

# DTG/3TC AS INITIAL THERAPY IN PEOPLE LIVING WITH HIV AND VIRAL LOAD >500,000 COPIES/ML

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**Background:** The effectiveness of initial antiretroviral therapy (ART) with DTG/3TC in people living with HIV (PLWH) with HIV viral load (HIV-VL)  $\geq 500,000$  copies/ml is not well established. This study aims to compare the effectiveness of DTG/3TC versus BIC/F/TAF at 24 weeks in ART-naïve PLWH with HIV-VL  $\geq 500,000$ . Additionally, the study assesses immune recovery and safety profiles.

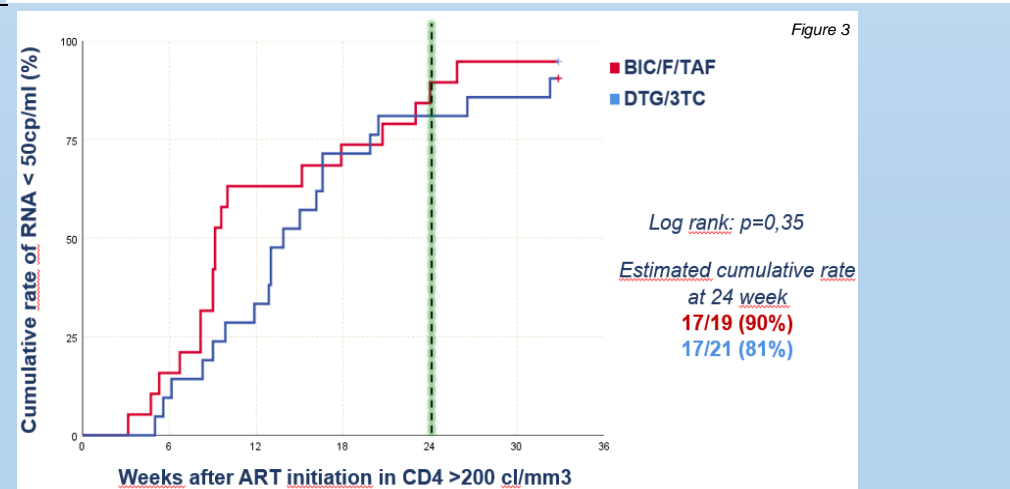
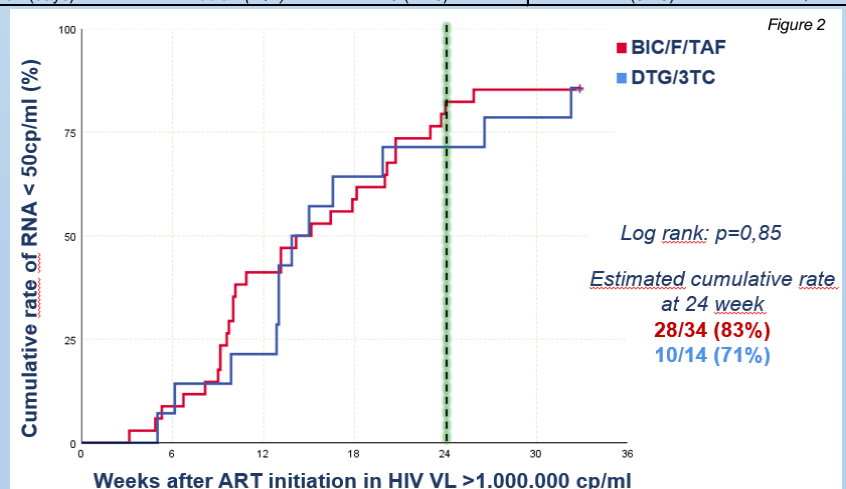
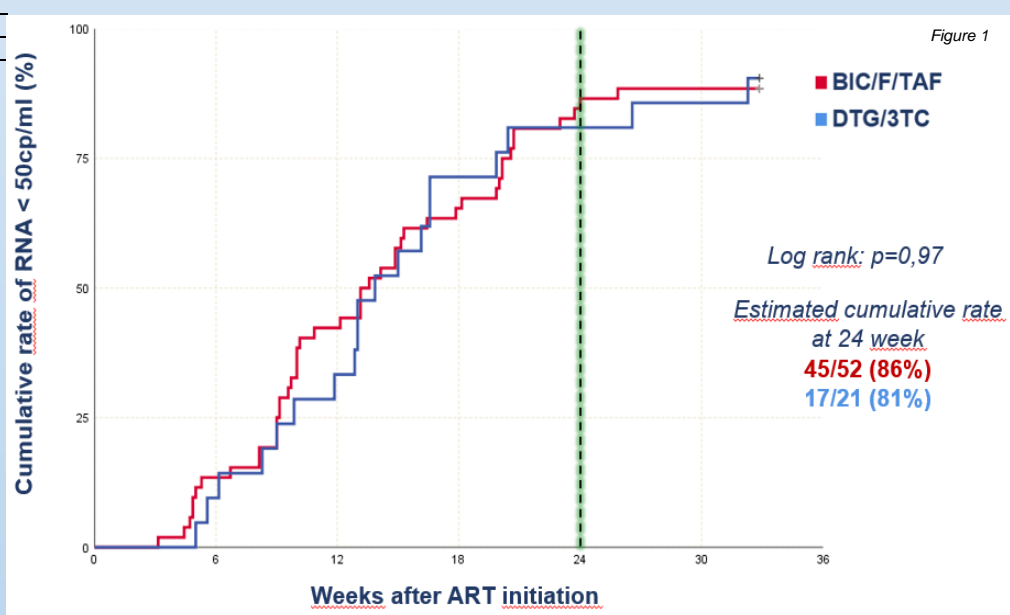
**Materials and methods:** This single-center retrospective cohort study included all PLWH with HIV-VL  $\geq 500,000$  copies/ml initiating ART with either DTG/3TC or BIC/F/TAF from 1/2019 to 1/2024 in a monographic HIV unit. We conducted descriptive and bivariate comparative analyses to evaluate treatment effectiveness (HIV-VL  $< 50$  copies/ml 24 weeks, ITT M=F), immune recovery (CD4 count), and safety profiles (weight, lipid profile, and creatinine levels). A time-to-event analysis was performed using Kaplan-Meier curves and log-rank tests.

**Results:** A total of 73 patients (29% on DTG/3TC and 71% on BIC/F/TAF) were included. No baseline differences were observed between groups, except for CDC stage and immunological status. Detailed participant characteristics are provided in Table 1.

The median time to reach undetectability was 91 days (IQR 64-116) for DTG/3TC and 88 days (IQR 63-130) for BIC/F/TAF.

No ART discontinuations were observed in any of the therapeutic strategies. No significant differences in effectiveness were observed at 24 week (Figure 1) Nor in subgroups with VL  $> 10^6$  cp/ml or CD4  $> 200$  (Figures 2,3).

	DTG/3TC (n=21)	BIC/F/TAF (n=52)	
		n (%)	p
Age at diagnosis (yr)	median (IQR)	31 (26-35)	0,3
Sex at birth			1
Male	20 (95%)	48 (92%)	
Female	1 (5%)	4 (8%)	
Gender identity			1
Cisgender	21 (100%)	51 (98%)	
Transgender	0	1 (2%)	
Risk factor			0,07
MSW	3 (14%)	18 (35%)	
MSM	18 (86%)	33 (65%)	
Native-born Spaniards	9 (43%)	20 (38%)	0,5
Weight (Kg)	median (IQR)	71 (64-77)	0,3
Comorbidities			
Arterial Hypertension	2 (9%)	5 (10%)	1
Diabetes mellitus	0	3 (6%)	0,5
Dyslipidaemia	0	9 (17%)	0,06
Smoking	8 (38%)	20 (38%)	0,3
AIDS	0	34 (65%)	<0,001
Immunovirological status			
HIV- VL baseline(cp/ml)	median (IQR)	1156000 (813000- 7700000)	0,9
HIV-VL (log)	median (IQR)	6,1 (5,9 - 6,9)	0,9
HIV-VL baseline $\geq 1.000.000$ cp/ml	14 (67%)	34 (65%)	0,9
CD4 baseline (cel/mm <sup>3</sup> )	median (IQR)	320 (273-424)	<0,001
Time to ART initiation (days)	median (IQR)	10 (4-16)	0,5



Sub-analysis including only patients who initiated ART with CD4  $> 200$  cells/mm<sup>3</sup>, immune recovery was independent of the ART regimen recovery (median increase of CD4 were 285 cells/mm<sup>3</sup> [IQR 188-527] and 187 cells/mm<sup>3</sup> [IQR 52-320] for DTG/3TC and BIC/F/TAF respectively; p=0.4).

Both therapies demonstrated a good safety profile, with no significant differences in weight gain, lipid profile, or creatinine levels.

**Conclusions:** In PLWH initiating ART with HIV-VL  $\geq 500,000$  copies/ml, DTG/3TC and BIC/F/TAF showed similar effectiveness and safety profiles at 24 weeks.