (45.8%)
IDU, n (%)	7 (8.4%)
MSM, n (%)	34 (41.0%)
Other/Unknown, n (%)	4 (4.8%)
Italian nationality, n (%)	67 (80.7%)
Education, n (%)	
High school or University, n (%)	32 (38.6%)
Primary or Middle education, n (%)	22 (26.5%)
Unknown, n (%)	29 (34.9%)
Employment status, Unemployed	10 (12.0%)
HIV-RNA zenith (log ₁₀), median (IQR)	4.9 (4.4–5.4)
Nadir CD4 (cells/mL), median (IQR)	311.0 (149.0–444.0)
<200 (cells/mL), n(%)	23 (27.7%)
200–350 (cells/mL), n(%)	24 (28.9%)
350–500 (cells/mL), n(%)	19 (22.9%)
>500 (cells/mL), n(%)	15 (18.1%)
missing	2 (2.4%)
AIDS, n(%)	12 (14.5%)
Years living with HIV, median (IQR)	8.2 (4.4–13.3)
Years on ART, median (IQR)	7.7 (3.6–11.4)
Previous number of regimens, median (IQR)	4.0 (3.0–6.0)
Previous treatment, n(%)	
3TC/DTG	72 (86.7%)
RPV/DTG	11 (13.3%)
Years of TAF/FTC/BIC starting, median (IQR)	2022 (2021–2024)
HIV-RNA at BIC/FTC/TAF start, n(%)	
Detectable	36 (43.4%)
Undetectable	47 (56.6%)
CD4 cells/mL at TAF/FTC/BIC start, median (IQR)	692.0 (530.0–866.0)

Figure 1. Kaplan–Meier estimates of the cumulative probability of (A) achieving HIV-RNA <50 copies/mL among dVL group, (B) having a VF among uVL group, (C) treatment discontinuation for any cause, and (D) for toxicity/AEs

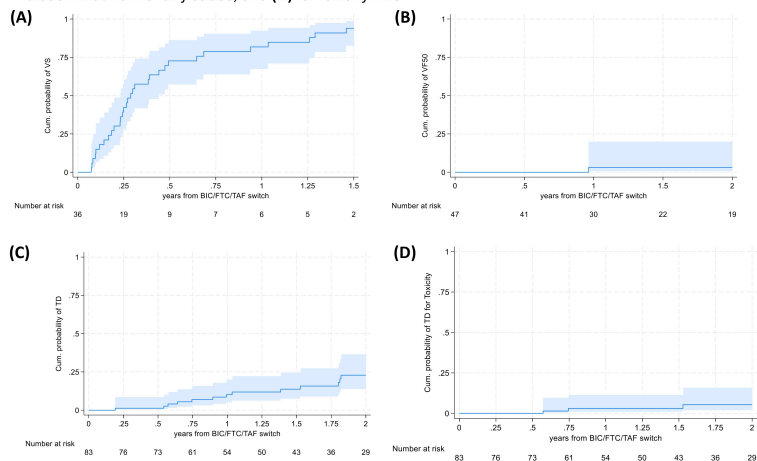


Figure 2. Mean change from baseline in CD4 cell count and CD4/CD8 ratio (A) among PWH viremic at baseline (dVL) and (B) among PWH with undetectable HIV-RNA at baseline (uVL).

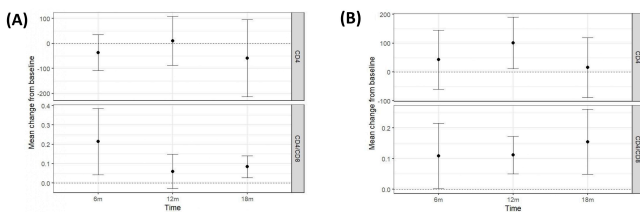


Figure 3. Mean change from baseline in (A) liver enzymes and (B) lipids. Lipid analyses are adjusted for initiation of lipid-lowering drugs.

