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Efficacy and safety of B/F/TAF in naive people with HIV: real-life data from the SHiNE and SHiC cohorts.

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Background

- The combination of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a single-tablet antiretroviral therapy regimen with a **high genetic barrier**, **favorable tolerability**, and **few interactions with other drugs**.
- The combination of B/F/TAF is recommended for the treatment of people with HIV (PWH), both naïve and experienced[1].
- Our study aims to **investigate the efficacy and safety of B/F/TAF for naive PWH in real life**.

Methods

- We used data from the *SHiNE and SHiC cohort studies*, who collect data of PWH from centers in Sardinia and Sicily,
- We performed a multicenter, retrospective, observational analysis including **all PWH who started B/F/TAF as first-line antiretroviral treatment**.
- We collected demographical, clinical, viro-immunological, and biochemical data at three time points: **baseline**, **6 months**, and **12 months**.
- To identify significant changes across these time points we used Wilcoxon rank-sum test, after assessing distribution normality. A significant *p*-value was defined as <0.05.

Results – 1

- 159 naïve PWH were included, with a median age of 42.3 years (IQR 33.5-52-5).
- Most of them were male (127, 79.9%), while 30 were cis female (18.9%) and 2 were transgender female (1.2%).
- Notably 91 (57.2%) PWH had less than 350 CD4 cells/mm^3 at diagnosis, 49 (30.8%) less than 200 CD4 cells/mm^3, and 19 (11.9%) had AIDS defining conditions.
- The characteristics of the population are summarized in Table 1.
- At 6 months 107/134 (79.8%) PWH had a HIVRNA < 50 copies/mL, while 133 (99.2%) had less than 200 copies/mL. At 12 months, 78/89 (87.6%) had an HIVRNA <50 copies/mL and 88 (98.9%) less than 200 copies/mL (Figure.1).
- Of the 107 PWH undetectable at 24 weeks, only 6 had a viral blip at 48 weeks. Of the 26 PWH who still had >50 copies/ml at 24 weeks, 14/18 (77.8%) were found to be undetectable at 48 weeks.

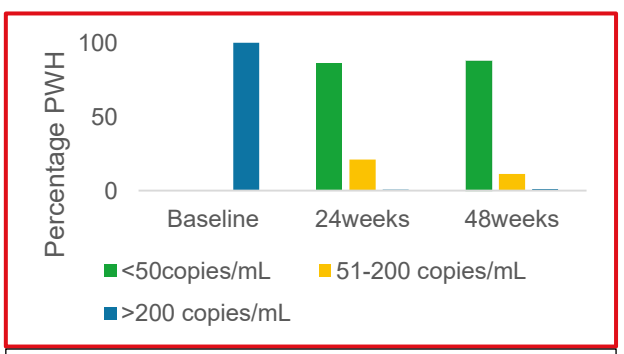

Figure 1. HIV-RNA copies/ml changes after 24 and 48 weeks of ARV therapy with BIC/TAF/FTC in 159 naïve people with HIV.

Characteristics	
Age (years), median (IQR)	42.3 (33.5-52.5)
Sex, n (%)	
Male	127 (79.9)
Cis Female	30 (18.9)
Trans Female	2 (1.2)
Italian, n (%)	189 (87.4)
Risk factor for acquiring HIV, n (%)	
Heterosexual	60 (37.7)
MSM	93 (58.5)
IDU	6 (3.8)
Smoking, n (%)	45 (28.3)
Alcohol, n (%)	41 (25.8)
Comorbidities, n (%)	
Hypertension	25 (15.7)
Hypercholesterolemia	20 (12.6)
Psychiatric disorders	14 (8.8)
Diabetes	11 (6.7)
HCV coinfection, n (%)	8 (5)
HBsAg positive, n (%)	3 (1.9)
Not ART drugs, n (%)	
0	86 (54)
1	47 (29.5)
2	10 (6.3)
3	6 (3.8)
4	8 (5)
>4	2 (1.2)
Zenith HIV-RNA (log_{10} copies/mL), median (IQR)	5.12 (4.35-5.60)
HIV-RNA >100,000 copies/mL, number (%)	85 (53.4)
Nadir CD4+ (cells), median (IQR)	310 (160-472)
CD4+ <200 cells/mm^3, number (%)	49 (30.8)
AIDS defining conditions at baseline, number (%)	19 (11.9)

MSM: men who have sex with men; IDU: intravenous drug users

Table 1. Characteristics of 159 naïve people with HIV starting BIC/TAF/FTC

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Results – 2

- **Median CD4 cells/mm^3 and ratio CD4/CD8 increased significantly at 24 and 48 weeks** (Table 2).
- Regarding tolerability, we observed a **significant reduction in transaminase values**, with creatinine values increasing slightly at 24 weeks and then stabilizing at 48 weeks. There was a modest increase in total cholesterol, and LDL values during the observation period, with an unchanged total cholesterol/HDL ratio (Table 2)

	Baseline	6 months	12 months
CD4 cells/ml, median (IQR)	331 (154-508)	484.5 (310-780)*	552 (394-843)*#
CD8 cells/mL, median (IQR)	839 (516-1214)	824 (647-1159)	851 (645-1242.3)
CD4/CD8 cells/ml, median (IQR)	0.35 (0.16-0.53)	0.57 (0.35-0.83)*	0.65 (0.39-0.95)*#
Creatinine mg/mL, median (IQR)	0.8 (0.67-0.92)	0.88 (0.78-1)*	0.87 (0.8-1.01)*
ALT UI/L, median (IQR)	26 (18-38)	22 (16-29.5)*	21 (16-29)*
AST UI/L, median (IQR)	27 (22-36)	23.5 (19.5-29)*	23 (19-29)*
Blood glucose mg/dl, median (IQR)	87 (78-93)	86 (78-94)	91 (82-104)
Total cholesterol mg/dl, median (IQR)	160 (136-186)	176 (149-199)*	174 (150-204)*
HDL mg/dl, median (IQR)	40 (33-49)	44 (37-53)	45 (39-52)
LDL mg/dl, median (IQR)	95.4 (78.2-115)	104 (87.4-127.3)*	102.6 (87.2-136.4)*
Triglycerides mg/dl, median (IQR)	91 (71-130)	96 (68-139)	91 (68-123)
Total cholesterol/HDL	3.8 (3.3-4.8)	3.7 (3.3-4.8)	3.9 (3.3-4.7)

* p-value<0.05 when compared with baseline; #p-value<0.05 when compared with 6-month. IQR: interquartile range; ALT: alanine aminotransferase; AST: aspartate aminotransferase; HDL: high-density lipoprotein; DL: low-density lipoprotein

Table 2. Characteristics at baseline and after 6 and 12 months of follow-up of 159 naïve people with HIV starting BIC/TAF/FTC.

- **Eighteen (11.3%) PWH interrupted B/F/TAF** during the observation period. Of note only 3 (1.9%) discontinued due to toxicity. The reasons for discontinuation are detailed in Table 3.

Reasons	Number (%)
Toxicity n (%)	3 (16.6)
DDI n (%)	1 (5.6)
LTFU n (%)	4 (22.2)
Switch to LA n (%)	1 (5.6)
Switch to dual therapy n (%)	4 (22.2)
Patient's choice n (%)	1 (5.6)
Moved to other hospital n (%)	2 (11.1)
Others n (%)	2 (11.1)

Table 3. Reasons for discontinuation of B/F/TAF in 18 PWH.

Conclusions

Our study confirms the great efficacy of B/F/TAF in naive PWH, regardless of baseline viral load. The regimen's tolerability is further highlighted by the minimal adverse events that led to discontinuation, underlining its suitability also in a severely immunocompromised population. These findings contribute to affirm the pivotal role of B/F/TAF as a preferred choice for starting treatment in real-world settings[2].

References

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