Patient-Reported Outcomes in Treatment-Naïve People With HIV Initiating B/F/TAF: A Pooled Analysis of the BICSTaR Cohort

P094

BICSTaR

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Conclusions

- In the observational BICSTaR (BICtegravir Single Tablet Regimen) cohort, treatment-naïve (TN) people with HIV-1 starting bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) reported improvements in quality of life and were highly satisfied with their treatment over 24 months
- Participants reported an increase from baseline to Month (M) 24 in the mental component summary (MCS) and physical component summary (PCS) scores of the 36-Item Short Form Health Survey (SF-36)
  - Those who started B/F/TAF within 7 days of HIV diagnosis (rapid initiation) and with CD4 count < 200 cells/μL had the lowest MCS scores at baseline and the most rapid improvements at M24
  - Those with advanced HIV (CD4 count < 200 cells/μL and HIV-1 RNA > 100,000 copies/mL) had the lowest PCS scores at baseline and the most rapid improvements at M24
- Participants reported a reduction in overall bothersome symptom count at M12, including those with rapid initiation, CD4 count < 200 cells/μL, and HIV-1 RNA > 100,000 copies/mL
- HIV treatment satisfaction was high at M3 regardless of rapid initiation status, CD4 cell count, and HIV-1 viral load, and remained generally stable through M24

Plain Language Summary

- B/F/TAF is a once-daily tablet that combines three human immunodeficiency virus (HIV) medicines: bictegravir (B), emtricitabine (F), and tenofovir alafenamide (TAF)
- The BICSTaR study looked at how well B/F/TAF worked and how safe it was for people with HIV in routine medical care around the world
- In this part of the study, researchers focused on people who started B/F/TAF as their first HIV treatment after being diagnosed with HIV. They looked at people's mental and physical health, side effects, and satisfaction with treatment over 2 years
- Overall, people who started B/F/TAF reported improvements in their mental and physical health. Those who started treatment within 7 days of their HIV diagnosis had the poorest mental health at the start of the study and showed the fastest improvements. Those with more advanced HIV had the poorest physical health and showed the fastest improvements
- After 1 year, the number of bothersome symptoms decreased, including in people who started treatment within 7 days of their HIV diagnosis and those with more advanced HIV
- People reported high satisfaction with B/F/TAF after 3 months of treatment, which was generally maintained through 2 years

Introduction

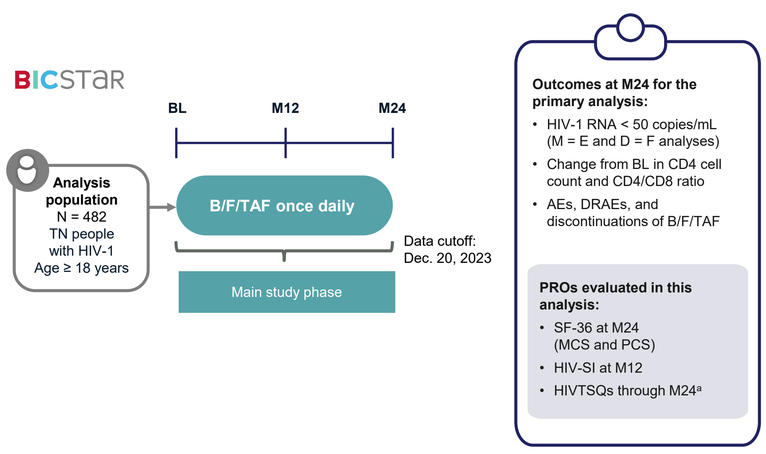
- B/F/TAF is a guideline-recommended first-line treatment for most people with HIV and is suitable for rapid initiation after a new HIV diagnosis[1-3]
- Patient-reported outcome (PRO) data evaluating quality of life and treatment satisfaction in newly diagnosed people initiating B/F/TAF are limited, particularly in those with more advanced HIV disease or those with rapid initiation
- BICSTaR was a large, observational study evaluating the effectiveness, safety, and PROs of B/F/TAF in TN and treatment-experienced people with HIV enrolled in routine clinical practice across 14 countries. The pooled analysis at M24 showed that:
  - B/F/TAF was highly effective and well tolerated across a broad range of people with HIV[4]
  - MCS and PCS scores improved or remained stable over time and treatment satisfaction improved[5]

Objective

- To evaluate PROs through M24 in newly diagnosed TN BICSTaR participants initiating B/F/TAF, with a focus on rapid initiation and HIV severity

Methods

Figure 1. Study Design



[a]Following a protocol amendment, HIVTSQs data collection in TN participants was extended from M3 to M6, M12, and M24.
[b]Vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BICSTaR, BICtegravir Single Tablet Regimen; BL, baseline; CD#, cluster of differentiation #; D = F, discontinued = failure; DRAE, drug-related adverse event; HIV-SI, HIV Symptom Index; HIVTSQs, HIV Treatment Satisfaction Questionnaire: status version; M, Month; M = E, missing = excluded; MCS, mental component summary; PCS, physical component summary; PRO, patient-reported outcome; SF-36, 36-Item Short Form Health Survey; TN, treatment-naïve.

Patient-Reported Outcome Measures and Statistical Analyses

- Descriptive statistics and logarithmic mixed-effects models adjusted for potential confounders, with bootstrapped CIs, were used to analyze MCS/PCS scores through M24 (**Figure 1**)
- HIV-SI score through M12 and HIV Treatment Satisfaction Questionnaire: status version (HIVTSQs) score through M3 were analyzed using descriptive statistics (**Figure 1**)
  - Following a protocol amendment, HIVTSQs data collection in TN participants was extended to M6, M12, and M24

Results

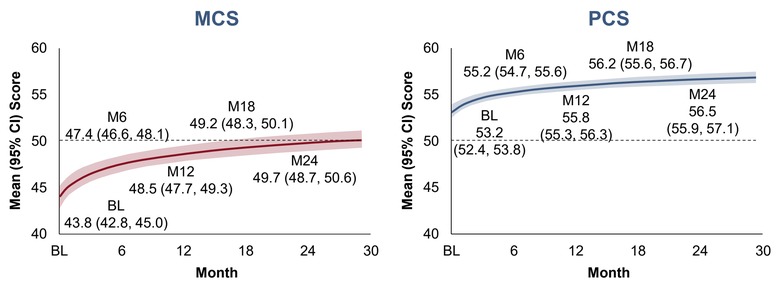
Table 1. Baseline Demographic and Clinical Characteristics

	TN Participants With PRO Data N = 482
Age, years, median (Q1, Q3)	36.0 (29.0, 45.0)
50-64 years, n (%)	74 (15)
≥ 65 years, n (%)	13 (3)
Male sex at birth, n (%)	438 (91)
Race/ethnicity, n (%)	
White	353 (73)
Black	24 (5)
Asian	83 (17)
Other[a]	22 (5)
HIV-1 RNA, n (%)[b]	
≥ 50 copies/mL	465 (99)
≥ 200 copies/mL	461 (98)
> 100,000 copies/mL	227 (48)
CD4 count, n (%)[c]	
< 200 cells/μL	123 (27)
< 350 cells/μL	232 (50)
CD4 count < 200 cells/μL and/or ≥ 1 AIDS-defining event at baseline, n (%)[d]	331 (71)
Comorbidities, n (%)	215 (45)
Neuropsychiatric disorder	45 (9)
Rapid B/F/TAF initiation (within 7 days of HIV diagnosis), n (%)[e]	116 (27)

Percentages are calculated based on the number of participants with available data.
[a]Includes American Indian or Alaska Native (n = 5), Asian and White (n = 1), Caribbean (n = 1), First Nation (n = 1), Hispanic (n = 1), Hispanic/Latin (n = 1), Latin (n = 2), Latin American (n = 1), Latino (n = 5), Moroccan (n = 1), Mixed (n = 1), Pakistan (n = 1), Pardo (n = 1). [b]Missing data, n = 12. [c]Missing data, n = 19. [d]Missing data, n = 15. [e]Missing data, n = 45.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CD4, cluster of differentiation 4; PRO, patient-reported outcome; Q, quartile; TN, treatment-naïve.

- BICSTaR participants with PRO data had a median age of 36 years, 91% were assigned male at birth, and 73% were White (**Table 1**)
  - Among these, 27% had rapid B/F/TAF initiation, 27% had CD4 count < 200 cells/μL, and 48% had HIV-1 RNA > 100,000 copies/mL (**Table 1**)

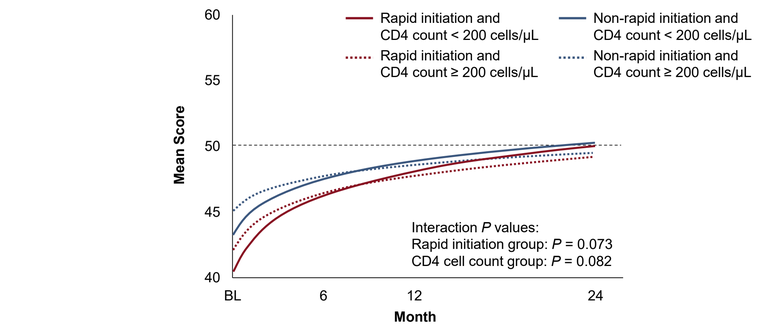
Figure 2. Increase in Unadjusted Predicted SF-36 Scores Over 24 Months



Unadjusted predicted scores were calculated using bootstrap CIs (log-time model).
BL, baseline; M, Month; MCS, mental component summary; PCS, physical component summary; SF-36, 36-Item Short Form Health Survey.

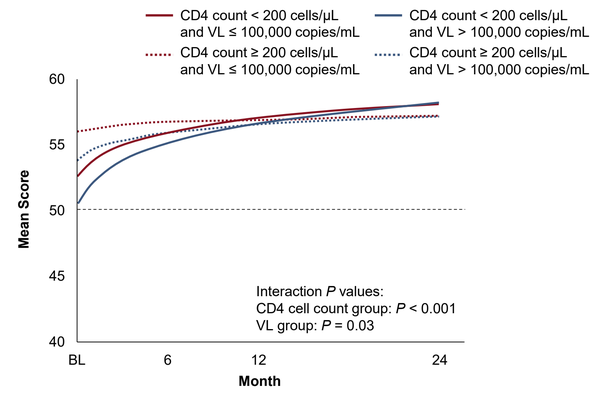
- Overall, mean (95% CI) unadjusted MCS and PCS scores increased over 24 months by +5.8 (4.1, 7.1) and +3.3 (2.4, 4.2), respectively (n = 407) (**Figure 2**)

Figure 3A. Change in MCS Score Adjusted by Rapid Initiation Status and Baseline CD4 Cell Count



	BL	6	12	24
Rapid initiation and CD4 count < 200 cells/μL	40.2	46.2	48.0	50.0
Rapid initiation and CD4 count ≥ 200 cells/μL	42.0	46.3	47.7	49.2
Non-rapid initiation and CD4 count < 200 cells/μL	43.1	47.5	48.8	50.3
Non-rapid initiation and CD4 count ≥ 200 cells/μL	44.9	47.6	48.5	49.4

Figure 3B. Change in PCS Score Adjusted by Baseline CD4 Cell Count and Baseline HIV-1 Viral Load

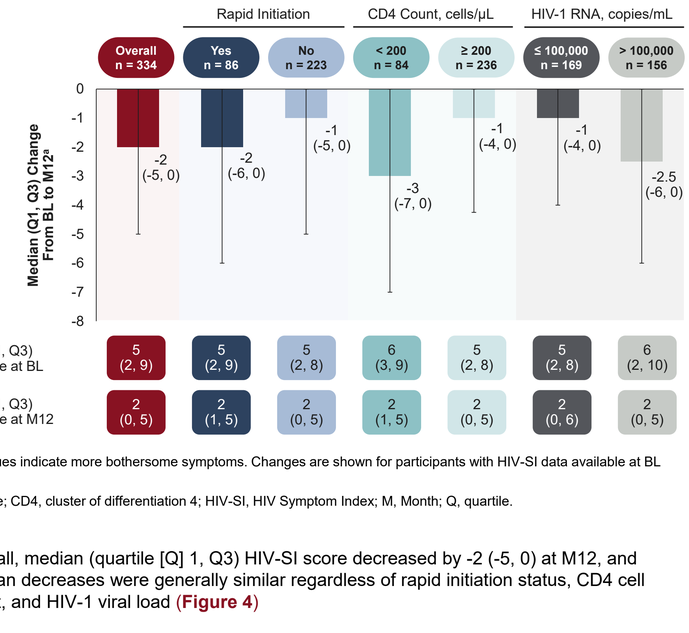


	BL	6	12	24
CD4 count < 200 cells/μL and VL ≤ 100,000 copies/mL	52.6	56.0	57.0	58.2
CD4 count ≥ 200 cells/μL and VL ≤ 100,000 copies/mL	56.0	56.7	57.0	57.2
CD4 count < 200 cells/μL and VL > 100,000 copies/mL	50.5	55.2	56.6	58.2
CD4 count ≥ 200 cells/μL and VL > 100,000 copies/mL	53.9	55.9	56.6	57.2

The MCS/PCS scores are standardized to a mean of 50 (indicated by the horizontal dotted line); scores > 50 indicate above-average function. Model interaction terms were retained if $P < 0.1$. The model is adjusted for race, sex, age group, comorbidities, ongoing neuropsychiatric disorders, number of comedications, CD4 cell count group, HIV-1 RNA group, and B/F/TAF initiation status.
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BL, baseline; CD4, cluster of differentiation 4; MCS, mental component summary; PCS, physical component summary; VL, viral load.

- Model-adjusted MCS scores at baseline were lowest in participants with rapid initiation and CD4 count < 200 cells/μL at baseline, and increased more rapidly from baseline to M24 than in other groups (+9.8 [95% CI: 6.9, 13.1]) (**Figure 3A**)
- Model-adjusted PCS scores at baseline were lowest in participants with CD4 count < 200 cells/μL and HIV-1 RNA >100,000 copies/mL at baseline, and increased more rapidly from baseline to M24 than in other groups (+7.7 [95% CI: 5.7, 9.7]) (**Figure 3B**)

Figure 4. Median Change at Month 12 in HIV-SI Score (Bothersome Symptom Count) by Rapid Initiation Status and CD4 Cell Count



[a]Higher values indicate more bothersome symptoms. Changes are shown for participants with HIV-SI data available at BL and M12.
BL, baseline; CD4, cluster of differentiation 4; HIV-SI, HIV Symptom Index; M, Month; Q, quartile.

- Overall, median (quartile [Q] 1, Q3) HIV-SI score decreased by -2 (-5, 0) at M12, and median decreases were generally similar regardless of rapid initiation status, CD4 cell count, and HIV-1 viral load (**Figure 4**)

HIV Treatment Satisfaction Score

- Median (Q1, Q3) HIVTSQs score was high at M3 (55 [50, 59]; n = 366)
  - Median (Q1, Q3) score was similarly high in participants with rapid initiation (56 [50, 59]; n = 93) and non-rapid initiation (55 [50, 59]; n = 244); CD4 count < 200 cells/μL (55 [51, 59]; n = 93) and CD4 count ≥ 200 cells/μL (55 [50, 59]; n = 258); and HIV-1 RNA ≤ 100,000 copies/μL (56 [50, 60]; n = 191) and HIV-1 RNA > 100,000 copies/μL (55 [49, 58]; n = 165)
- Among participants with data available at M6, M12, and M24, median (Q1, Q3) HIVTSQs scores were 56 (50, 59) [n = 134], 57 (51, 60) [n = 169], and 56 (50, 59) [n = 259], respectively

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