BICSTaR: 24-Month Effectiveness and Tolerability of B/F/TAF by HIV Diagnosis Era

P095

BICSTaR

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Conclusions

- In the observational BICSTaR (BICtegravir Single Tablet Regimen) cohort:
  - High rates of virologic suppression were maintained through 24 months in all diagnosis era groups
  - Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) was generally well tolerated, with similar rates of drug-related adverse events (DRAEs) and low rates of discontinuations due to DRAEs in all diagnosis era groups
  - Quality-of-life measures improved or remained stable across diagnosis era groups
- These findings reinforce the effectiveness and durability of B/F/TAF in treatment-experienced people with HIV in routine clinical practice, including individuals diagnosed prior to 1996, a population characterized by older age, extensive antiretroviral therapy (ART) experience, and a higher prevalence of primary resistance-associated mutations

Plain Language Summary

- People who have lived with human immunodeficiency virus (HIV) for a long time may have received many HIV treatments and may have other health conditions. This can make HIV harder to treat
- Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a single tablet treatment for HIV
- Researchers wanted to find out how well B/F/TAF worked and how safe it was for people who were diagnosed with HIV at different times
- They found that, over 24 months, B/F/TAF effectively controlled HIV and had generally similar numbers of side effects in people who were diagnosed with HIV before 1996, between 1996 and 2014, and after 2014
- After 24 months, most people in all three groups were more satisfied with B/F/TAF than with their previous treatment

Introduction

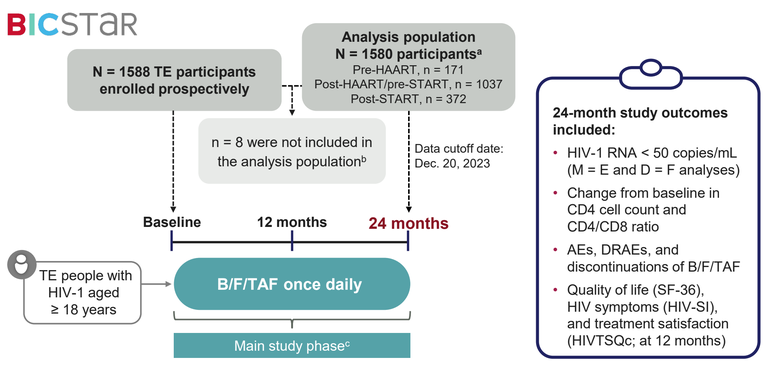
- ART and treatment recommendations have changed considerably since the beginning of the HIV epidemic[1-4]
  - The introduction of highly active ART (HAART) in 1996 was associated with reduced morbidity and mortality, although guidelines delayed initiation until CD4 cell count declined or AIDS-defining symptoms appeared[1]
  - Results from the START (Strategic Timing of Antiretroviral Treatment) trial in 2015 supported immediate ART initiation, irrespective of CD4 cell count, and helped establish guideline recommendations for treatment initiation at diagnosis[1-4]
- Consequently, people diagnosed in earlier diagnosis eras may differ clinically from those diagnosed more recently; they may have greater cumulative viremia, more extensive ART experience, more primary resistance-associated mutations, and a higher comorbidity burden[5]
  - These factors may limit treatment options and potentially contribute to less favorable outcomes
- BICSTaR was a multicountry, prospective, observational, 24-month cohort study evaluating the effectiveness and safety of B/F/TAF single tablet regimen in people with HIV-1 in routine clinical practice[6]
  - The pooled analysis showed that B/F/TAF was highly effective and well tolerated through 24 months among a broad range of people with HIV-1[6]

Objective

- To assess effectiveness, tolerability, and patient-reported outcomes of B/F/TAF over 24 months of follow-up in treatment-experienced people in the prospective, observational BICSTaR study who received an HIV diagnosis in the pre-HAART, post-HAART/pre-START, or post-START era

Methods

Figure 1. Study Design



[a]Enrolled from Canada (n = 183), France (n = 182), Germany (n = 325), Ireland (n = 61), Israel (n = 124), Italy (n = 171), Japan (n = 8), the Netherlands (n = 54), South Korea (n = 51), Singapore (n = 3), Spain (n = 189), Taiwan (n = 164), Türkiye (n = 13), and the UK (n = 52). [b]Excluded due to missing diagnosis date. [c]The BICSTaR study had a follow-up duration of 24 months; participants from Canada, France, and Germany could continue into an optional 36-month extension phase.
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BICSTaR, BICtegravir Single Tablet Regimen; CD#, cluster of differentiation #; D = F, discontinuation = failure; DRAE, drug-related adverse event; HAART, highly active antiretroviral therapy; HIV-SI, HIV Symptom Index; HIVTSQc, HIV Treatment Satisfaction Questionnaire: change version; M = E, missing = excluded; SF-36, 36-Item Short Form Health Survey; START, Strategic Timing of Antiretroviral Treatment; TE, treatment-experienced.

Results

Table 1. Baseline Demographic and Clinical Characteristics

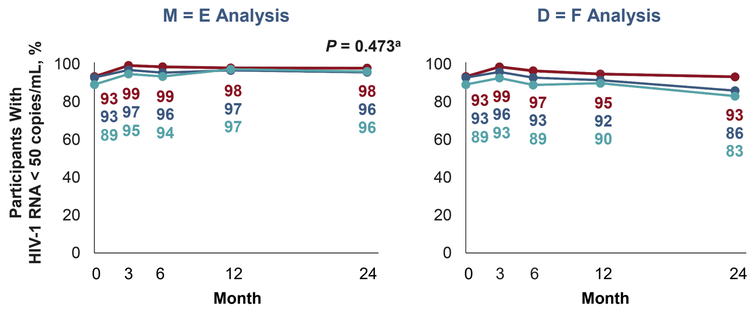
	Pre-HAART (Pre-1996) n = 171	Post-HAART/ Pre-START (1996-2014) n = 1037	Post-START (Post-2014) n = 372
Age at B/F/TAF initiation, years, median (Q1, Q3)	56 (53, 61)	48 (40, 55)	38 (30, 49)
Age ≥ 65 years, n (%)	26 (15)	67 (6)	11 (3)
Time from diagnosis to B/F/TAF initiation, years, median (Q1, Q3)	n = 171 28.0 (25.0, 31.4)	n = 1037 12.1 (8.3, 16.5)	n = 348 2.7 (1.7, 3.9)
Number of prior ART regimens, median (Q1, Q3)	n = 167 6 (3, 9)	n = 1028 3 (2, 4)	n = 368 1 (1, 2)
Most common ART just prior to B/F/TAF initiation, n (%)[a] E/C/F/TAF DTG + F/TAF	n = 169 35 (21) 10 (6)	n = 1035 340 (33) 56 (5)	n = 369 129 (35) 43 (12)
Any comorbidity/coinfection at B/F/TAF initiation, n (%)[b]	154 (90)	778 (75)	217 (58)
Number of comorbidities/coinfections at B/F/TAF initiation, median (Q1, Q3)	n = 171 3 (1, 5)	n = 1037 2 (1, 3)	n = 371 1 (0, 2)
Most common comorbidities/coinfections at B/F/TAF initiation, n (%)[b,c] Hyperlipidemia Hypertension Neuropsychiatric disorder Osteopathic disorder	 61 (36) 54 (32) 51 (30) 41 (24)	 265 (26) 196 (19) 248 (24) 113 (11)	 50 (13) 30 (8) 58 (16) 24 (6)
≥ 1 concomitant medication at B/F/TAF initiation, n (%)	n = 165 125 (76)	n = 988 596 (60)	n = 359 156 (43)
Number of concomitant medications at B/F/TAF initiation, median (Q1, Q3)	n = 147 2 (0, 4)	n = 931 1 (0, 2)	n = 342 0 (0, 1)
HIV-1 RNA < 50 copies/mL at B/F/TAF initiation, n (%)	n = 152 142 (93)	n = 879 817 (93)	n = 324 289 (89)
Nadir CD4 count, cells/μL, median (Q1, Q3)	n = 139 256 (109, 390)	n = 892 268 (142, 407)	n = 337 328 (147, 518)
≥ 1 primary RAM at B/F/TAF initiation, n (%)[d] NRTI NNRTI PI INSTI	36 (21) 30 (18) 19 (11) 13 (8) 0	94 (9) 56 (5) 53 (5) 23 (2) 1 (< 1)	27 (7) 13 (4) 14 (4) 4 (1) 1 (< 1)

[a]Reported in ≥ 10% of participants in any group. [b]Data were not available for 1 participant in the post-START group. [c]Reported in ≥ 20% of participants in any group. [d]Primary RAM data were not available for 5 and 1 participants in the post-HAART/pre-START and post-START groups, respectively. NRTI data were not available for 2 and 1 participants in the post-HAART/pre-START and post-START groups, respectively. NNRTI data were not available for 3 participants in the post-HAART/pre-START group. PI data were not available for 5 participants in the post-HAART/pre-START group. INSTI data were not available for 11, 82, and 49 participants in the pre-HAART, post-HAART/pre-START, and post-START groups, respectively.
ART, antiretroviral therapy; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CD4, cluster of differentiation 4; DTG, dolutegravir; E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; F/TAF, emtricitabine/tenofovir alafenamide; HAART, highly active antiretroviral therapy; INSTI, integrase strand-transfer inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; Q, quartile; RAM, resistance-associated mutation; START, Strategic Timing of Antiretroviral Treatment.

Results (cont.)

- **Participants diagnosed pre-HAART had a higher median age, higher median numbers of prior ART regimens, concomitant medications, and comorbidities/coinfections, and a higher prevalence of primary resistance-associated mutations at B/F/TAF initiation than those diagnosed post-HAART/pre-START or post-START (Table 1)**

Figure 2. Virologic Effectiveness Through 24 Months (M = E and D = F Analyses)



Number of participants with available data[b]

Pre-HAART	152	138	138	149	142
Post-HAART/ pre-START	879	767	824	870	818
Post-START	324	268	294	293	281

Number of participants with available data[c]

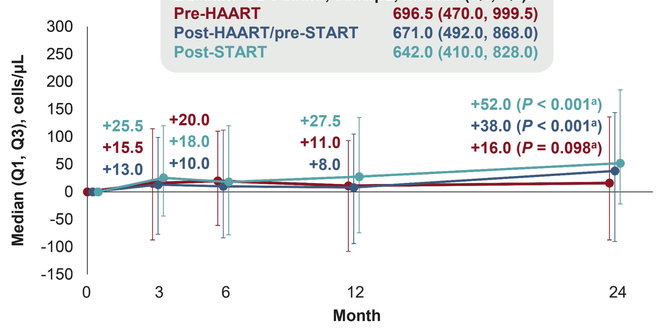
Pre-HAART	152	139	141	154	149
Post-HAART/ pre-START	879	775	847	919	910
Post-START	324	274	309	317	325

[a]Chi-square test (between group comparison at Month 24). [b]Reasons for missing data: study drug discontinued (pre-HAART: n = 7; post-HAART/pre-START: n = 92; post-START: n = 44), discontinued study before start of 24-month window (pre-HAART: n = 14; post-HAART/pre-START: n = 60; post-START: n = 34), and viral load data missing but still in study on B/F/TAF during 24-month window (pre-HAART: n = 8; post-HAART/pre-START: n = 67; post-START: n = 13). [c]Reasons for discontinuation (imputed as failure): adverse events (pre-HAART: n = 5; post-HAART/pre-START: n = 49; post-START: n = 28); participant's decision (pre-HAART: n = 1; post-HAART/pre-START: n = 13; post-START: n = 4); investigator's decision (pre-HAART: n = 1; post-HAART/pre-START: n = 6; post-START: n = 4); death (pre-HAART: n = 0; post-HAART/pre-START: n = 8; post-START: n = 1); lack of efficacy (pre-HAART: n = 0; post-HAART/pre-START: n = 6; post-START: n = 3); treatment interruption, study not discontinued (pre-HAART: n = 0; post-HAART/pre-START: n = 6; post-START: n = 0); missing data (pre-HAART: n = 0; post-HAART/pre-START: n = 2; post-START: n = 2); new treatment available (pre-HAART: n = 0; post-HAART/pre-START: n = 1; post-START: n = 1); pregnancy (pre-HAART: n = 0; post-HAART/pre-START: n = 1; post-START: n = 1).
B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; D = F, discontinuation = failure; HAART, highly active antiretroviral therapy; M = E, missing = excluded; START, Strategic Timing of Antiretroviral Treatment.

- **Rates of virologic suppression with B/F/TAF were high through 24 months in all groups (Figure 2)**
- **No treatment-emergent resistance to the components of B/F/TAF was reported through 24 months among those assessed**

Figure 3. Immunologic Outcomes Through 24 Months

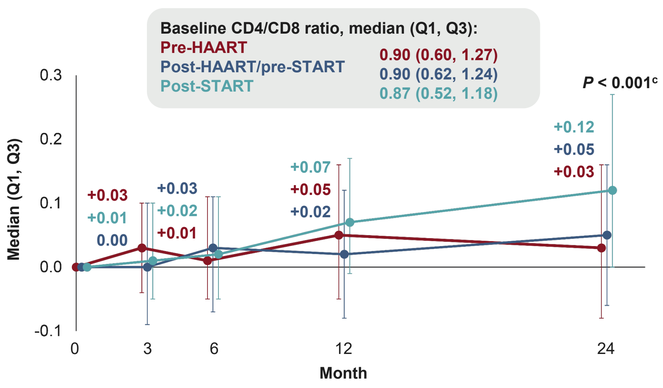
Change From Baseline in CD4 Cell Count



Number of participants with available data[b]

Pre-HAART	108	108	103	111	108
Post-HAART/ pre-START	626	597	656	677	626
Post-START	213	218	239	236	213

Change From Baseline in CD4/CD8 Ratio



Number of participants with available data[b]

Pre-HAART	101	103	99	104	101
Post-HAART/ pre-START	552	526	588	604	552
Post-START	194	200	220	216	194

[a]Sign test. [b]Number of participants at baseline includes those with available data at baseline and Month 24; number of participants at subsequent timepoints includes those with data available at baseline and the respective timepoint. [c]Kruskal–Wallis test (between group comparison at Month 24).
CD#, cluster of differentiation #; HAART, highly active antiretroviral therapy; Q, quartile; START, Strategic Timing of Antiretroviral Treatment.

- **Improvements in CD4 cell count and CD4/CD8 ratio were maintained through Month 24 in all groups (Figure 3)**

Table 2. Safety Outcomes Through 24 Months

	Pre-HAART (Pre-1996) n = 171	Post-HAART/ Pre-START (1996-2014) n = 1037	Post-START (Post-2014) n = 372
Any AEs	99 (58)	659 (64)	252 (68)
Any DRAEs[a]	20 (12)	120 (12)	58 (16)
Serious DRAEs	0	1 (< 1)[b]	0
DRAEs leading to B/F/TAF discontinuation[c]	6 (4)	52 (5)	26 (7)

Data are shown as n (%). [a]DRAEs occurring in ≥ 1% of participants overall: weight increase, 3.4%; depression, 1%; headache, 1%. [b]Depression. [c]DRAEs leading to discontinuation occurring in ≥ 1% of participants overall: weight increase (pre-HAART: n = 3; post-HAART/pre-START: n = 16; post-START: n = 9).
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DRAE, drug-related adverse event; HAART, highly active antiretroviral therapy; START, Strategic Timing of Antiretroviral Treatment.

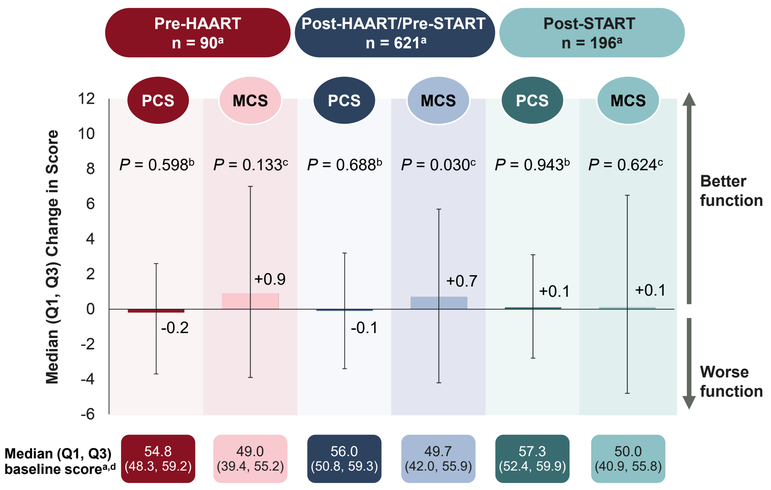
Table 3. B/F/TAF Discontinuations Through 24 Months

	Pre-HAART (Pre-1996) n = 171	Post-HAART/ Pre-START (1996-2014) n = 1037	Post-START (Post-2014) n = 372
B/F/TAF discontinuation[a]	11 (6)	106 (10)	47 (13)
Reasons for B/F/TAF discontinuation[b]			
Any AE[c]	7 (64)	58 (56)	29 (64)
Participant's decision	3 (27)	19 (18)	4 (9)
Investigator's discretion	1 (9)	8 (8)	5 (11)
Death	0	10 (10)[d]	1 (2)[e]
Lack of efficacy	0	6 (6)	3 (7)
New treatment available	0	2 (2)	2 (4)
Pregnancy	0	1 (1)	1 (2)

Data are shown as n (%). [a]All discontinuations within 913 days (upper bound of the 24-month time window) after treatment initiation have been considered. [b]Reasons were missing for 2 participants in both the post-HAART/pre-START and post-START groups. [c]Not all AEs leading to discontinuation were considered related to study drug by the investigators. [d]Meningeosis carcinomatosa, metastasis of the brain, pancreatic cancer, pulmonary insufficiency following trauma, respiratory failure, sepsis with multiorgan failure (all n = 1), unknown cause (n = 4). [e]Heart failure.
AE, adverse event; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; HAART, highly active antiretroviral therapy; START, Strategic Timing of Antiretroviral Treatment.

- **B/F/TAF was generally well tolerated with generally similar rates of AEs, DRAEs, and serious DRAEs**
- **Few participants had DRAEs that led to discontinuation of B/F/TAF (Table 2)**
- **Reasons for discontinuation are shown in Table 3**

Figure 4. Change From Baseline to Month 24 in QoL (SF-36 PCS and MCS Scores)



[a]Participants with SF-36 scores available at baseline and 24 months. [b]Sign test. [c]Wilcoxon signed-rank test. [d]The component summary scores are standardized to have a mean score of 50; scores above or below 50 can be interpreted as indicating better or worse QoL, respectively, than in the general population.
HAART, highly active antiretroviral therapy; MCS, Mental Component Summary; PCS, Physical Component Summary; Q, quartile; QoL, quality of life; SF-36, 36-Item Short Form Health Survey; START, Strategic Timing of Antiretroviral Treatment.

- **Physical and mental wellbeing remained generally stable from baseline to Month 24 (Figure 4)**

Treatment Satisfaction and Bothersome Symptom Count

- **Participants in all groups experienced improved treatment satisfaction following the switch to B/F/TAF, compared with their previous ART regimen**
  - **Median (Q1, Q3) HIV Treatment Satisfaction Questionnaire: change version (HIVTSQc) score[a] at Month 12: 24.0 (17.0, 30.0), 25.0 (14.0, 30.0), and 25.0 (13.0, 30.0) in the pre-HAART (n = 123), post-HAART/pre-START (n = 769), and post-START (n = 243) groups, respectively**
- **Overall bothersome symptom count remained stable in the pre-HAART group and improved in the post-HAART/pre-START and post-START groups**
  - **Median (Q1, Q3) change in HIV Symptom Index (HIV-SI) score[b] from baseline to Month 24:0.0 (-3.0, 2.0) (*P* = 0.579[c]) in the pre-HAART group (n = 113); 0.0 (-2.0, 2.0) (*P* = 0.011[c,d]) in the post-HAART/pre-START group (n = 726); and 0.0 (-2.0, 1.0) (*P* = 0.005[c,d]) in the post-START group (n = 229)**

[a]The HIVTSQc score ranges from -30 to 30; values > 0 indicate an improvement in satisfaction compared with previous treatment. [b]Overall bothersome symptom count (HIV-SI) can range from 0 to 20, with higher values indicating more bothersome symptoms. [c]Wilcoxon signed-rank test; the null hypothesis is that the median change in bothersome symptom count is equal to zero, where there are an equal number of values above and below zero. [d]*P* values < 0.05 associated with a median change of 0.0 indicate that there was a higher proportion of changes in bothersome symptom count below zero (i.e., an improvement) than above zero, and these *P* values were statistically significant.

Limitations

- **Diagnosis era was used descriptively to reflect correlated factors including age, time living with HIV, and cumulative ART experience; analyses were not intended to estimate causal effects of diagnosis era**
- **Interpretation of findings should consider potential survivor bias in the pre-HAART group, as participants diagnosed before 1996 who remained engaged in care may not be representative of all people diagnosed during that era**
- **Interpretation of patient reported outcomes (SF-36, HIVTSQc, and HIV-SI) should consider the relatively high proportion of participants with missing data**

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