Real-World Effectiveness in Treatment-Experienced People With HIV Switching to B/F/TAF With Distinct Patterns of Self-Reported Adherence

P068

BICSTaR

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Conclusions

- Despite participants self-reporting a high level of adherence overall, trajectory modeling identified individuals with distinct adherence patterns, including those with decreasing or increasing adherence over 24 months
- Specific baseline characteristics were found to be associated with particular adherence groups; for example, age, race, CD4 cell count, presence of neuropsychiatric disorder, and virologic suppression at baseline
- Regardless of adherence group, high levels of effectiveness were observed through 24 months following the switch to B/F/TAF, including in those participants with a decreasing adherence trajectory over 24 months

Plain Language Summary

- It is important for people with human immunodeficiency virus (HIV) to continue to take their medication for it to be effective
- BICSTaR (**BIC**tegravir **S**ingle **Ta**blet **R**egimen) is a study that is helping us to learn how well a specific HIV medication, B/F/TAF, works in everyday life in people with HIV
- In this study, people who have taken other HIV medicines before receiving B/F/TAF were asked to estimate how much of their prescribed B/F/TAF medication they were taking
  - Taking medication as prescribed is often called "adherence"
- People were grouped together depending on how well they kept taking B/F/TAF during the study
- The study then looked to see how well HIV was controlled (whether or not it was found in the blood) in each of these groups
- After 2 years, B/F/TAF was still working in all the groups studied, including a small group of people with HIV whose adherence was reduced over the 2 years

Introduction

- BICSTaR is a large, multi-country, observational study evaluating the effectiveness, safety, and patient-reported outcomes of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in treatment-naïve and treatment-experienced (TE) people with HIV (PWH) in routine clinical practice[1]
- Patient-reported outcomes, such as self-reported adherence, provide valuable insights into an individual's experience of treatment over time
- Adherence to antiretroviral therapy (ART) is important for maintaining virologic suppression in PWH[2]
  - Despite this, a recent global survey indicated that suboptimal adherence is frequent: almost a quarter of PWH self-reported missing their ART dose ≥ 5 times over the past month[3]
  - Therefore, selection of a treatment regimen that is forgiving in the presence of less-than-perfect adherence may improve long-term health outcomes in PWH[4]
- We present an analysis of real-world treatment adherence through 24 months in TE participants who switched to the single tablet regimen of B/F/TAF

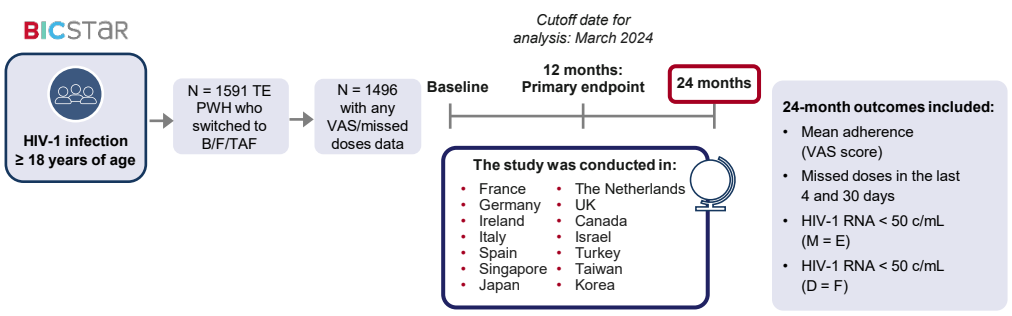
Objective

- To identify distinct patterns of treatment adherence over 24 months, using a trajectory modeling approach, in TE people switching to B/F/TAF
- To identify significant associations between baseline characteristics and each identified adherence trajectory group
- To describe adherence and effectiveness outcomes by adherence trajectory group through 24 months

Methods

- Self-reported adherence at baseline and at 6, 12, and 24 months was measured using:
  - A visual analog scale (VAS) adherence questionnaire (% ART doses taken in last month)
  - Missed doses in the last 4 and 30 days
- Group-based joint trajectory modeling (GBTM) is a technique used to identify subgroups within a population based on similar patterns of behavior[5]
  - GBTM was used to identify groups of individuals with distinct adherence trajectories over 24 months of follow-up
  - Self-reported VAS adherence scores and missed pill doses over the previous 4 and 30 days were jointly modeled measures of adherence
  - The best-fitting model was selected using the Bayesian information criteria
- Univariate multinomial logistic regression was used to calculate odds ratios and associated 95% CIs to identify significant associations between baseline characteristics and each adherence trajectory group
- Effectiveness at 24 months was analysed for each adherence trajectory group

Study Design



B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BICSTaR, BICtegravir Single Tablet Regimen; c, copies; D = F, discontinuation = failure; M = E, missing = excluded; PWH, people with HIV; TE, treatment-experienced; VAS, visual analog scale.

Results

Self-Reported Adherence Over Time

Assessment		Baseline[a]	Month 6	Month 12	Month 24
VAS adherence score	n	1298	992	966	941
	Mean (SD), %	95.3 (14.2)	96.9 (9.0)	97.5 (5.8)	97.0 (6.8)
Missed doses: Last 4 days	n	1250	958	923	904
	Mean (SD)	0.1 (0.6)	0.1 (0.4)	0.1 (0.3)	0.1 (0.3)
Missed doses: Last 30 days	n	1252	961	930	905
	Mean (SD)	1.2 (3.7)	0.7 (1.9)	0.7 (1.5)	0.6 (1.4)

n refers to the number of participants with available data at each timepoint.
[a]Baseline refers to adherence/missed doses on regimen prior to switching to B/T/TAF.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; VAS, visual analog scale.

Adherence Trajectory Groups

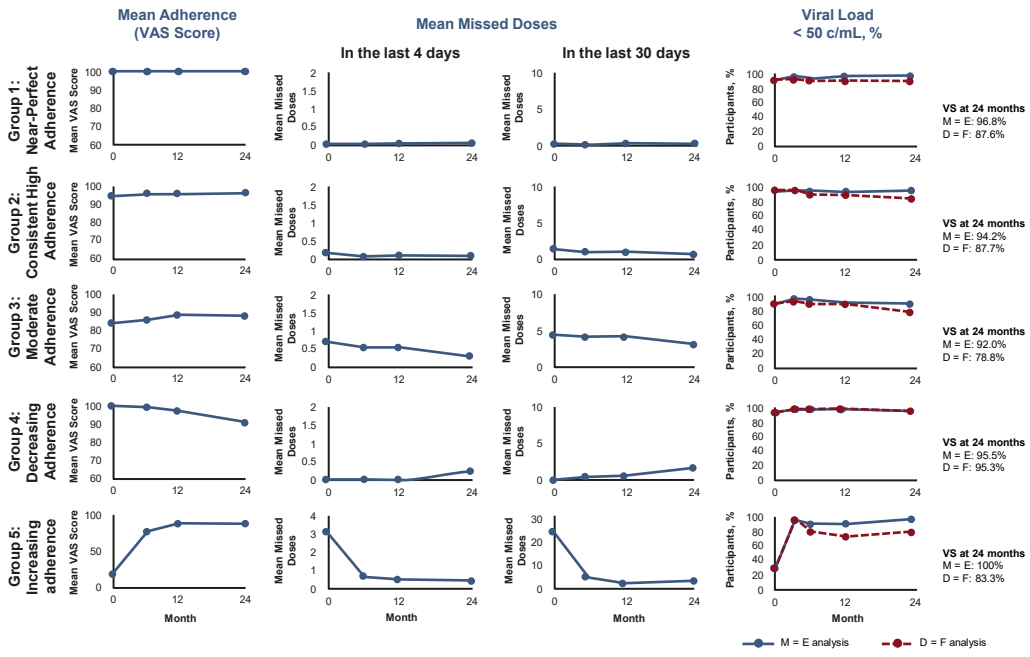
- From 1496 included participants, GBTM identified five groups of individuals with distinct patterns of adherence through 24 months:
  - Three groups had stable adherence over time:
    - Group 1: "Near-perfect adherence" (n = 810; 54.1%; mean VAS score at 24 months: 99.7%)
    - Group 2: "Consistent high adherence" (n = 457; 30.5%; mean VAS score at 24 months: 96.4%)
    - Group 3: "Moderate adherence" (n = 107; 7.2%; mean VAS score at 24 months: 87.9%)
  - Two groups had dynamic adherence over time:
    - Group 4: "Decreasing adherence" (n = 94; 6.3%; mean VAS score declining from 99.7% at baseline to 91.4% at 24 months)
    - Group 5: "Increasing adherence" (n = 28; 1.9%; mean VAS score increasing from 16.9% at baseline to 89.6% at 24 months)
      - The small number of participants in this group means that findings should be interpreted with caution

Baseline Clinical and Demographic Characteristics, by Adherence Trajectory Group

	Group 1: Near-Perfect Adherence (n = 810)	Group 2: Consistent High Adherence (n = 457)	Group 3: Moderate Adherence (n = 107)	Group 4: Decreasing Adherence (n = 94)	Group 5: Increasing Adherence (n = 28)	Total (N = 1496)
Male sex at birth, n (%)	677 (83.6)	387 (84.7)	88 (82.2)	82 (87.2)	23 (82.1)	1257 (84.0)
Black race, n (%)	79 (9.8)	52 (11.4)	13 (12.1)	7 (7.4)	7 (25.0)	158 (10.6)
Age at B/F/TAF initiation, years, median (IQR)	49 (40-56)	47 (37-54)	45 (35-53)	44.5 (35-55)	45.5 (38-51.5)	48 (38-55)
Baseline CD4/CD8 ratio, median (IQR)	0.8 (0.6-1.2)	0.9 (0.6-1.3)	0.8 (0.6-1.3)	0.9 (0.7-1.3)	0.5 (0.3-0.7)	0.9 (0.6-1.2)
Baseline CD4 count, cells/μL, median (IQR)	669.0 (420.0-874.0)	659.0 (492.0-902.0)	664.5 (453.5-835.0)	680.0 (520.0-834.0)	442.0 (309.6-946.0)	668.0 (457.0-874.0)
HIV-1 RNA viral load < 50 c/mL at baseline, n (%)	652 (92.9)	375 (94.7)	80 (90.9)	76 (96.2)	6 (27.3)	1189 (92.4)
History of or ongoing neuropsychiatric disorder, n (%)	189 (23.3)	131 (28.7)	28 (26.2)	21 (22.3)	6 (21.4)	375 (25.1)
Baseline MCS score,[a] median (IQR)	51.1 (42.5-56.4)	47.7 (38.7-54.3)	46.3 (38.0-52.3)	47.6 (40.3-52.9)	44.9 (38.8-55.0)	49.5 (40.6-55.8)
Baseline HIV-SI overall bothersome symptom count, median (IQR)	3.0 (1.0-6.0)	4.0 (1.0-7.0)	5.0 (2.0-8.0)	4.0 (1.5-7.0)	3.5 (1.0-10.5)	3.0 (1.0-7.0)

Data in participants with data available at baseline.
[a]MCS score is standardized to a mean of 50 (range: 1-100), scores of > 50 and < 50 represent better-than-average and poorer-than-average function, respectively.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; CD, cluster of differentiation; HIV-SI, HIV Symptom Index; MCS, mental component summary.

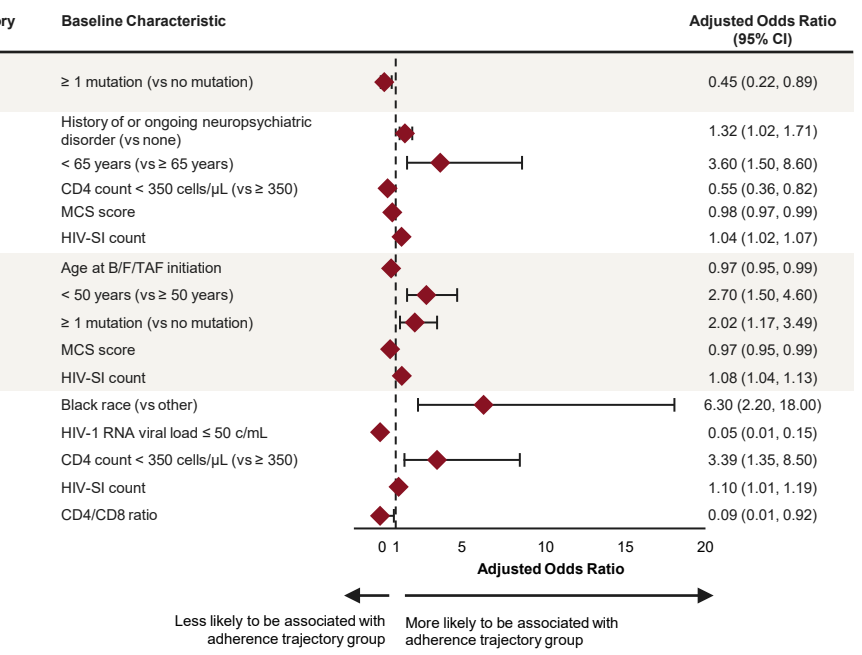
Summary of Adherence and Effectiveness Over Time Across Adherence Trajectory Groups



c, copies; D = F, discontinuation = failure; M = E, missing = excluded; VAS, visual analog scale; VS, virologic suppression.

- Virologic suppression was high in people at 24 months, regardless of their adherence trajectory, including those individuals with moderate and decreasing adherence
- In a small number of participants who reported missing ≥ 4 doses of B/F/TAF in the last month at 6 months (n = 25), 12 months (n = 31), and 24 months (n = 34), high levels of virologic suppression were maintained through 24 months, with HIV-1 RNA < 50 copies/mL in 92%, 100%, and 94%, respectively

Baseline Characteristics Significantly Associated With Adherence Trajectory Group (vs Reference Group 1: Near-Perfect Adherence)



HIV-SI is scored from 0-5, with a higher score representing worse symptoms. MCS is measured on a scale of 0-100, where a score of < 50 indicates poorer-than-average function.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; c, copies; CD#, cluster of differentiation #; HIV-SI, HIV Symptom Index; MCS, mental component summary.

References: **1.** Esser S, et al. *HIV Med*. 2024;25:440-53. **2.** Robbins RN, et al. *Curr HIV/AIDS Rep*. 2014;11:423-33. **3.** de los Rios P, et al. *Prev Med*. 2020;139:106182. **4.** Maggiolo F, et al. *J Int Assoc Provid AIDS Care*. 2022;21:2325958221140208. **5.** Lore H, et al. *Clin Epidemiol*. 2020;12:1205-22.

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