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Effectiveness and Safety Profile of BIC/TAF/FTC in People living with HIV Switched from Other Antiretroviral Regimens: A Real-Life Retrospective Cohort Analysis

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SUMMARY

Background: Switching antiretroviral therapy (ART) is a common strategy in people living with HIV (PLWH) to improve tolerability, to manage comorbidities, and to optimize long-term safety. Bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC) is a single-tablet regimen with proven effectiveness in clinical trials. Real-world data continue to confirm its effectiveness across diverse clinical settings.

Methods: We conducted a retrospective observational cohort study including PLWH who switched to BIC/TAF/FTC from other ART regimens in routine clinical practice. At both baseline and during follow-up, we collected demographic characteristics, comorbidities, virological and immunological markers, and laboratory safety parameters.

Results: The study included 177 PLWH, with a median age of 55 years (IQR 44.4–60.3). 70.6% were male and 68.9% were aged ≥50 years. The median follow-up was 38.7 months (IQR 26.9–52.2). At baseline, 93.2% (165/177) of participants had suppressed HIV-RNA (<50 copies/mL). After switching to BIC/TAF/FTC, virological suppression (HIV-RNA <50 copies/mL) improved to 98.3% (174/177) at follow-up (p=0.007). Three participants had HIV-RNA ≥50 copies/mL at follow-up; none showed confirmed virological failure and no new resistance mutations were identified. Median CD4+ T-cell count showed a non-statistically significant trend toward increase from 562 (IQR 373–774) to 596 cells/μL (IQR 396–753) (p=0.057), while the CD4/CD8 ratio increased from 0.90 (IQR 0.60–1.30) to 0.94 (IQR 0.65–1.51) (p<0.001). A statistically significant decrease in total cholesterol (189 *vs* 180 mg/dL, p=0.013) was also observed. No clinically significant changes were observed in renal, hepatic, or hematological parameters.

Conclusions: In this real-life cohort, switching to BIC/TAF/FTC was associated with an improvement in virological suppression, an increase in CD4/CD8 ratio, and a favorable safety and metabolic profile, supporting its use as an effective and well-tolerated switch option in routine clinical practice.

Keywords: HIV, bictegravir, tenofovir alafenamide, emtricitabine, antiretroviral therapy, real-life study.

INTRODUCTION

The widespread availability of effective antiretroviral therapy (ART) has transformed HIV from a once fatal infection into a chronic and manageable condition [1, 2]. Accordingly, the life expectancy of people living with HIV (PLWH)

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now approximates that of the general population, driving a shift in the focus of HIV care toward long-term treatment optimization, management of comorbidities, and prevention of drug-related toxicity rather than solely attempting to achieve survival [1-3]. Data from the ICONA cohort highlight that switching to BIC/FTC/TAF represents one of the most effective strategies for maintaining long-term therapeutic success [4]. Consequently, clinical practice often employs the strategy of switching ART regimens in virologically suppressed PLWH in order to address such issues as the need to simplify treatment, improve tolerability, reduce drug-drug interactions (DDIs), and/or adapt therapies to comorbidities, such as renal, cardiovascular, and metabolic disease, with particular attention to managing polypharmacy [3-6].

Integrase strand transfer inhibitor (INSTI)-based regimens are currently recommended as both first-line and switch options due to their high effectiveness, rapid viral suppression, and favorable safety profile [7-10]. Bictegravir/tenofovir alafenamide/emtricitabine (BIC/TAF/FTC) represents one such regimen and consists of a once-daily single-tablet regimen that combines a second-generation INSTI with a nucleos(t)ide backbone. It is characterized by good tolerability and a high genetic barrier to resistance [11]. Furthermore, tenofovir alafenamide (TAF) has demonstrated improved renal and bone safety compared with tenofovir disoproxil fumarate, making it particularly suitable for aging populations and PLWH with pre-existing renal impairment [11, 12].

Several large prospective and retrospective multicentric cohorts have investigated BIC/FTC/TAF, confirming high effectiveness and favorable safety across diverse real-world settings. Our study contributes to this evidence base by providing single-center, real-world data from a predominantly older population with significant comorbidity burden.

The aim of this study was to evaluate the effectiveness and safety profile of BIC/TAF/FTC in a real-life cohort of PLWH who were switched from other ART regimens. We focused on virological outcomes, immunological parameters, and a broad panel of laboratory safety markers reflecting renal, hepatic, hematological, electrolyte, and inflammatory status

MATERIALS AND METHODS

This was a retrospective, observational cohort study conducted in a real-world clinical setting at ARNAS Civico-Di Cristina Hospital, Palermo, Italy. The study included adult PLWH followed in routine clinical care who were switched to BIC/TAF/FTC between January 2020 and December 2024.

Eligible patients were aged ≥18 years and had documented HIV infection. Inclusion criteria were: (1) switch from any previous ART regimen to BIC/TAF/FTC and (2) availability of at least one laboratory assessment at baseline and at least one HIV-RNA assessment after 2 years from switch to BIC/FTC/TAF. Patients without follow-up data were excluded.

The decision to switch therapy was made by the treating physician in accordance with clinical judgment and routine practice. Demographic data and the ongoing ART regimen at the time of switch to BIC/FTC/TAF were collected from medical records.

Laboratory parameters were collected at baseline (closest value before switch) and during follow-up. The following variables were analyzed: HIV-1 RNA (copies/mL), CD4+ T-cell count (cells/μL), CD4/CD8 ratio, complete blood count (hemoglobin, leukocytes, platelets), serum creatinine (mg/dL), serum sodium and potassium (mmol/L), aspartate aminotransferase (AST, U/L), alanine aminotransferase (ALT, U/L), and C-reactive protein (CRP, mg/L).

The primary outcome was maintenance of virological suppression at follow-up, defined as HIV-1 RNA <50 copies/mL, after switching to BIC/TAF/FTC. Virological suppression was assessed using the last available HIV-RNA measurement after the minimum 2-year follow-up period. Secondary outcomes included changes in CD4+ T-cell count and CD4/CD8 ratio. Safety outcomes entailed changes in renal, hepatic, hematological, electrolyte, and inflammatory laboratory parameters.

Continuous variables were summarized as Median and Interquartile Range (25^{th}-75^{th} percentile). Categorical variables were reported as absolute numbers and percentages. Comparisons between baseline and follow-up values were performed using the Wilcoxon signed-rank test for continuous variables and McNemar's test for dichotomous

variables. A p-value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS© (IBM), ver. 30.

RESULTS

A total of 177 PLWH were included in the analysis. The median age at the time of switch was 55 years (IQR 44.4–60.3). 125 individuals (70.6%) were male. A substantial proportion of the cohort consisted of older individuals, with122 participants (68.9%) aged 50 years or older. The median follow-up from switch to BIC/FTC/TAF was 38.7 months (IQR 26.9–52.2). The most common prior ART regimen was Genvoya (n=31, 17.5%), followed by Atripla (n=17, 9.6%), Odefsey (n=14, 7.9%), and Symtuza (n=13, 7.3%). Overall, 52.0% were switched from INSTI-based regimens, 31.6% from PI-based regimens, and 10.7% from NNRTI-based regimens. Baseline laboratory parameters were overall within normal ranges (*Table 1*).

At baseline, HIV-1 RNA was below 50 copies/mL in 165/177 participants (93.2%), while 12 participants (6.8%) had detectable viremia. During follow-up, 174/177 participants (98.3%) maintained virological suppression (HIV-RNA <50 copies/mL) after switching to BIC/TAF/FTC (p=0.007). Three participants had HIV-RNA ≥50 copies/mL at follow-up; none met criteria for confirmed virological failure, and resistance genotyping revealed no new resistance mutations attributable to BIC/TAF/FTC. The median CD4+ T-cell count was 562 cells/µL (IQR 373-774), and the median CD4/CD8 ratio was 0.90 (IQR 0.60-1.30) (*Table 2*).

Immunological parameters showed favorable trends during follow-up. The median CD4+ T-cell count showed a non-statistically significant trend toward increase from 562 cells/µL (IQR 373-774) at baseline to 596 cells/µL (IQR 396-753) at follow-up (p=0.057). Notably, the CD4/CD8 ratio showed a statistically significant increase from 0.90 (IQR 0.60-1.30) to 0.94 (IQR 0.65-1.51) (p<0.001), suggesting a clinically meaningful improvement in immune reconstitution following the switch to BIC/TAF/FTC (*Table 2*).

Hematological parameters showed no clinically relevant changes during follow-up (*Table 3*). Median hemoglobin levels remained stable (14.6 g/dL *vs* 14.6 g/dL, p=0.43), as did platelet counts (224×10^3/µL *vs* 215×10^3/µL, p=0.29). White blood cell subpopulations showed no statistically significant changes.

Renal function remained stable after switching to BIC/TAF/FTC. Median serum creatinine was 0.95 mg/dL (IQR 0.81-1.08) at baseline and 0.96 mg/dL (IQR 0.80-1.08) at follow-up (p=0.900.28). Urea, phosphorus, and creatine kinase values did not show significant changes.

Liver safety parameters were preserved. Median AST and ALT values remained unchanged (AST: 19.5 vs 21.0 U/L, p=0.17; ALT: 20.0 *vs* 20.0 U/L, p=0.76). GGT and alkaline phosphatase were stable (p=0.09 and p=0.36, respectively). Total protein showed a statistically significant decrease (7.4 *vs* 7.2 g/dL, p<0.001) and albumin decreased modest-

Table 1 - Baseline Demographic and Clinical Characteristics.

Variable	*Overall Population*
Number of participants	177
Age, years (median, IQR)	55 (44.4–60.3)
Sex (Male), n (%)	125/177 (70.6%)
Participants ≥50 years, n (%)	122/177 (68.9%)
Median follow-up, months (IQR)	38.7 (26.9–52.2)
Prior ART – INSTI-based, n (%)	92 (52.0%)
Prior ART – PI-based, n (%)	56 (31.6%)
Prior ART – NNRTI-based, n (%)	19 (10.7%)
Most common prior regimen (Genvoya), n (%)	31 (17.5%)

IQR: Interquartile range; INSTI: Integrase Strand Transfer Inhibitor; PI: Protease Inhibitor; NNRTI: Non-Nucleoside Reverse Transcriptase Inhibitor.

Table 2 - Virological and Immunological Parameters at Baseline and Follow-up.

Parameter	*Baseline*	*Follow-up*	*p value*
HIV-RNA ≥50 copies/mL	12/177 (6.8%)	3/177 (1.7%)	*0.007**
CD4 count (cells/µL)	562 (373–774)	596 (396–753)	0.057
CD4/CD8 ratio	0.90 (0.60–1.30)	0.94 (0.65–1.51)	*<0.001**

HIV: Human Immunodeficience Virus.

Table 3 - Laboratory Parameters at Baseline and Follow-up.

Parameter	*Baseline*	*Follow-up*	*p value*
Neutrophils (cells/μL)	3700 (2900–4800)	3800 (3100–4700)	0.58
Lymphocytes (cells/μL)	1651 (1353–2223)	1685 (1366–2181)	0.77
Monocytes (cells/μL)	500 (400–600)	500 (400–600)	0.94
Hemoglobin (g/dL)	14.6 (13.5–15.3)	14.6 (13.5–15.5)	0.43
Platelets (×10³/μL)	224 (180–261)	215 (177–255)	0.29
AST (U/L)	19.5 (16.0–23.8)	21.0 (18.0–25.2)	0.17
ALT (U/L)	20.0 (14.0–27.0)	20.0 (15.0–25.8)	0.76
GGT (U/L)	24.5 (16.0–39.0)	24.0 (17.0–34.0)	0.09
Alkaline Phosphatase (U/L)	75.0 (61.0–90.0)	71.0 (62.0–85.0)	0.36
Total Protein (g/dL)	7.4 (7.0–7.8)	7.2 (6.9–7.5)	*<0.001**
Albumin (g/dL)	4.5 (4.2–4.6)	4.4 (4.1–4.5)	*0.019**
Cholesterol (mg/dL)	189 (156–223)	180 (150–201)	*0.013**
HDL (mg/dL)	47.9 (42.0–56.2)	49.2 (42.1–58.0)	0.24
Triglycerides (mg/dL)	116 (86–164)	101 (74–146)	0.06
Creatinine (mg/dL)	0.95 (0.81–1.08)	0.96 (0.80–1.08)	0.28
Urea (mg/dL)	34 (28–41)	34 (28–40)	0.22
Sodium (mmol/L)	140 (138–141)	140 (139–142)	0.37
Potassium (mmol/L)	4.33 (4.04–4.59)	4.21 (4.00–4.45)	*0.007**
Phosphorus (mg/dL)	3.2 (2.7–3.4)	3.1 (2.7–3.5)	0.73
Creatine Kinase (U/L)	96 (68–135)	95 (68–152)	0.72
Amylase (U/L)	71 (60–93)	70 (56–88)	0.06
Lipase (U/L)	36 (28–47)	33 (26–44)	0.88
C-Reactive Protein (mg/dL)	0.15 (0.08–0.38)	0.13 (0.08–0.38)	0.39
Glycemia (mg/dL)	89 (80–98)	85 (78–95)	0.06
Ferritin (ng/mL)	76 (46–132)	130 (70–205)	*<0.001**
Iron (μg/dL)	88 (67–108)	85 (70–108)	0.89

AST: Aspartate Aminotransferase. ALT: Alanine Aminotransferase. GGT: Gamma-Glutamyl Transferase. HDL: High-Density Lipoprotein. LDL: Low-Density Lipoprotein

ly (4.5 *vs* 4.4 g/dL, p=0.019); both values remained well within the normal range and are not considered clinically significant.

Electrolyte balance was largely maintained. Sodium levels were stable (140 *vs* 140 mmol/L, p=0.37). Potassium showed a statistically significant decrease from 4.33 to 4.21 mmol/L (p=0.007), although both values remained within the normal physiological range without clinical consequences. Regarding lipid parameters, total cholesterol showed a statistically significant decrease from 189 to 180 mg/dL (p=0.013), which may reflect a beneficial metabolic effect of the switch. HDL (p=0.24) and triglycerides (p=0.06) did not change significantly.

Inflammatory status, as assessed by C-reactive protein, remained low and stable (0.16 *vs* 0.180.15 *vs* 0.13 mg/dL, p=0.39), indicating no notable change in this non-specific inflammatory marker. Ferritin levels showed a statistically significant increase from 76 ng/mL (IQR 46-132) to 130 ng/mL (IQR 70-205) (p<0.001). Glycaemia showed a non-significant trend toward decrease (89 *vs* 85 mg/dL, p=0.059).

DISCUSSION

In this real-life retrospective cohort study involving 177 PLWH, switching to the single-tablet regimen BIC/TAF/FTC was associated with a statistically significant improvement in virological suppression, a significant increase in CD4/CD8 ratio, and a favourable overall laboratory safety profile. These results are consistent with previous real-world evidence and support the utility of BIC/TAF/FTC as an effective switch option in routine clinical practice [13].

Our finding of a statistically significant improvement in virological control (from 93.2% to 98.3% suppression, p=0.007) aligns with outcomes reported in large retrospective cohorts [14]. A recent systematic review and meta-analysis confirm virological suppression rates exceeding 93% in treatment-experienced cohorts switched to BIC/FTC/TAF [15]. Recent European data confirm suppression rates exceeding 95% at 12 months, maintaining effectiveness comparable to modern dual-therapy regimens, even when switching from non-INSTI-based therapies [16-18].

A particularly noteworthy finding was the statistically significant increase in the CD4/CD8 ratio from 0.90 to 0.94 (p<0.001). The CD4/CD8 ratio is an established marker of immune senescence and residual immune activation in HIV infection; its normalization toward 1.0 is associated with reduced immune activation and potentially lower risk of non-AIDS-defining events. While the absolute change was modest, its statistical significance and consistency across the entire cohort suggest a genuine immunological benefit of BIC/TAF/FTC, possibly related to reduced viral replication and inflammatory drive. This observation is consistent with findings from other real-world cohorts, including women living with HIV switched to BIC/FTC/TAF, where significant improvements in CD4/CD8 ratio were reported over prolonged follow-up [19].

Renal and hepatic safety represent particularly relevant outcomes in aging populations and people with comorbidities. Our cohort showed no significant changes in serum creatinine, electrolytes, or liver enzyme levels after switching to BIC/TAF/FTC. This is concordant with published data demonstrating metabolic benefits and stable renal function following transitions from protease inhibitor-based regimens [20].

From a metabolic standpoint, the statistically significant decrease in total cholesterol (189 to 180 mg/dL, p=0.013) is a clinically relevant finding consistent with known metabolic improvements described after switching from PI-based or NNRTI-based regimens to INSTI/TAF-based therapy [17, 20]. The significant increase in ferritin levels (76 to 130 ng/mL, p<0.001) deserves attention; ferritin can be influenced by residual immune activation and iron redistribution following ART changes in people with HIV, and its non-specificity requires cautious interpretation. The significant decrease in potassium (4.33 to 4.21 mmol/L, p=0.007) and total protein (7.4 to 7.2 g/dL, p<0.001), while statistically significant, remained well within physiological reference ranges and are unlikely to be clinically meaningful at the population level.

Beyond classical effectiveness and safety endpoints, adjunctive immuno-virological dynamics remain contextually relevant. A recent retrospective study examining the impact of SARS-CoV-2 vaccination on HIV viral markers in PLWH receiving BIC/TAF/FTC suggests vaccination may influence immune activation and virological control [21], contributing to a broader understanding of how BIC/TAF/FTC performs in real-world immunological environments.

In our cohort, where 68.9% of PLWH were aged ≥50 years, the clinical stability observed is supported by integrated analyses of aging populations and Italian multidisciplinary experience in managing polypharmacy [2, 6].

The strengths of our study lie in its comprehensive assessment of a wide range of laboratory parameters reflecting multiple organ systems and focus on an older clinical population with significant comorbidity burden. Limitations include the retrospective design, lack of a comparator group, unavailability of nadir CD4, CDC stage, years on ART, and number of prior regimens due to institutional data system limitations, as well as the absence of eGFR calculation and advanced inflammatory biomarkers (IL-6, D-dimer).

In summary, the real-world evidence presented here aligns with existing literature supporting BIC/TAF/FTC as an effective, tolerable, and safe switch option in ART-experienced HIV populations.

In this real-life cohort of 177 PLWH, switching to BIC/TAF/FTC resulted in a statistically significant improvement in virological suppression

(p=0.007), a significant increase in the CD4/CD8 ratio reflecting improved immune reconstitution (p<0.001), a beneficial reduction in total cholesterol, and excellent laboratory safety across all assessed domains. These findings strongly support BIC/TAF/FTC as a reliable and well-tolerated option for ART optimization in routine clinical practice.

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Conflict of interest
Authors declare no conflict of interest.

Ethical consideration
Local ethics committee approval was waived since this study is a sub-analysis of a previous observational study performed in our Infectious Diseases Unit.

Authors contribution
GP, MD, MaG, MyG, MA, AG, AS, FGM, ClI, SA, GN, CA, ChI; Writing Original draft: GP. Writing/revision: GP, MaG, AC, ChI. Data curation: MyG. Visualization: GP, MD, MaG, MyG, MA, AG, AS, FGM, ClI, SA, GN, CA, ChI. Supervision: GP, DM, MaG, AC, ChI.

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