

# HIGH RATES OF VIROLOGICAL SUPPRESSION AFTER 24 WEEKS OF TENOFOVIR ALAFENAMIDE/EMTRICITABINE/BICTEGRAVIR (BIC/FTC/TAF) IN PEOPLE LIVING WITH HIV (PLH) STARTING ANTIRETROVIRAL THERAPY WITH <200 CD4 CELL COUNT

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## BACKGROUND

- Approximately 28% of newly diagnosed people with HIV (PWH) in Spain in 2020 have advanced HIV infection (CD4 <200 cel/mm<sup>3</sup> at diagnosis). There is limited of evidence regarding the effectiveness of BIC/FTC/TAF in PLH starting ART with a CD4 cell count <200 cells/mm<sup>3</sup> (CD4<200) or previous AIDS diagnosis.
- The aim of this study is to evaluate the rate of Viral Suppression (HIV-RNA <50 cop/mL) at week 24 with BIC/FTC/TAF treatment in PLH naïve and advanced HIV infection.

## MATERIAL AND METHODS

- Retrospective analysis performed to evaluate the rate of virological suppression (VS) after 24 weeks of BIC/FTC/TAF in PLH with severe immunodepression.
- Study population:** All the participants with CD4<200 or a previous diagnosis of AIDS, enrolled in a multicenter, prospective, Spanish HIV Cohort (CORIS), who started therapy with BIC/FTC/TAF (2019-2020) and with at least 24 weeks of follow up, were included and allocated in two groups based on their initial ART regimen: BIC/FTC/TAF vs. other regimens.
- Outcomes (24 Weeks after ART initiation):**
  - Our primary objective was to evaluate the rate of VS (HIV-RNA <50 cop/mL) at week 24 with BIC/FTC/TAF.
  - As secondary objectives we compared the rates of VS in both study groups, using chi-square, and we assessed factors associated with achieving VS at week 24 using logistic regression.

## RESULTS

Between 2019-2020, **232** CORIS participants started ART; 95 (41%) with BIC/FTC/TAF and 137 (59%) with other regimens. **Baseline characteristics** (table 1) were similar between groups.

After **24 weeks** of therapy, **73.7%** of the participants starting BIC/FTC/TAF achieved VS versus **59.9%** of the participants starting other regimens (Primary outcome) (Figure 1).

The probability of achieving VS at week 24 was **1.9 times higher** with BIC/FTC/TAF than with other regimens (95% confidence interval [CI]( **1.1 – 3.3**). (Secondary outcome) (Table 2).

**Factors independently associated** with achieving VS at week 24 were being on BIC/FTC/TAF (Odds ratio [OR]: 2.2 [95%CI: 1.1 – 4.2]) and HIV-RNA >100.000 cop/mL at baseline (OR: 0.2 [95%CI: 0.1 – 0.3]). (Table 2)

TABLE 1: BASELINE CHARACTERISTICS AT ART INITIATION (N=232)

Baseline characteristics	BIC/FTC/TAF (n=95)	Other ART options (n=137)	P Value
<b>Gender, n (%)</b>			
Men	83 (87.4)	116 (84.6)	0.563
Women	12 (12.6)	21 (15.3)	
<b>Age (yrs.), median (IQR)</b>	39.9 (31.7-48.1)	39.6 (32.8 – 49.0)	0.532
<b>Way of transmission, n (%)</b>			
Homosexual	52 (54.7)	76 (55.5)	0.088
Heterosexual	39 (41.1)	43 (31.4)	
Intravenous drug use	1 (1)	2 (1.4)	
Unknown	3 (3.2)	16 (11.7)	
<b>Country of born, n (%)</b>			
Spain	45 (47.4)	67 (48.9)	0.867
Other	50 (52.6)	70 (51.1)	
<b>AIDS diagnosis, n (%)</b>	35 (36.8)	49 (35.8)	0.867
<b>CD4 nadir, median (IQR)</b>	103 (53-162)	92 (47-167)	0.566
<b>CD4 nadir &lt;50 cel/mm<sup>3</sup>, n (%)</b>	22 (23.2)	33 (24.1)	0.142
<b>HIV RNA &gt;10<sup>5</sup> cop/mL</b>	61 (64.2)	85 (62.0)	0.639

FIGURE 1: OUTCOME VIRAL SUPPRESSION 24W IN BOTH REGIMENS (n=232)

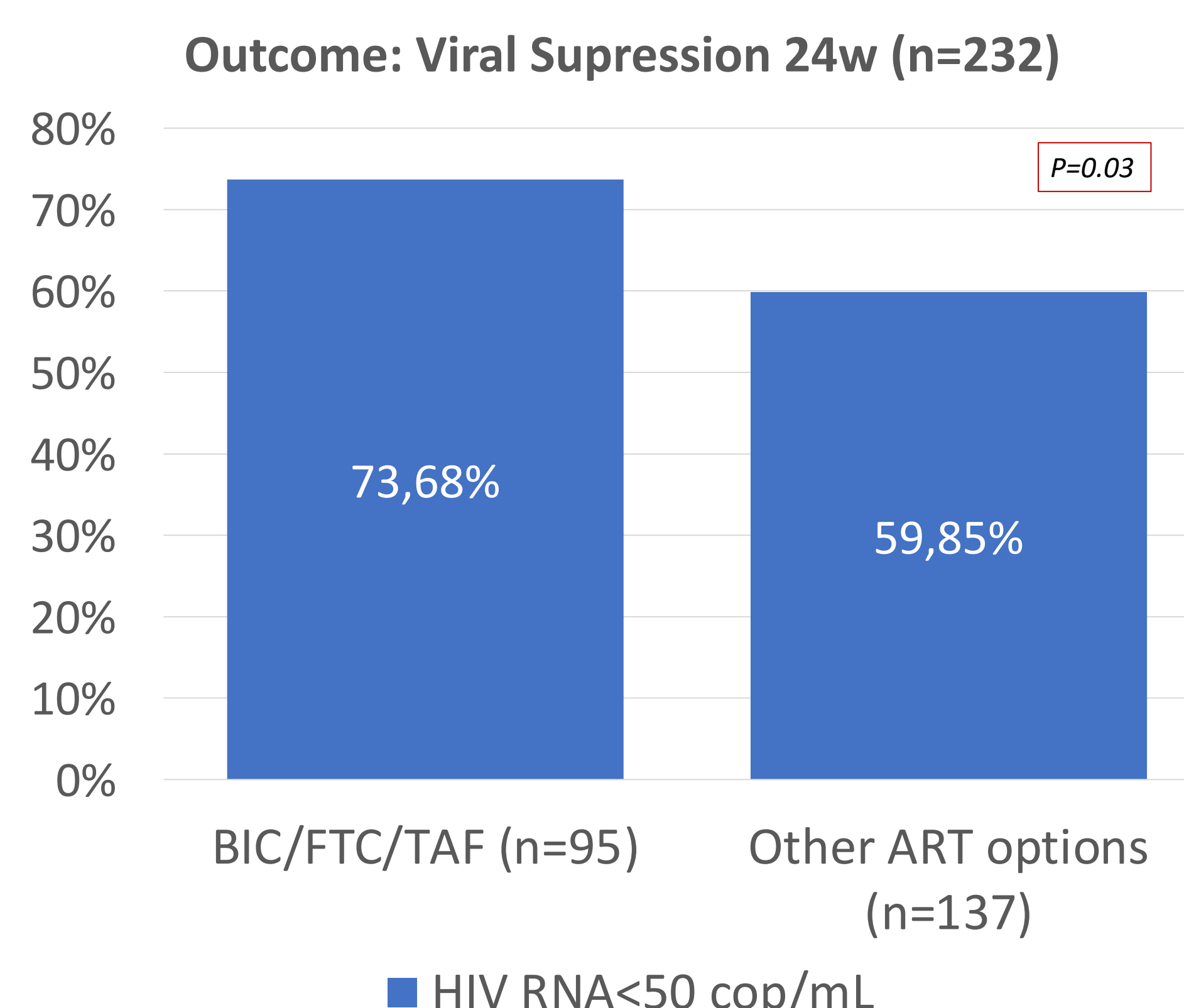


TABLE 2: FACTORS INDEPENDENTLY ASSOCIATED WITH ARCHIEVING VS AT 24 W (N=232)

FACTOR	P adjusted	OR adjusted (IC95%)
<b>ART</b>		
Other ART options		1 (ref.)
<b>BIC/FTC/TAF</b>	<b>0.02</b>	<b>2.18 (1.14-4.12)</b>
<b>Gender</b>		
Men		1 (ref.)
Women	0.89	0.94 (0.32-2.68)
<b>Age</b>		
<30		1(ref.)
30-49	0.57	1.28 (0.55-2.97)
>=50	0.24	1.89 (0.65-5.52)
<b>Way of transmission</b>		
Homosexual		1 (ref.)
Heterosexual	0.64	1.22 (0.53-2.78)
Other/unknown	0.09	2.75 (0.85-8.95)
<b>Country of born</b>		
Spain		1(ref.)
Other	0.05	1.91 (1.01-3.67)
<b>Educational level</b>		
Basic		1 (ref.)
Secondary or superior	0.18	1.94 (0.74-5.11)
Unknown	0.75	1.18 (0.42-3.24)
<b>AIDS diagnosis</b>	0.53	1.25 (0.62-2.52)
<b>CD4 nadir &gt;50 cel/mm<sup>3</sup></b>	0.54	1.26 (0.61-2.64)
<b>HIV RNA&gt;100.000 cop/ml</b>	<b>&lt;0.001</b>	<b>0.15 (0.07-0.34)</b>

## CONCLUSION

In the CORIS cohort, starting ART with BIC/FTC/TAF in PLH with severe immunodepression was associated with high rates of effectiveness at week 24.

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