P076

PERSISTENCE, SAFETY, AND VIROLOGIC OUTCOMES OF B/F/TAF AS A BASELINE OR SWITCH REGIMEN IN HIV-INFECTED PEOPLE LIVING WITH ADVANCED HIV DISEASE IN THE REAL WORLD: THE BIC-CD4 STUDY

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Background:

- Real-world data on B/F/TAF showed high levels of virologic suppression (VS) in treatment-naïve (TN) and experienced (TE) people living with HIV (PLWH).
- WHO defines advanced HIV disease (AHD) as a CD4 cell count <200 cells/mm^3 or clinical stage 3 or 4 in adults. This population is underrepresented in clinical trials and real-world studies.
- The BIC-CD4 study aims to describe safety, persistence, and VS (<50 c/mL) in adult PLWH who started B/F/TAF with CD4 <200/mm^3.

Material and Methods:

- Retrospective multisite observational open cohort study (real world data). TN and TE PLHIV who started B/F/TAF from October 2019 to January 2024 were registered in three HIV clinics in Argentina.
- The primary outcome was the proportion of participants achieving virologic suppression (viral load <50 copies/mL) at weeks 24 and 48 after B/F/TAF initiation.
- Secondary outcomes included characterization of persistence, tolerability and safety (drug-related adverse events, serious adverse events) at weeks 24 and 48.

Results:

- Registries of 12768 PLWH were screened, of which 3823 started B/F/TAF. Of them, 250 (6.5%) had CD4 T-cell count <200/mm^3: 132 TN (52.8%) and 118 TE (47.2%). Study flowchart is shown in **Figure 1**.
- Baseline characteristics: 74% male; median (IQR) age, 43 (35–51) years; >99% of Latin ethnicity.
- TN group had a median baseline viral load and CD4 count of 169500 c/mL (37250–473000) and 94/mm^3 (45–149); 18% had comorbidities.
  - *24 and 48-week persistence rates were 100 and 99%, VS was 81 and 83%, and CD4 significantly increased to a median of 236 (146–326) and 284 (195–416), respectively.*
  - *Adverse event rate (AER) was zero.*
- Of TE group, median CD4 count was 141/mm^3 (92-177); 40% had comorbidities. Only 50% had VS when started B/F/TAF (TE-undetectable: TEU); the rest had no VS (TENU). The TENU subgroup had lower CD4 (119 vs. 161, p<0.001) and higher frequency of exposure to EFV and ATV/r, ongoing toxicity (31% vs. 14%), and virologic failure (14% vs. zero). Among TEU, predominant reasons for switching were simplification (58%) and toxicity prevention (28%).
  - *VS rates at 24 and 48 weeks for TEU and TNEU were 98 vs. 73% (p<0.001) and 98 vs. 89% (p = 0.2), respectively.*
  - *Overall persistence was >99%, and AER was zero.*
  - *Median CD4 increased to 190 (157–235) and 212 (178–281) at 24 and 48 weeks, respectively, without differences between subgroups.*
- Summary of baseline characteristics and 24 and 48-week outcomes is shown in **Table 1**.

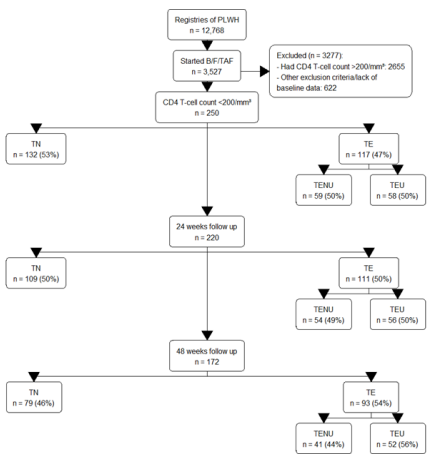

Figure 1. Flowchart describing inclusion and 48-week follow-up of people living with HIV (PLWH) with CD4 T-cell count <200/mm^3 exposed to bictegravir/emtricitabine/tenovofir alanfenamide (B/F/TAF) in real word cohort from Argentina. TN: treatment naive; TE: treatment experienced; TENU: treatment experienced not undetectable; TEU: treatment experienced undetectable

Table 1. Baseline characteristics and 24 and 48-week outcomes in a cohort of people living with HIV with advanced HIV disease under therapy B/F/TAF in Argentina.

	Treatment Naive (TN)	Treatment Experienced (TE)			
Variable	**N = 132**[1]	**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 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%)	
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. *Only most frequent regimens listed.

[2]Statistical comparison between the TEU and TENU groups

[3]HIV wasting syndrome: 19 (29.23%), *Pneumocystis jirovecii* pneumonia: 16 (24.62%), esophageal candidiasis: 8 (12.31%), cryptococcal meningitis: 7 (10.77%), disseminated histoplasmosis: 6 (9.23%), central nervous system toxoplasmosis: 5 (7.69%), *Cytomegalovirus* disease: 4 (6.15%), extra pulmonary tuberculosis: 3 (4.62%), cryptosporidiosis: 2 (3.08%), other: 14

[4]Dyslipidemia: 19 (26.76%), hypertension: 17 (23.94%), obesity: 15 (21.13%), neuropsychiatric: 9 (12.68%), solid neoplasia: 8 (11.27%), osteopenia-osteoporosis: 7 (9.86%), diabetes: 7 (9.86%), asthma/COPD: 5 (7.04%), gastrointestinal disorders: 5 (7.04%), other comorbidities: 29

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Conclusions:

- B/F/TAF appears to be an effective and well-tolerated option for PLWH with AHD, a population often underrepresented in clinical trials and real-world studies.
- The regimen showed efficacy in both TN PLWH and as a switch option TE subjects, including those with detectable viral loads at baseline.
- The study highlights the potential of B/F/TAF to address challenges in treating advanced HIV disease, such as the need for rapid viral suppression and immune recovery while maintaining a favorable safety profile.
- These real-world data support the use of B/F/TAF in a diverse population of PLWH with AHD, complementing existing clinical trial data and potentially expanding treatment options for this complex group.
- Further long-term follow-up studies may be beneficial to confirm the durability of these outcomes in PLWH with AHD.