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Original article

BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE FIXED-DOSE COMBINATION IN ADVANCED HIV DISEASE

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Abstract

Introduction: Real-world data on bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) showed high virologic suppression (VS) in treatment-naive (TN) and experienced (TE) people living with HIV (PLWH). The BIC-CD4 study aims to describe safety, persistence, and VS in PLWH who started B/F/TAF with CD4 <200/mm^3, representing advanced HIV disease (AHD).

Materials and methods: This retrospective, multisite, observational, open cohort study, included TN and TE PLWH who started B/F/TAF from October 2019 to January 2024 in three HIV clinics in Argentina.

Results: Of 3527 patients starting B/F/TAF, 250 (7%) had CD4 <200/mm3: 132 TN and 117 TE. The cohort was predominantly male (74%) with a median age of 43 years. For TN patients, 48-week persistence was 99%, VS was 83%, and median CD4 increased from 94 to 284/mm^3. TE patients were divided into those with and without VS at baseline (TEU: treatment-experienced undetectable; TENU: treatment-experienced not-undetectable). Half of the TE patients corresponded to TENU subgroup which had lower CD4 counts and higher frequencies of exposure to efavirenz and atazanavir/ritonavir, ongoing toxicity, and virologic failure compared to TEU. At 48 weeks, VS rates for TEU and TENU were 98% and 89%, respectively. Overall persistence was >99% for both groups. Median CD4 counts increased in both TEU and TENU groups. No adverse events were reported.

Discussion: B/F/TAF demonstrated excellent persistence, safety, and adequate VS rates in PLWH with AHD, including both TN and TE patients, supporting its use in this population.

Key words: antiretroviral therapy, HIV, bictegravir, real world

Resumen

Combinación de dosis fija de bictegravir/emtricitabina/tenofovir alafenamida en enfermedad por HIV avanzada

Introducción: Los datos en vida real sobre bictegravir/emtricitabina/tenofovir alafenamida (B/F/TAF) mostraron alta supresión virológica (SV) en personas que viven con HIV (PVHIV). El estudio BIC-CD4 tiene como objetivo describir la persistencia, SV y seguridad en PVHIV que iniciaron B/F/TAF con CD4 <200/mm^3, representando enfermedad por HIV avanzada.

Materiales y métodos: Este estudio observacional, retrospectivo, multicéntrico, de cohorte abierta, incluyó PVHIV *naive* y experimentados que iniciaron B/F/TAF desde octubre 2019 hasta enero 2024 en tres clínicas de HIV en Argentina.

Resultados: De 3527 PVHIV que iniciaron B/F/TAF, 250 (7%) tenían CD4 <200/mm^3: 132 *naive* y 117 experimentados. La cohorte fue predominantemente masculina

(74%) con una mediana de edad de 43 años. Para los *naive*, la persistencia a 48 semanas fue 99%, la SV 83%, y la mediana de CD4 aumentó de 94 a 284/mm^3. Las PVHIV experimentadas fueron divididas entre aquellas con y sin SV basal (TEI: tratamiento-experimentado indetectable; TENI: tratamiento-experimentado no indetectable). La mitad de los experimentados correspondió al subgrupo TENI, el cual presentó recuentos de CD4 más bajos y mayor frecuencia de exposición a efavirenz y atazanavir/ritonavir, toxicidad y fallo virológico en comparación con TEI. A 48 semanas, las tasas de SV para TEI y TENI fueron 98% y 89% respectivamente. La persistencia fue >99% para ambos grupos. Las medianas de CD4 aumentaron tanto en TEI como en TENI. No se reportaron eventos adversos.

Discusión: B/F/TAF demostró excelente persistencia, seguridad y tasas adecuadas de SV en enfermedad por HIV avanzada, incluyendo tanto PVHIV *naive* como experimentados, respaldando su uso en esta población.

Palabras clave: tratamiento antirretroviral, HIV, bictegravir, vida real

KEY POINTS
Current knowledge

- Advanced HIV disease (AHD) poses significant challenges globally, particularly in resource-limited settings. Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) has shown efficacy and safety in HIV treatment, but data on its use in AHD are limited.

Contribution of the article to current knowledge

- This study demonstrates that B/F/TAF offers excellent persistence, safety, and adequate virologic suppression rates in individuals with AHD, including both treatment-naive and experienced patients. The findings support the use of B/F/TAF in this population, particularly in settings with limited treatment options.

Advanced HIV disease (AHD) remains a significant global health challenge, particularly in resource-limited settings[1]. AHD is defined by the World Health Organization as a CD4 cell count of less than 200 cells/mm^3 or as an adult or adolescent's disease in stage 3 or stage 4[2]. People with AHD face a high risk of morbidity and mortality, even after initiating antiretroviral therapy (ART)[1]. In Latin America, despite progress in HIV care and treatment, late diagnosis and treatment interruptions contribute to the persistence of AHD cases[1,3]. According to official statistics in Argentina, 17% of the estimated 140 000 people living with HIV (PLWH) remain undiagnosed, with approximately 30% of new HIV diagnoses considered late across various demographic groups[4].

In PLWH, the single-tablet regimen of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) has shown efficacy and safety[5–8]. However, data on its use in people with AHD, particularly in resource-constrained settings like Latin America, are limited. Given that B/F/TAF is recommended for both initiating and switching ART in most international and local guidelines[9–11], generating real-world data on its effectiveness and safety in PLWH with CD4 T-cell counts <200/mm^3 is necessary for informing clinical practice in this challenging and often underrepresented population.

Materials and methods

This was an observational, retrospective, multicenter study conducted in Argentina. The study population comprised PLWH, both antiretroviral therapy (ART) naive (TN) and experienced (TE), who were prescribed the B/F/TAF single-tablet regimen as part of routine clinical care and had a CD4 T-cell count <200 cells/mm^3 at the time of B/F/TAF initiation. TE population was defined as those with prior ART but never exposed to B/F/TAF. TE PLWH were stratified in two groups:

- TEU: treatment-experienced undetectable, those with virologic suppression (VS, viral load <50 copies/mL) when starting B/F/TAF
- TENU: treatment-experienced not undetectable, those without VS (viral load >50 copies/mL) when starting B/F/TAF

We identified eligible subjects through electronic medical records in three private HIV clinics located in Buenos Aires and Tucumán cities. Data were collected from October 2019 to January 2024 and entered into a clinical research form on the REDCap platform. Inclusion criteria were: (1) HIV-1 positive serology confirmed by at least two different serological tests or a detectable viral load;

(2) age 18 years or older; (3) prescription of B/F/TAF in routine clinical care; and (4) CD4 T-cell count <200 cells/mm^3 when starting B/F/TAF. Exclusion criteria were exposure to B/F/TAF in a clinical trial or lack of baseline data.

The primary outcome was the proportion of participants achieving VS at weeks 24 (+/- 4 weeks) and 48 (+/- 8 weeks) after B/F/TAF initiation. Secondary outcomes included characterization of persistence (remaining on therapy without experiencing a treatment gap), tolerability and safety (drug-related adverse events, serious adverse events) at weeks 24 (+/- 4 weeks) and 48 (+/- 8 weeks).

Statistical analysis

Descriptive statistics were used to characterize the demographic and clinical profile of the study population. Continuous variables were summarized using medians and interquartile ranges (IQR), while categorical variables were described through absolute and relative frequencies. Persistence rates and virologic suppression were calculated at 24 and 48 weeks. Variables with missing values were excluded. Statistical comparisons between the TEU and TENU subgroups were performed using the Chi-square or Fisher's exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. All analyses were performed using R Statistical Software (v4.4.0; R Core Team 2024).

Ethical statement

The study protocol was reviewed and approved by the *Comité de Ética en Investigación Clínica* (CEIC) in Buenos Aires, Argentina (registry number 9738). Due to its retrospective design, analyzing existing medical record data, a waiver of informed consent was granted as this involved no direct patient contact.

Results

We screened registries of 12 768 PLWH, of which 3527 started B/F/TAF. Among these, 250 (7%) had a CD4 T-cell count <200 cells/mm^3 and were included in the analysis. The study population comprised 132 (52.8%) TN and 117 (47.2%) TE individuals (Fig. 1). Baseline characteristics and outcomes are described in Table 1. Briefly, the majority of patients were male, with a median age of 43 years, and a vast majority were of Latin ethnicity.

In the TN group, the median baseline viral load was 169 500 copies/mL (IQR: 37 250-473 000), and the median CD4 count was 94 cells/mm^3 (IQR: 45-149). Comorbidities were present in 18%. At 24 and 48 weeks, persistence rates were 100% and 99%, respectively. VS rates were 81% at 24 weeks and 83% at 48 weeks. CD4 counts increased significantly to a median of 236 cells/mm^3 at 24 weeks and 284 cells/mm^3 at 48 weeks. No tolerability issues or adverse events were reported in this group.

In the TE group, the median baseline CD4 count was 141 cells/mm^3 (IQR: 92-177), and 40% had comorbidities. Half of the TE patients (50%) had VS when starting B/F/TAF (TEU subgroup), while the other half did not (TENU subgroup). The TENU subgroup had significantly lower CD4 counts (119 vs. 161 cells/mm^3, $p < 0.001$) and higher frequencies of exposure to efavirenz and atazanavir/ritonavir, ongoing toxicity, and virologic failure compared to the TEU subgroup.

For the TEU subgroup, the main reasons for switching to B/F/TAF were simplification (58%) and toxicity prevention (28%). VS rates at 24 weeks were significantly higher in the TEU compared to the TENU subgroup (98% vs. 73%, $p < 0.001$) at 24 weeks but not at 48 weeks (98% vs. 89%, $p = 0.2$).

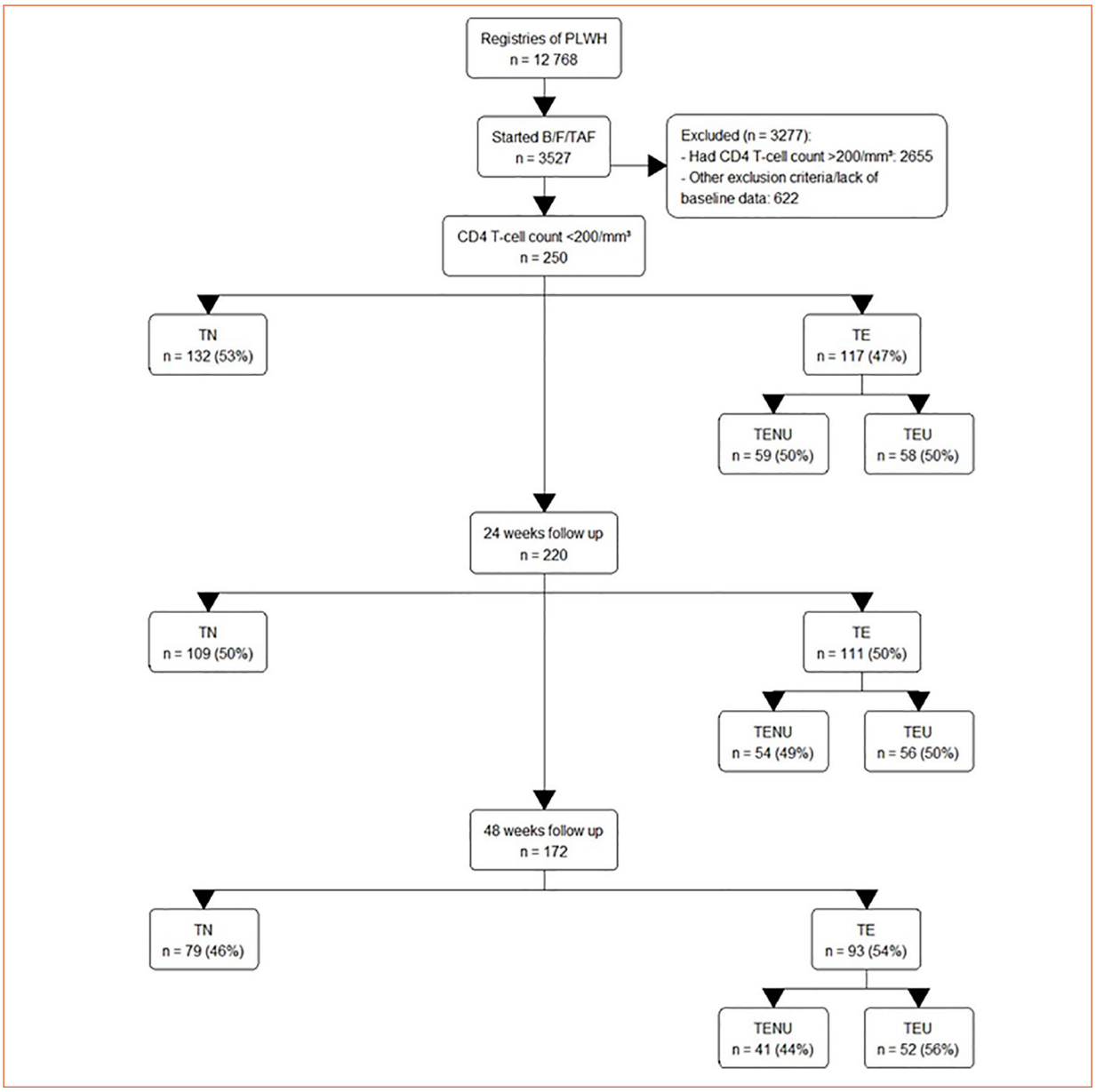
Overall persistence in the TE group was >99%, and no tolerability issues or adverse events were reported. Median CD4 counts increased to 190 cells/mm^3 (IQR: 157-235) at 24 weeks and 212 cells/mm^3 (IQR: 178-281) at 48 weeks, with no significant differences between TEU and TENU subgroups.

Discussion

By examining the effectiveness and safety of B/F/TAF in PLWH with AHD, we aimed to provide insights that address a gap regarding treatment options in resource-limited settings, such as Latin American countries, where this is a prevalent issue[12].

B/F/TAF has demonstrated robust efficacy and safety profiles in both clinical trials and real-world cohorts. In clinical trials, B/F/TAF has shown high rates of VS, with studies reporting rates largely exceeding 90% in TN and TE populations[5]. However, there is a notable scarcity of data specifically focusing on those subjects with CD4 counts below 200 cells/mm^3, in whom a rapid VS and immune restoration is mandatory to prevent short-term adverse outcomes. In

Figure 1 | Flowchart describing inclusion and 48-week follow-up of people living with HIV (PLWH) with CD4 T-cell count <200/mm3 exposed to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in a real-world cohort from Argentina



TN: treatment naive; TE: treatment experienced; TENU: treatment-experienced, not undetectable; TEU: treatment-experienced, undetectable

this report, 81% of TN participants achieved VS at 24 weeks and 83% at 48 weeks, despite their advanced disease status. This suggests that B/F/TAF can be an effective option even in severely immunocompromised individuals. Similar findings were reported in the CORIS cohort, with a 73.7% VS rate at 24 weeks and 86.1% at 48 weeks for TN individuals with CD4 counts <200 cells/mm³ starting B/F/TAF[13]. The US OPERA database showed that those who received B/F/TAF were significantly less likely to discontinue their treatment regimen than those who received 3-drug regimens with DTG, EVG/c, or boosted DRV and had a significantly increased likelihood of CD4 count recovery to levels ≥200 cells/mm³ and VS (<200 copies/mL) compared with these regimens[14]. Such cohorts included subjects receiving alternative options, allowing for a broader com-

Table 1 | Baseline characteristics and 24- and 48-week outcomes in a cohort of people living with HIV with advanced HIV disease under therapy with bictegravir/emtricitabine/tenofovir alafenamide in Argentina

Variable	Treatment naive (TN) N = 1321	Treatment experienced (TE) Overall*, N = 117[1]	TENU, N = 59[1]	TEU, N = 58[1]	p-value[2]
Baseline					
Sex at birth, male	106/132 (80)	78/117 (67)	37/59 (63)	41/58 (71)	0.4
Race					
Hispanic/Latin	132/132 (100)	117/117 (100)	59/59 (100)	58/58 (100)	
Age (years)	41 [32-51]	44 [39-50]	46 [41-50]	43 [38-52]	0.4
Number of previous ARTs	N/A				0.3
1		47/107 (44)	23/53 (43)	24/54 (44)	
2		31/107 (29)	12/53 (23)	19/54 (35)	
3		16/107 (15)	10/53 (19)	6/54 (11)	
>3		13/107 (12)	8/53 (15)	5/54 (9.3)	
History of virologic failure	N/A	15/114 (13)	10/57 (18)	5/57 (8.8)	0.2
AIDS defining event[3]	49/131 (37)	16/114 (14)	6/59 (10)	10/55 (18)	0.2
Presence of comorbidities[4]					0.056
Yes	24/131 (18)	46/117 (39)	18/59 (31)	28/58 (48)	
No	70/131 (53)	43/117 (37)	22/59 (37)	21/58 (36)	
Unknown-missing	37/131 (28)	28/117 (24)	19/59 (32)	9/58 (16)	
Viral load <50 c/mL	1/129 (0.8)	58/117 (50)	N/A	58/58 (100)	<0.001
Viral load (c/mL, absolute value)	169 500				
	[37 250-473 000]	51 [19-39 225]	38 000		
	[537-122 500]	19 [19-19]	<0.001		
CD4 T-cell count (cell/mm³)	94 [46-149]	142 [92-177]	119 [64-162]	161 [129-189]	<0.001
Reason for switching to B/F/TAF	N/A				<0.001
Simplification		58/115 (50)	25/58 (43)	33/57 (58)	
Toxicity of ongoing ART		26/115 (23)	18/58 (31)	8/57 (14)	
Avoiding future toxicities		23/115 (20)	7/58 (12)	16/57 (28)	
Virologic failure		8/115 (7.0)	8/58 (14)	N/A	
Last ART	N/A				<0.001
XTC-TDF-DRV/r		25/114 (22)	8/56 (14)	17/58 (29)	
XTC-TDF-ATV/r		20/114 (18)	12/56 (21)	8/58 (14)	
XTC-TDF-EFV		18/114 (16)	14/56 (25)	4/58 (6.9)	
XTC-TDF-DTG		14/114 (12)	7/56 (13)	7/58 (12)	
XTC-TDF-RAL		14/114 (12)	1/56 (1.8)	13/58 (22)	
Other					
XTC-ABC-EFV		5/114 (4.4)	4/56 (7.1)	1/58 (1.7)	
XTC-ABC-ATV/r		4/114 (3.5)	1/56 (1.8)	3/58 (5.2)	
AZT-3TC-NVP		1/114 (0.9)	1/56 (1.8)	N/A	
FTC/TAF/EVG/co		1/114 (0.9)	1/56 (1.8)	N/A	
XTC-ABC-DRV/r		1/114 (0.9)	1/56 (1.8)	N/A	
XTC-ABC-DTG		1/114 (0.9)	N/A	1/58 (1.7)	

(continúa)

(continuación)

Variable	Treatment naive (TN) N = 1321	Treatment experienced (TE) Overall*, N = 117[1]	TENU, N = 59[1]	TEU, N = 58[1]	p-value[2]
XTC-ABC-NVP		1/114 (0.9)	1/56 (1.8)	N/A	
XTC-ABC-RAL		1/114 (0.9)	N/A	1/58 (1.7)	
XTC-AZT-LPV/r		1/114 (0.9)	1/56 (1.8)	N/A	
XTC-AZT-MVC		1/114 (0.9)	1/56 (1.8)	N/A	
XTC-TDF-LPV/r		1/114 (0.9)	1/56 (1.8)	N/A	
24 weeks					
Persistence	109/109 (100)	110/111 (99)	54/55 (98)	56/56 (100)	0.5
Viral load <50 c/mL	74/91 (81)	74/86 (86)	29/40 (73)	45/46 (98)	<0.001
CD4 T-cell count (cell/mm³)	236 [146-326]	190 [157-235]	189 [162-227]	192 [152-236]	0.9
48 weeks					
Persistence	80/81 (99)	93/93 (100)	41/41 (100)	52/52 (100)	
Viral load <50 c/mL	57/69 (83)	75/80 (94)	31/35 (89)	44/45 (98)	0.2
CD4 T-cell count (cell/mm³)	284 [195-416]	213 [180-284]	207 [175-299]	227 [186-269]	0.5

[1]*n/N (%); Median [25%-75%]; ART: antiretroviral therapy; N/A: not applicable; TENU: treatment experienced not undetectable; TEU: treatment experienced undetectable; *Overall: all treatment experienced participants (TENU + TEU)*
[2]Statistical comparison between the TEU and TENU groups
[3]HIV wasting syndrome: 19 (29.2%), *Pneumocystis jirovecii* pneumonia: 16 (24.6%), Kaposi sarcoma: 12 (18.5%), esophageal candidiasis: 8 (12.3%), cryptococcal meningitis: 7 (10.8%), disseminated histoplasmosis: 6 (9.2%), central nervous system toxoplasmosis: 5 (7.7%), cytomegalovirus disease (excluding liver, spleen, and lymph node involvement): 4 (6.15%), extrapulmonary tuberculosis: 3 (4.6%), cryptosporidiosis: 2 (3.1%), other: 2 (3.1%)
[4]Dyslipidemia: 19 (26.8%), hypertension: 17 (23.9%), obesity: 15 (21.1%), neuropsychiatric: 9 (12.7%), solid neoplasia: 8 (11.3%), osteopenia-osteoporosis: 7 (9.9%), diabetes: 7 (9.9%), asthma/COPD: 5 (7.04%), gastrointestinal disorders: 5 (7.04%), other comorbidities: 29.

parison of treatment effectiveness. In the phase 4 RAINBOW study in which PLWH with ADH started B/F/TAF within 7 days of HIV diagnosis, 90% of participants achieved VS (<50 copies/mL) at week 48[15]. In all studies, discontinuation rates were low, supporting the safety profile of this fixed-dose combination even in an adverse clinical context. Of note, our study shows in the real world comparable results to those observed in the DOLCE study, a randomized clinical trial that evaluated dolutegravir/lamivudine (DTG/3TC) dual therapy versus triple therapy in a similar population with CD4 counts <200 cells/mm³. VS at 48 weeks, rates were 82.2% in DTG/3TC versus 80.5% with DTG-based triple therapy, similar to what was observed here with B/F/TAF, but outside strictly controlled conditions of clinical trials and reflecting everyday clinical practice with less stringent monitoring[16].

Our TE population was unexpectedly heterogeneous, with 50% of subjects lacking VS at the time of starting B/F/TAF, a finding not described previously for an AHD cohort. This off-label use reflects real-life clinical scenarios where PLWH may change therapies due to various factors, including ongoing treatment failure or toxicity. The presence of a significant proportion of subjects without prior virologic control underscores the need for tailored strategies in this population, highlighting the challenges faced by persons with severe immunosuppression and the necessity for effective treatment options. It would be expected that the TENU population was more complex for clinical management than TEU for several reasons. First, they had more frequent exposure to more toxic ARTs such as EFV and ATV/r, which is consistent with a higher prevalence of ongoing adverse events that may ulti-

mately impact adherence. Second, the history of virologic failure was more prevalent. Third, TNEU had a higher degree of immunosuppression. Despite this, we found no significant differences in adverse events between both groups. In terms of virologic outcomes, while the TEU subgroup exhibited a significantly higher rate of VS at 24 weeks, this statistical difference disappeared by 48 weeks. Furthermore, immune recovery, as measured by CD4 counts, was comparable across both groups.

Our study has limitations that must be acknowledged. The absence of a comparator group (dolutegravir-based therapy, which is the standard of care in the public health system) limits our ability to draw definitive conclusions regarding the relative efficacy of B/F/TAF compared to other ART regimens in AHD. Data from the CORIS cohort suggest that B/F/TAF may provide better virologic outcomes, at least in the short term, in comparison with other treatment options[13]. However, clinical experience is limited and merely observational, requiring clinical trials in this context. Additionally, the relatively small number of PLWH with 48-week follow-up data may affect the robustness of our long-term efficacy assessments. Future studies should aim to include, in addition to clinical trials, larger real-life cohorts and comparative analyses to strengthen the evidence base for B/F/TAF in this population[17].

Our study stands out for its substantial sample size, being one of the largest cohorts evaluating B/F/TAF in individuals with AHD in the literature and unique for a Latin American context. Furthermore, we uniquely characterize two distinct TE populations, providing insights into the complexities of managing HIV in individuals with varying treatment histories and clinical presentations. The 48-week follow-up in three distinct populations of AHD subjects allows for a more comprehensive evaluation of treatment durability and safety in different clinical contexts.

This study underscores the importance of developing effective treatment strategies for a population that faces high rates of morbidity and mortality due to late diagnosis and inadequate access to care. The focus on a Latin American population adds unique demographic and clinical perspectives that may influence treatment outcomes and warrant further investigation. Our findings support the use of B/F/TAF as a viable option for people with AHD, particularly in settings where treatment options may be limited. Continued research is essential to elucidate the long-term outcomes and optimize treatment strategies for this complex population.

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