Infect Chemother. 2025 Sep;57(3):424-430
https://doi.org/10.3947/ic.2025.0061
pISSN 2093-2340·eISSN 2092-6448

Infection & Chemotherapy

Brief Communication

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Effectiveness and Safety of Bictegravir/Emtricitabine/Tenofovir Alafenamide in People with HIV in Korea: 24-Month Data from BICSTaR

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ABSTRACT

BICtegravir Single Tablet Regimen is a multi-national observational cohort study evaluating the effectiveness and safety of bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in people with human immunodeficiency virus. We present 24-month data from participants in Korea. Eighty-eight participants (36 treatment-naïve [TN], 52 treatment-experienced [TE]) were included. At 24 months, 100% (29/29) of TN and 100% (37/37) of TE participants had HIV-1 RNA <50 copies/mL (missing=excluded analysis). BIC/FTC/TAF persistence was 100% (33/33) and 96.1% (49/51) in TN and TE participants, respectively. Drug-related adverse events occurred in 2 TN participants. Improvements in some patient-reported outcomes were observed. BIC/FTC/TAF maintained effectiveness, persistence, and tolerability over 24 months.

Keywords: Combination antiretroviral therapy; Korea; Asia; Bictegravir; Observational study

Received: Jun 16, 2025
Accepted: Aug 11, 2025
Published online: Sep 9, 2025

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The population of people with human immunodeficiency virus (HIV) in Korea has increased substantially since the early 2000s [1]. In 2022, HIV incidence rates in Korea were 4.14 per 100,000, and 98% of people with HIV were receiving antiretroviral therapy (ART) [2]. Improvements in treatment have been associated with increased life expectancy and decreased mortality, leading to an increase in the mean age of people with HIV [3, 4]. The higher burden of comorbidities and polypharmacy in older individuals presents new challenges in HIV management [5]. Additionally, there is an increasing need for convenient ART regimens with a low pill burden and few drug–drug interactions.

Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) is a three-drug ART regimen coformulated as a single tablet that has demonstrated efficacy and safety in people with HIV [6-13] and is recommended as a first-line treatment for HIV-1 by the Korean Society for AIDS [14]. BICtegravir Single Tablet Regimen (BICSTaR) is a multinational, observational cohort study evaluating the effectiveness and safety of BIC/FTC/TAF in routine clinical care across 14 countries from five observational cohorts in Asia (Korea, Singapore, Taiwan), Canada, Europe, Israel, and Japan. To date, pooled analyses of 12- and 24-month data for the BICSTaR full cohort and 12-month data for the BICSTaR Asia cohort have demonstrated that BIC/FTC/TAF was generally well tolerated, with high effectiveness and persistence observed among a broad range of people with HIV [15-17]. Here, we report the final 24-month effectiveness and safety analysis for treatment-naïve (TN) and treatment-experienced (TE) people with HIV in Korea from the BICSTaR Asia cohort.

Detailed methods for the BICSTaR study and the BICSTaR Asia cohort have been described [15, 16]. In this analysis, people with HIV aged ≥21 years receiving BIC/FTC/TAF (50/200/25 mg) in routine care at one of seven sites in Korea were included. Prospective and retrospective data were collected between January 28, 2021 and March 1, 2024, from clinical records, hospital files, clinic visits, electronic medical records, and (for prospective participants) validated patient-reported outcome (PRO) questionnaires. Outcomes assessed included HIV-1 RNA suppression (missing-equals-excluded [M=E] and discontinuation-equals-failure [D=F] analyses; **Supplementary Methods**) at 12 and 24 months, change from baseline to 24 months in CD4 count and CD4/CD8 ratio, and safety. Other endpoints included treatment persistence at 24 months, changes in weight and body mass index (BMI), laboratory analyses including changes in lipid profile, and changes in PROs (prospective participants) including physical and mental health-related quality of life measured using the 36-item Short Form Health Survey (SF-36) mental and physical component summary (MCS/PCS) scores, bothersome symptom count measured using HIV-Symptom Index (HIV-SI) questionnaire, and treatment satisfaction (TE participants only) using the HIV Treatment Satisfaction Questionnaire-status (HIVTSQs; baseline) and change (HIVTSQc; 12 months only) versions. Statistical analysis was performed using SAS software (Version 9.4, SAS Institute, Cary, NC, USA). TN and TE groups were analyzed separately. All participants provided written informed consent. The protocol was approved by an independent ethics committee and the study was conducted in line with Good Pharmacoepidemiology Practice and the Heads of Medicines Agencies' Good Pharmacovigilance Practices.

In total, 88 people with HIV were included (12 retrospective, 76 prospective; TN: n=36; TE: n=52; **Supplementary Fig. 1**). Participants were predominantly male (TN: 97.2%; TE: 88.5%), with a median age of 32.0 years (TN) and 52.5 years (TE) (**Supplementary Table 1**). The majority of participants had ≥1 comorbidity (TN: 72.2%; TE: 65.4%) and a high proportion of TN participants had either a BMI of ≥23 to <25 kg/m^2 (41.7%) or ≥25 kg/m^2 (33.3%; **Supplementary Fig. 2**).

In the M=E analysis, high rates of virologic suppression (HIV-1 RNA <50 copies/mL) were seen at month 24 with BIC/FTC/TAF in TN (100% [29/29]; 95% confidence interval [CI], 88.1–100%) and TE (100% [37/37]; 95% CI, 90.5–100%) participants with available data (**Fig. 1**). The D=F analysis showed similar levels of HIV-1 RNA suppression in TN (100%; 29/29) and TE (92.5%; 37/40) participants at month 24.

Median CD4 cell counts and CD4/CD8 ratios increased from baseline to month 24 in both TN and TE participants (**Supplementary Fig. 3**. Median (quartile [Q]1, Q3) CD4 cell count increased by +252 (155, 386) cells/μL in TN (P<0.001) and +69 (3, 176) cells/μL in TE participants (P=0.015). Median (Q1, Q3) CD4/CD8 ratio also increased by +0.38 (0.23, 0.41) in TN (P<0.001) and by +0.10 (0.00, 0.20) in TE participants (P=0.019). Persistence was high, with 100% (33/33) of TN and 96.1% (49/51) of TE participants with data available still receiving BIC/FTC/TAF at 24 months. Two TE participants discontinued BIC/FTC/TAF (the investigator citing the reasons "participant's

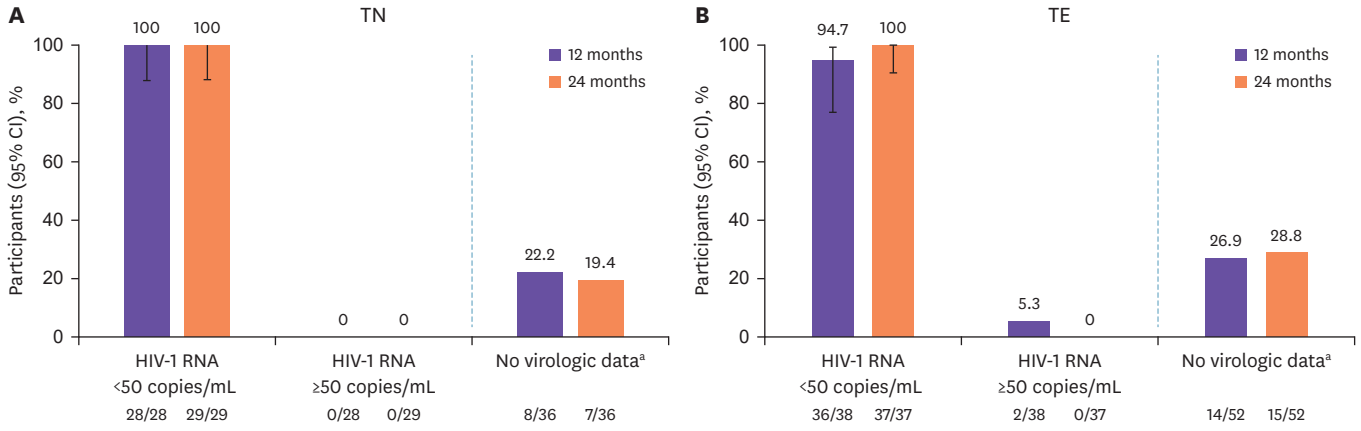

Figure 1. HIV-1 RNA <50 copies/mL (M=E) at 12 and 24 months in TN participants (A) and TE participants (B).
[a]For the "No virologic data category", numerators include participants with missing data and those who discontinued the study and/or BIC/FTC/TAF before the 24-month visit window (≥549 days [18 months] to ≤913 days [30 months]; denominators represent the total analysis population of TN and TE participants).
HIV, human immunodeficiency virus; M=E, missing-equals-excluded; TN, treatment-naïve; TE, treatment-experienced; BIC/FTC/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CI, confidence interval.

decision" [n=1] and "lack of effectiveness" [n=1; last on treatment viral load: 55 copies/mL at day 203]; see **Supplementary Table 2** for details).

Overall, 78.4% (69/88) of participants reported ≥1 adverse event (TN: 83.3% [30/36]; TE: 75.0% [39/52]; **Table 1**). Serious adverse events (SAEs) were reported in 8.0% (7/88) of participants (TN: 5.6% [2/36]; TE: 9.6% [5/52]). Drug-related adverse events (DRAEs) occurred in 2.3% (2/88) of participants, both of whom were TN. All DRAEs (diarrhea, insomnia, urticaria) were mild and none led to discontinuation of BIC/FTC/TAF, SAEs, or deaths. Small increases in median (Q1, Q3) body weight (TN: +2.0 [0.2, 7.0] kg; TE: +1.0 [-1.2, 4.0] kg) and BMI (TN: +0.6 [0.1, 2.1] kg/m^2; TE: +0.4 [-0.5, 1.3] kg/m^2) were observed from baseline to month 24 in TN and TE participants (**Supplementary Figs. 2** and **4**). Small increases in some lipid parameters from baseline to month 24 were observed; these reached statistical significance for total cholesterol (P=0.003) and high-density lipoprotein cholesterol (HDL; P<0.001) in TN participants and for low-density lipoprotein cholesterol (LDL; P=0.003) in TE participants. There was a statistically significant reduction in total cholesterol:HDL ratio in TN participants (P=0.003) and triglycerides in TE participants (P=0.014; **Supplementary Fig. 5**).

There was a statistically significant improvement in SF-36 MCS scores in TN (P=0.002) and TE (P=0.048) participants at month 24, with a median (Q1, Q3) change from baseline of +6.1 (0.5, 17.2) in TN and +2.5 (-3.5, 7.5) in TE participants; SF-36 PCS scores remained stable

Table 1. Adverse events reported through 24 months

Summary of AEs, n (%)	All (N=88)	TN (n=36)	TE (n=52)
Participants with ≥1 AE	69 (78.4)	30 (83.3)	39 (75.0)
Participants with ≥1 DRAE[a]	2 (2.3)	2 (5.6)	0
Gastrointestinal disorders	1 (1.1)[b]	1 (2.8)[b]	0
Psychiatric disorders	1 (1.1)[c]	1 (2.8)[c]	0
Skin and subcutaneous tissue disorders	1 (1.1)[d]	1 (2.8)[d]	0
Participants with ≥1 SAE	7 (8.0)	2 (5.6)	5 (9.6)
Any SAE related to BIC/FTC/TAF	0	0	0
Discontinued BIC/FTC/TAF due to DRAE	0	0	0
Death	0	0	0

[a]Participants could have experienced ≥1 DRAE; if a participant experienced ≥1 DRAE of the same preferred term, only one event was counted.
[b]Diarrhea.
[c]Insomnia.
[d]Urticaria.
AE, adverse event; TN, treatment-naïve; TE, treatment-experienced; DRAE, drug-related adverse event; SAE, serious adverse event; BIC/FTC/TAF, bictegravir/emtricitabine/tenofovir alafenamide.

https://doi.org/10.3947/ic.2025.0061

Table 2. Patient-reported outcomes (prospective cohort only)[a] at baseline and change from baseline at 24 months (12 months for HIVTSQc)

Outcomes	TN (n=25)	TE (n=51)
SF-36 MCS score[b]		
Baseline		
n	24	46
Median (Q1, Q3) score	39.1 (31.8, 49.0)	52.0 (44.8, 56.6)
24 months		
n	24	46
Median (Q1, Q3) change from baseline	+6.1 (0.5, 17.2)	+2.5 (−3.5, 7.5)
P-value for change from baseline[c]	*P*=0.002	*P*=0.048
SF-36 PCS score[b]		
Baseline		
n	24	46
Median (Q1, Q3) score	57.3 (51.6, 58.7)	53.9 (48.5, 56.3)
24 months		
n	24	46
Median (Q1, Q3) change from baseline	−0.1 (−6.9, 2.8)	−0.5 (−4.9, 4.0)
P-value for change from baseline[c]	*P*=0.337	*P*=0.529
HIV-SI overall bothersome symptom count[d]		
Baseline		
n	24	46
Median (Q1, Q3) overall score	4.0 (2.0, 11.0)	2.5 (1.0, 6.0)
24 months		
n	24	46
Median (Q1, Q3) change from baseline	−2.0 (−5.5, −1.0)	0.0 (−2.0, 1.0)
P-value for change from baseline[c]	*P*<0.001	*P*=0.544
HIVTSQ treatment satisfaction score		
Baseline (HIVTSQs)[e]		
n		50
Median (Q1, Q3) total score		53.0 (49.0, 59.0)
12 months (HIVTSQc)[f]		
n		45
Median (Q1, Q3) change from baseline		29.0 (23.0, 30.0)
P-value for change from baseline[c]		*P*<0.001

[a]Participants with score available at baseline and 24 months.
[b]Median scores >50 indicate better-than-average function.
[c]*P*-values were calculated using the Student *t* test for PCS and MCS scores, the signed-rank test for HIV-SI, and the Sign test for the HIVTSQ.
[d]Bothersome symptom count ranges from 0–20, with a higher count indicating more bothersome symptoms.
[e]HIVTSQs score ranges from 0–60, with higher scores indicating greater treatment satisfaction.
[f]HIVTSQc score ranges from −30 to 30, with higher scores indicating an improvement in treatment satisfaction, lower scores indicating lower satisfaction, and a score of 0 indicating no change in treatment satisfaction.
HIVTSQc/s, HIV treatment satisfaction questionnaire–change/status version; TN, treatment-naïve; TE, treatment-experienced; SF-36, 36-item Short Form Health Survey; MCS, mental component summary; Q, quartile; HIV-SI, HIV-Symptom Index; PCS, physical component summary.

through 24 months (**Table 2**). HIV-SI overall bothersome symptom count showed a statistically significant decrease from baseline to month 24 in TN participants (*P*<0.001), with a median (Q1, Q3) change of −2.0 (−5.5, −1.0); HIV-SI remained stable in TE participants (**Table 2**). In TE participants, median (Q1, Q3) HIVTSQs score was 53.0 (49.0, 59.0) at baseline, indicating high treatment satisfaction before switching to BIC/FTC/TAF. At 12 months, median (Q1, Q3) HIVTSQc score was +29.0 (23.0, 30.0), indicating an improvement in treatment satisfaction with BIC/FTC/TAF versus the previous treatment (*P*<0.001; **Table 2**).

ART is a life-long treatment, and selection of appropriate regimens is a key factor for successful long-term management of HIV [18]. These 24-month data support the growing body of evidence demonstrating the effectiveness of BIC/FTC/TAF in people with HIV [15, 17], including those in Asia [16].

There was a high level of HIV-1 RNA suppression with BIC/FTC/TAF through 24 months in this cohort of people with HIV in Korea, with all TN and TE participants demonstrating virologic suppression by month 24. This was mirrored by statistically significant improvements in

CD4 count and CD4/CD8 ratio, indicating a restoration of immunologic function.

No new safety concerns were observed. The rate of DRAEs found in this analysis (2%) was lower than that reported in the 24-month analysis of the pooled BICSTaR cohort from 14 countries (12%) [17]. The three DRAEs found in the Korean cohort (diarrhea, insomnia, urticaria [all occurring in 1%]) were also rare in the pooled BICSTaR analysis (occurring in ≤1%) [17]. A small amount of weight gain was reported in TN and TE participants; most weight gain occurred during the first 6 months for TN participants. This weight gain was consistent with the increase previously observed in Asian people with HIV who initiated other ART regimens [19]. Furthermore, a large proportion of TN participants had a high BMI at baseline, in accordance with the overall prevalence of obesity among Korean men in a similar age range over the last decade [20]. Statistically significant changes in total cholesterol, HDL, and total cholesterol:HDL ratio were observed in TN participants, as well as in LDL and triglycerides in TE participants, although these were not deemed clinically relevant. However, it is important to consider changes in lipid profile in the context of other cardiovascular risk factors when assessing potential implications on long-term cardiovascular health [21]. At 24 months, PROs indicated improvements in treatment satisfaction rates and increases in MCS scores in both groups, indicating an improvement in mental health. A statistically significant reduction (*i.e.*, an improvement) in the number of bothersome symptoms was noted in TN participants.

Limitations of the BICSTaR study have been discussed previously [15, 16]. Limitations of this analysis include the small sample, the potential for selection and information bias (due to the non-randomized, observational design and lack of consecutive enrollment), and the potential for immortal time bias by including retrospective participants. A strength of this analysis is that the cohort was representative of the wider Korean population of people with HIV, with the largest demographic group of newly diagnosed people with HIV in Korea between 2017–2022 being aged 31–40 years [2] compared with a median age of 32 years in our cohort of TN participants. Therefore, these findings may be considered generalizable.

This 24-month analysis demonstrated that BIC/FTC/TAF maintained high levels of effectiveness, persistence, and tolerability, with improvements in PROs in people with HIV receiving routine clinical care in Korea.

ACKNOWLEDGMENTS

We thank all participants and investigators involved in the BICSTaR Asia cohort. Medical writing support, including development of a draft outline and subsequent drafts in consultation with the authors, collating author comments, copyediting, fact checking, and referencing, was provided by Josh Lilly, at Aspire Scientific Limited (Manchester, UK). Funding for medical writing support for this article was provided by Gilead Sciences, Inc. (Foster City, CA, USA).

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Funding
The BICSTaR program was funded by Gilead Sciences, Inc. (Foster City, CA, USA). Funding for medical writing support for this article was provided by Gilead Sciences. The study sponsor, Gilead Sciences, played a role in the study design, data collection and analysis, decision to publish, and preparation of the manuscript.

Conflicts of Interest
THK has received advisor honorarium from Gilead Sciences, Inc. SHL has received advisor honorarium from Gilead Sciences and GSK Korea. JR was an employee of Gilead Sciences and owned shares in Gilead Sciences at the time of writing. J-aL and FP are employees of Gilead Sciences and own shares in Gilead Sciences. RH is a contractor for Gilead Sciences and an employee of IQVIA. JYC and SHL are editorial board members of *Infect Chemother*; however, they were not involved in peer reviewer selection, evaluation, and decision processes for this article. No other potential conflicts of interest relevant to this article were reported.

Author Contributions

Data curation: YSK, JYC, DWP, SWK, THK, SHL. Formal analysis: all authors. Writing – review & editing: all authors. All authors approved the final draft and agree to be accountable for the work.

Data sharing statement

Gilead Sciences shares anonymized individual participant data upon request or as required by law or regulation with qualified external researchers based on submitted curriculum vitae and reflecting non-conflict of interest. The request proposal must also include a statistician. Approval of such requests is at Gilead Sciences' discretion and is dependent on the nature of the request, the merit of the research proposed, the availability of the data, and the intended use of the data. Data requests should be sent to DataSharing@gilead.com.

SUPPLEMENTARY MATERIALS

Supplementary Methods

Statistical analysis, study assessments.

Supplementary Table 1

Baseline demographics and clinical characteristics

Supplementary Table 2

Reasons for BIC/FTC/TAF discontinuation

Supplementary Figure 1

Participant disposition.

Supplementary Figure 2

BMI category change from baseline to 24 months for TN (A) and TE (B) participants.

Supplementary Figure 3

Change in CD4 count (A and B) and CD4/CD8 ratio (C and D) from baseline to 24 months.

Supplementary Figure 4

Change in weight (A and B) and BMI (C and D) from baseline to 24 months.

Supplementary Figure 5

Change in lipid profile from baseline to 24 months for TN (A) and TE (B) participants.

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