Comparative effectiveness of BIC/FTC/TAF versus other ART regimens in patients with AIDS-defining conditions: virological suppression and immunological recovery at 24 and 48 weeks in the ACTUAS II study

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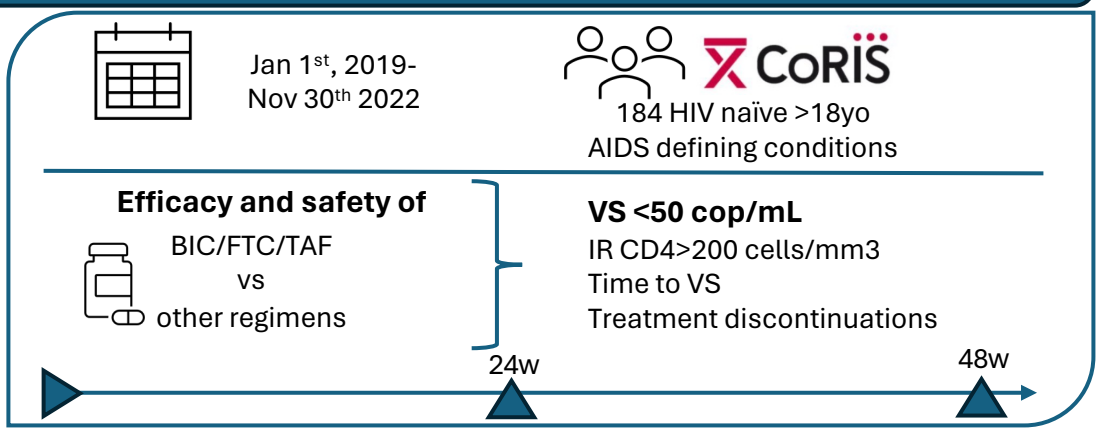
Background

The comparative efficacy and safety of BIC/FTC/TAF has not been sufficiently evaluated in PWH with AIDS-defining conditions who initiate therapy.

Methods

The aim of the current study was to compare the effectiveness and tolerability of BIC/FTC/TAF with other first-line antiretroviral therapies, in treatment-naïve adults from the CoRIS Cohort who starte ART with AIDS-defining conditions. Logistic regression models were used to estimate odds ratios (ORs) of association between initial regimen and achievement of viral suppression (VS), defined as HIV RNA <50 cop/mL (primary objective), and immunological recovery (IR), defined as CD4 count >200 cells/mm3, time to VS and treatment discontinuations (secondary objectives), all at weeks 24 and 48 after initiation of ART.



Results

We included 90 individuals starting ART with BIC/FTC/TAF and 94 with other regimens. Baseline characteristic were similar between them (Table 1). Viral suppression and immune recovery analyses are presented in Table 2. At week 24, BIC/FTC/TAF was associated with higher rates of VS (75.6% vs. 56.5% aOR: 2.78; 95%CI: 1.28 – 6.25) and with lower rates of IR (47.7% vs. 61.9%, aOR: 0.49; 95%CI: 0.25 – 0.99). These differences disappeared at week 48. Rates of treatment discontinuation were significantly lower with BIC/FTC/TAF than with other regimens (week 24: 4.4% vs. 21.6%. Week 48: 10% vs. 36.2%).

Table 1

	People with HIV and AIDS N = 184		
	BIC/FTC/TAF N = 90	Other regimens N = 94	p-value
Sex [N (%)]			0.931
Male	77 (85.6)	80 (85.1)	
Female	13 (14.4)	14 (14.9)	
Age, years [N (%)]			
Median (IQR)	42 (35 – 54)	43 (35 – 53)	0.633
<30	10 (11.1)	13 (13.8)	0.778
30-49	53 (58.9)	51 (54.3)	
≥50	27 (30.0)	30 (31.9)	
Transmission category [N (%)]			0.083
Men who have sex with men	53 (58.9)	43 (45.7)	
Heterosexual	30 (33.3)	35 (37.2)	
Intravenous drug users	2 (2.2)	1 (1.1)	
Other/Unknown	5 (5.6)	15 (16.0)	
Country of origin [N (%)]			0.203
Spain	55 (61.1)	48 (51.1)	
No Spain	34 (37.8)	46 (48.9)	
Unknown	1 (1.1)	0	
Educational level [N (%)]			0.108
No/compulsory education	12 (13.3)	13 (13.8)	
Upper secondary/university	55 (61.1)	44 (46.8)	
Unknown	23 (25.6)	37 (39.4)	
CD4 count, cells/⍰L [N (%)]			
Median (IQR)	58 (26 – 153)	78 (29 – 207)	0.230
<50	33 (36.7)	28 (29.8)	0.553
≥50	41 (45.6)	45 (47.9)	
Unknown	16 (17.8)	21 (22.3)	
Viral load, copies/mL [N (%)]			
Median (IQR)	364,857 (116,000– 1,065,259)	347,406 (113,000 – 775,000)	0.572
<100,000	17 (18.9)	17 (18.1)	0.785
≥100,000	61 (67.8)	61 (64.9)	
Unknown	12 (13.3)	16 (17.0)	

Viral suppression and IR at 24 and 48 weeks from ART initiation.

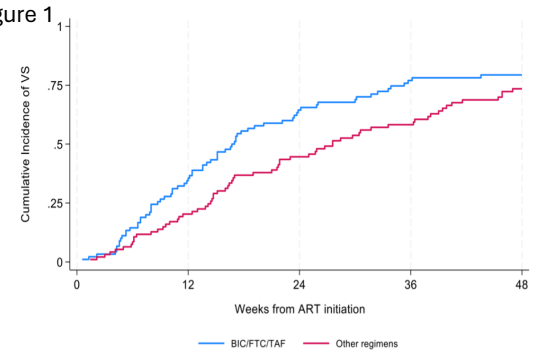
Table 2

	24 weeks			48 weeks		
	No./No. with data (%)[1]	Crude OR (95% CI)	Adjusted OR (95% CI)[2]	No./No. with data (%)[1]	Crude OR (95% CI)	Adjusted OR (95% CI)[2]
Viral suppression						
BIC/FTC/TAF	65/86 (75.6)	1.00	1.00	68/78 (87.2)	1.00	1.00
Other regimens	48/85 (56.5)	0.42 (0.20 – 0.89)	0.36 (0.16 – 0.78)	62/76 (81.6)	0.65 (0.30 – 1.42)	0.66 (0.25 – 1.74)
p-value		0.023	0.010		0.283	0.402
Immunological recovery						
BIC/FTC/TAF	41/86 (47.7)	1.00	1.00	54/77 (70.1)	1.00	1.00
Other regimens	52/84 (61.9)	1.78 (0.92 – 3.46)	2.03 (1.01 – 4.05)	62/75 (82.7)	2.03 (0.84 – 4.89)	2.25 (0.79 – 6.42)
p-value		0.087	0.046		0.114	0.130

[1] Number of subjects achieving viral suppression (VS) or immunological recovery (IR), as appropriate / Number of subjects with available data on VS or IR, as appropriate (percentage of subjects achieving VS or IR among those with available data)
[2] Adjusted for sex (male, female), age at ART initiation (<30, 30-49, ≥50 years), transmission category (men who have sex with men [MSM], heterosexual, other/unknown), educational level (no or compulsory education, secondary or university education, unknown), country of origin (Spain, No Spain, unknown), and CD4 cell count (<50, ≥50 cells/⍰L, unknown) and viral load (<100,000, >100,000 copies/mL, unknown) within the 6 months prior to ART initiation.

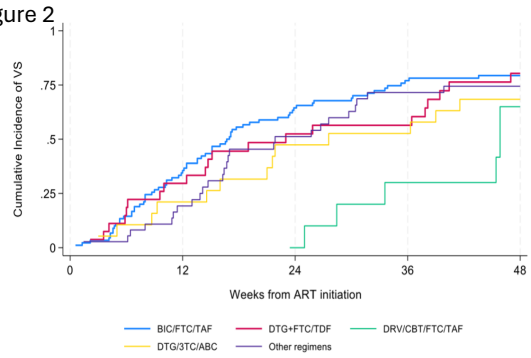
Time to VS during the first 48 weeks after initiation of ART

Figure 1



	BIC/FTC/TAF vs. other ART regimens (pooled)		
	Time to VS [Median (IQR)]	Crude sHR (95% CI)	Adjusted sHR (95% CI)
BIC/FTC/TAF	17 (9 – 35)	1.00	1.00
Other regimens	28 (14 – 48+)	0.70 (0.50 – 0.98)	0.76 (0.52 – 1.10)
p-value		0.040	0.151

Figure 2



	BIC/FTC/TAF vs. other AR regimens (individual regimens)		
	Time to VS [Median (IQR)]	Crude sHR (95% CI)	Adjusted sHR (95% CI)
BIC/FTC/TAF	17 (9 – 35)	1.00	1.00
DTG+FTC/TDF	23 (10 – 40)	0.87 (0.53 – 1.42)	1.09 (0.64 – 1.86)
DRV/COBI/FTC/TAF	46 (34 – 48+)	0.38 (0.20 – 0.70)	0.38 (0.20 – 0.73)
DTG/3TC/ABC	28 (15 – 48+)	0.64 (0.36 – 1.16)	0.61 (0.32 – 1.17)
Other regimens	22 (14 – 48+)	0.77 (0.49 – 1.20)	0.89 (0.54 – 1.44)
p-value		0.031	0.025

Treatment discontinuations during the first 24 and 48 weeks after ART initiation

Table 3	BIC/FTC/TAF N = 90	Other regimens N = 94	p-value*
During the first 24 weeks			
Treatment changes [N (%)]	4 (4.4)	19 (20.2)	0.001
During the first 48 weeks			
Treatment changes [N (%)]	9 (10.0)	34 (36.2)	<0.001

*Difference is primarily attributable to the lower proportion of discontinuations due to adverse events (AEs) (2.2% vs. 8.5%, p=0.06) and toxicity prevention (1.1% vs. 6.4%, p=0.06)

Conclusions

In the light of our results, BIC/FTC/TAF is an effective and safety option for starting ART in people with AIDS-defining conditions.

The CoRIS cohort was approved by the Clinical Research Ethics Committee of Gregorio Marañón General University Hospital. All patients consented to participate in CoRIS by signing an informed consent form. This study was approved by the Comité de Ética de la Investigación Provincial de Córdoba.