

Effectiveness and tolerability of BIC/FTC/TAF in PWH in routine clinical practice in Türkiye: 12- month outcomes from KLİMİK HIV TR Cohort

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PURPOSE

This study aimed to evaluate the 12-month effectiveness and tolerability of BIC/FTC/TAF in treatment-naïve (TN) and treatment-experienced (TE) people living with HIV (PWH) in Türkiye, using data from KLİMİK HIV-TR Cohort.

METHODS

This non-interventional, observational, retrospective study was conducted across 33 centers in Türkiye. PWH ≥18 years old on BIC/FTC/TAF regimen for at least 12 months, either as TN or TE were included. Primary endpoint was virological suppression at week 48 (HIV-1 RNA <200 copies/mL). Secondary endpoints included changes in CD4 count and CD4/CD8 ratio, tolerability, rate of treatment discontinuation due to drug-related adverse events, and reasons for switching to BIC/FTC/TAF in treatment-experienced PWH. Categorical variables were presented as frequency and percentage, continuous variables were described using median, 25 & 75 percentiles, and minimum & maximum values as descriptive statistics. Wilcoxon test was used to analyze the difference between dependent measurements over time. Statistical significance was defined as p<0.05.

CONCLUSIONS

BIC/FTC/TAF demonstrated high virologic suppression rates in PWH regardless of baseline viral load and CD4 levels; supporting its effectiveness on a broad range of population including those with very high baseline viral load. (HIV-1 RNA >1.000.000 and 5.000.000 copies/mL). No new or unexpected safety signals were observed.

RESULTS

Total of 2.262 PWH (1.122 TN, 1.140 TE) were included in the analysis. Before treatment, 24.2% of TN PWH had HIV-1 RNA >1.000.000 copies/mL, and 55.7% had CD4 counts <350 cells/mm³. At week 48, viral suppression (HIV-1 RNA <200 copies/mL) rates were 98.3% and 96.5% respectively for TN and TE PWH. Median CD4/CD8 ratio in treatment-naïve PWH increased from 0.44 at baseline to 1.06 by week 48 (p<0.001). For both TN and TE groups, total cholesterol/HDL ratio remained stable through 48 weeks; whereas median Non-HDL cholesterol levels had a decrease (p<0.001). The discontinuation rate was 1.7% and 2.6% in TN and TE groups, respectively. No additional or serious adverse events leading to treatment discontinuation were identified.

Figure 1. Virological Suppression Rates at Week 4-8, 24, and 48 in TN PWH

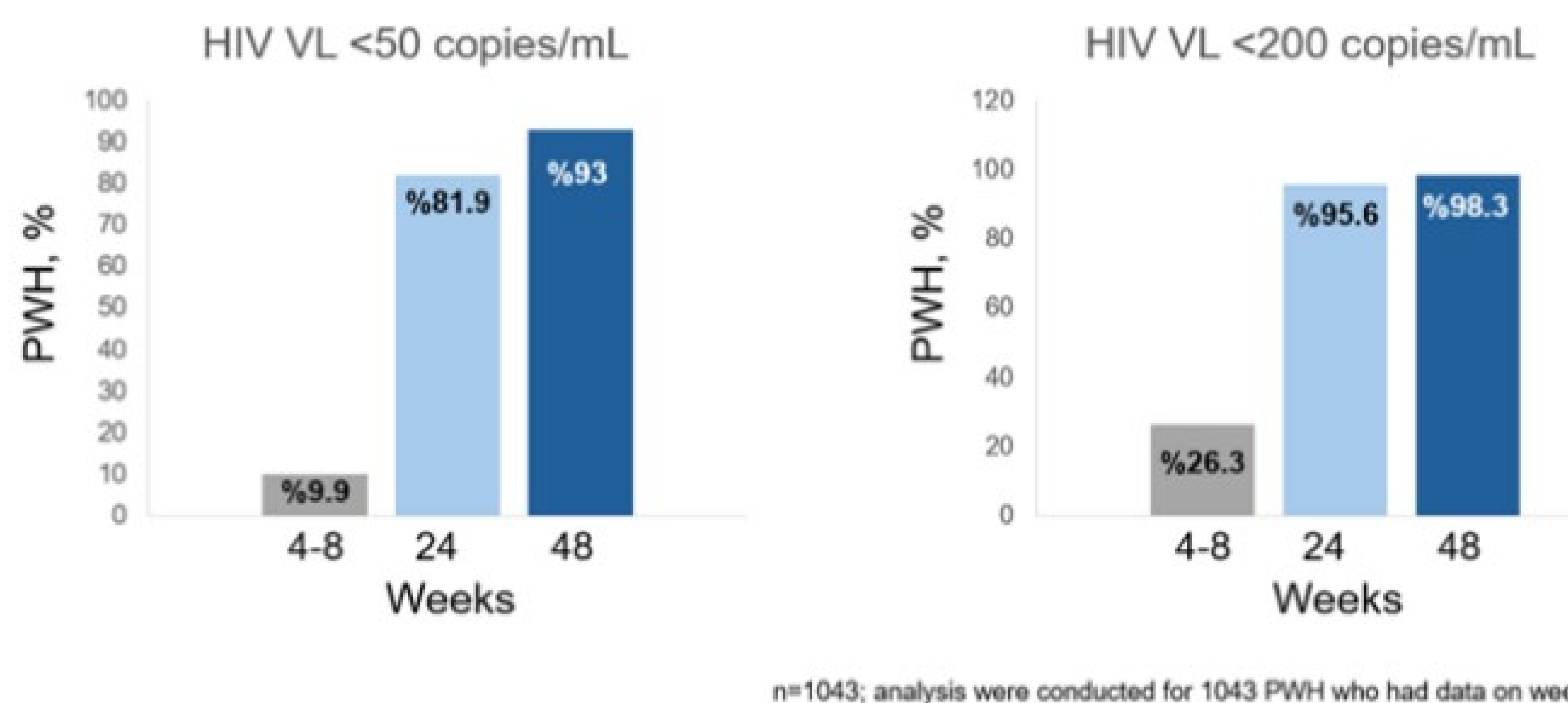


Table-1. Baseline viral loads of treatment-naïve PWH and virological suppression rates at 24 and 48 weeks after BIC/FTC/TAF treatment

Parameters	Week 24		Week 48	
	HIV-1 RNA < 50 c/mL (%)	HIV-1 RNA < 200 c/mL (%)	HIV-1 RNA < 50 c/mL (%)	HIV-1 RNA < 200 c/mL (%)
Before BIC/FTC/TAF				
HIV-1 RNA (c/mL)				
>100.000 (n=993)	80,4	95	92,5	98
>500.000 (n=521)	72,3	93,1	91,1	97,5
>1.000.000 (n=272)	67,1	91,4	88,4	98
>5.000.000 (n=36)	53,1	90,6	85,3	94,1

Table-2. Biochemical Parameters Before BIC/FTC/TAF Initiation and at Week 48 of Treatment

Parameters		N	Before B/F/TAF	Week 48	p-value
			Median (Q25–Q75)	Median (Q25–Q75)	
Treatment-Naïve	ALT	958	23 (18–29)	21 (14–29.1)	<0.001
	Creatinine	987	0.83 (0.70–0.98)	0.90 (0.78–1.00)	<0.001
	Total Cholesterol	929	167 (139–202)	160 (148–219)	<0,001
	Triglyceride	917	138 (106–171)	139 (122–145)	0,665
	HDL	927	44 (37–48)	45 (40–49)	<0,001
	LDL	914	101,7 (87–113)	110 (91–131)	<0,001
	Non-HDL Cholesterol	918	125 (97–157)	120 (104–169)	<0.001
Treatment-Experienced	Total Cholesterol/HDL Ratio	918	4.08 (3.25–4.93)	3.93 (3.23–4.93)	0.998
	ALT	1027	23 (18–28)	22 (16–30.4)	0.137
	Creatinine	1043	0.90 (0.75–1.05)	0.90 (0.80–1.00)	0.001
	Total Cholesterol	965	186 (153–218)	172 (150–222)	<0,001
	Triglyceride	949	145 (116–181)	140 (129–145)	<0,001
	HDL	952	46 (42–50)	45 (40–50)	<0,001
	LDL	951	108 (95–118)	117 (99–139)	<0,001
	Non-HDL Cholesterol	943	140 (106–171)	126 (104–176)	<0.001
	Total Cholesterol/HDL Ratio	943	4.05 (3.17–4.93)	3.93 (3.24–4.98)	0.839

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