

## Dettaglio abstract

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**Title:** BIC/FTC/TAF in ART-naïve key populations: real-life data from the Icona cohort

**Presentation type:** Oral Poster

### Session/Topic

Treatment of naïve PLWH: current strategies and rapid start of ART

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### Abstract

**Background:** Real world data are scarce on several key population starting a first line regimen with bicitgravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF). The aim of this study is to evaluate the effectiveness of BIC/FTC/TAF in ART-naïve people living with HIV (PLWH), focusing on the subgroups of female, late-presenters, PLWH with advanced HIV disease and PLWH >50 years.

**Methods:** Observational study on ART-naïve PLWH, enrolled in Icona who started BIC/FTC/TAF (Jun 2016 -Dec 2021). Primary endpoint: treatment failure (TF) i.e. virological failure (2 consecutive HIV-RNA > 200 cps/ml or 1 HIV-RNA>1000 cps/ml >6 months from start) or discontinuation (TD) of BIC/FTC/TAF for any reason. Secondary objectives: i) TD for any reason (TD); ii) TD for toxicity/intolerance (TDT); iii) TD for simplification (TDS).

Standard survival analysis (Kaplan-Meier curves and log-rank test) were used. Unadjusted and adjusted hazard ratios (HR) of TF were estimated by Cox regression according to the different exposures of interest: age ( $\geq 50$  years old); sex; late presenters ( $< 350$  cell/mm<sup>3</sup> or AIDS); PLWH with advanced HIV disease (CD4 $< 200$  cell/mm<sup>3</sup> or AIDS).

**Results:** 416 ART-naïve patients started BIC/FTC/TAF (Table 1): 124 patients  $\geq 50$  years (29.8%), 73 females (17.5%), 242 late presenters (58.1%) and 169 had advanced HIV disease (40.6%).

Over a median follow-up of 0.9 years (IQR 0.4-1.2), 51/416 PLWH had TF (12.2%), including 7 VF and 44 TD. The 1-year probability of TF was 11.0% (95%CI 7.9-15.1), (details in Table 2A). In the Cox regression models adjusted for confounders, none of the exposure groups analyzed have been found to be associated with a higher risk of TF (Table 3A).

45/416 PLWH had TD (10.8%). 16 PLWH discontinued for toxicity/intolerance (3.8%), 15 for simplification (3.6%), 4 for failure (1.0%), 1 for patient's decision (0.2%) and 9 (2.2%) for other reasons (5 for enrolment in RCT and 4 unknown). The most used ARV regimens after discontinuation were the DTG-based dual regimens (n=23).

The 1-year KM probabilities of discontinuing BIC/FTC/TAF for any reason, toxicity/intolerance or simplification are shown on Table 2B,2C,2D. By multivariate Cox analysis, none of the exposure groups were associated with the risk of the TD endpoints.

**Conclusions:** First line therapy with BIC/FTC/TAF demonstrated high effectiveness in a real world setting (11.0% TF at 1-year). This was also confirmed, although limited by the number of events, in populations at risk of lower response to therapy, i.e. older individuals, females, and severely immunosuppressed individuals.

Table 1. Baseline demographic and clinical characteristics of the ART-Naïve starting BIC/FTC/TAF

	ART- Naïve (N=416)	
Italian, n(%)	239	70.43
ethnicity, Caucasian, n(%)	319	79.1
Sex, Female, n(%)	73	17.5
Year of BIC/FTC/TAF start, median (IQR)	2020	2020-2021
Year HIV diagnosis, median (IQR)	2020	2019-2020
Age, years, median (IQR)	42	32-52
Age, >50 years, n(%)	124	29.81
Italian Geo Zone, n(%)		
Northem	237	57.25
Central	113	29.7
Southern/Islands	54	13
Mode of HIV Transmission, n(%)		
Heterosexual	172	41.35
IVDU	19	4.57
MSM	188	45.19
Other/Unknown	37	8.89
HCVAb positive status, n(%)	20	4.81
HIV-1 RNA positive status, n(%)	11	2.64
Smoker, Yes, n(%)	143	34.38
CD4 c-stage, n(%)	59	14.18
CD4, cells/mm <sup>3</sup> , median (IQR)	280	87-495
CD4<200 cells/mm <sup>3</sup> , n(%)	165	39.66
CD4<350 cells/mm <sup>3</sup> , n(%)	241	57.9
HIV-RNA, log <sub>10</sub> copies/mL, median (IQR)	5.02	4.39-5.60
HIV-RNA >5 log <sub>10</sub> copies/mL, median (IQR)	211	50.72
Total Cholesterol, median (IQR)	159	137-187
LDL cholesterol, median (IQR)	102	80-124
HDL cholesterol, median (IQR)	40	33-49
Triglycerides, median (IQR)	94	71-119
Serum glucose, median (IQR)	87	80-93
eGFR, CKD-EPI, median (IQR)	106.4	92.2-117.5
eGFR<90 ml/min/1.73m <sup>2</sup> , n(%)	307	73.8
BMI, kg/m <sup>2</sup> , median (IQR)	23	20.6-24.7
Diabetes diagnosis, n(%)	14	3.37
CVD diagnosis, n(%)	3	0.72
NADM diagnosis, n(%)	11	2.64
CVD diagnosis, n(%)	12	2.88
Follow-up on BIC/FTC/TAF, years, median (IQR)	0.89	0.44-1.22

Table 2. Number of the events and Kaplan-Meier estimated 1-yr probability of (A) TF, (B) TD for any reason (C) TD toxicity/intolerance (D) TD simplification, overall and in the 4 different groups

	Treatment Failure		
	events	1-yr cum. probability (95%CI)	log-rank p
<b>(A)</b>			
Overall	51/416 (12.2%)	11% (7.9-15.1)	
Age<50 years	23/292 (7.9%)	9.2% (6.1-13.8)	0.397
Age>=50 years	19/124 (15.3%)	14.9% (9.2-24.3)	
Female	7/73 (9.6%)	9.4% (4.3-19.9)	
Male	44/243 (18.2%)	11.3% (7.9-16.0)	0.536
Non late presenters	21/174 (12.1%)	9.4% (5.6-15.5)	
Late presenters	30/242 (12.4%)	12.1% (8.0-18.2)	0.514
Non advanced HIV disease	20/247 (8.1%)	8.7% (4.4-13.8)	
Advanced HIV disease	23/169 (13.6%)	14.3% (9.2-21.8)	0.263
<b>(B)</b>			
Overall	45/416 (10.8%)	9.9% (7.0-13.8)	
Age<50 years	29/292 (9.9%)	8.8% (5.7-13.4)	0.545
Age>=50 years	16/124 (12.9%)	12.3% (7.0-21.1)	
Female	7/73 (9.6%)	9.5% (4.4-20.0)	
Male	38/243 (15.6%)	9.5% (6.8-14.4)	0.822
Non late presenters	20/174 (11.5%)	8.3% (4.9-13.9)	0.860
Late presenters	25/242 (10.3%)	11% (7.0-16.9)	
Non advanced HIV disease	25/247 (10.1%)	7.9% (4.8-12.3)	
Advanced HIV disease	20/169 (11.8%)	12.7% (7.9-20.2)	0.310
<b>(C)</b>			
Overall	16/416 (3.8%)	3.9% (2.3-6.7)	
Age<50 years	12/292 (4.1%)	4.5% (2.4-8.2)	0.640
Age>=50 years	4/124 (3.2%)	2.7% (0.9-7.2)	
Female	3/73 (4.1%)	4.6% (1.5-13.6)	0.883
Male	13/243 (5.3%)	3.8% (2.0-6.9)	
Non late presenters	7/174 (4.0%)	3.0% (1.0-7.0)	0.883
Late presenters	9/242 (3.7%)	4.8% (2.3-9.1)	
Non advanced HIV disease	8/247 (3.2%)	3.1% (1.3-7.2)	0.352
Advanced HIV disease	20/169 (11.8%)	12.7% (7.9-20.2)	0.310
<b>(D)</b>			
Overall	15/416 (3.6%)	3.9% (2.3-6.7)	
Age<50 years	10/292 (3.4%)	4.5% (2.4-8.2)	0.641
Age>=50 years	5/124 (4.0%)	2.7% (0.9-7.2)	
Female	2/73 (2.7%)	4.6% (1.5-13.6)	0.883
Male	13/243 (5.3%)	3.8% (2.0-7.0)	
Non late presenters	7/174 (4.0%)	2.9% (1.2-7.0)	0.998
Late presenters	8/242 (3.3%)	4.8% (2.3-9.1)	
Non advanced HIV disease	11/247 (4.4%)	3.1% (1.3-7.2)	0.352
Advanced HIV disease	4/169 (2.4%)	5.1% (2.6-9.9)	

Table 3. Hazard ratios (HR) and Adjusted hazard ratios (AHR) of (A) TF, (B) TD for any reason, (C) TD toxicity/intolerance, (D) TD simplification of BIC/FTC/TAF from fitting different Cox regression models in the 4 different groups

(A)	Treatment Failure					
	HR	95%CI	p	AHR	95%CI	p
Age, >=50 years (vs <50years) <sup>1</sup>	1.28	0.72-2.26	0.398	1.36	0.74-2.48	0.323
Gender, Male (vs. female) <sup>2</sup>	1.28	0.58-2.85	0.537	1.37	0.61-3.05	0.443
Late presenters (vs. non late-presenters) <sup>3</sup>	1.21	0.68-2.12	0.514	1.23	0.68-2.21	0.496
Advanced HIV disease (vs. non advanced) <sup>4</sup>	1.37	0.78-2.39	0.265	1.46	0.81-2.63	0.208
<b>(B)</b>						
Age, >=50 years (vs <50years) <sup>1</sup>	1.21	0.65-2.23	0.546	1.14	0.51-2.57	0.748
Gender, Male (vs. female) <sup>2</sup>	1.09	0.49-2.45	0.832	1.30	0.68-2.47	0.431
Late presenters (vs. non late-presenters) <sup>3</sup>	1.05	0.58-1.92	0.861	1.02	0.54-1.90	0.961
Advanced HIV disease (vs. non advanced) <sup>4</sup>	1.36	0.75-2.46	0.312	1.37	0.73-2.55	0.327
<b>(C)</b>						
Age, >=50 years (vs <50years) <sup>1</sup>	0.76	0.25-2.37	0.642	0.93	0.28-3.03	0.903
Gender, Male (vs. female) <sup>2</sup>	0.91	0.26-3.20	0.883	1.01	0.29-3.55	0.990
Late presenters (vs. non late-presenters) <sup>3</sup>	1.00	0.37-2.69	0.998	1.04	0.37-2.92	0.938
Advanced HIV disease (vs. non advanced) <sup>4</sup>	1.59	0.59-4.23	0.357	1.72	0.62-4.78	0.300
<b>(D)</b>						
Age, >=50 years (vs <50years) <sup>1</sup>	1.07	0.37-3.14	0.896	0.97	0.31-3.0	0.954
Gender, Male (vs. female) <sup>2</sup>	1.28	0.29-5.8	0.745	1.27	0.28-5.68	0.756
Late presenters (vs. non late-presenters) <sup>3</sup>	0.94	0.34-2.58	0.898	0.9	0.30-2.64	0.846
Advanced HIV disease (vs. non advanced) <sup>4</sup>	0.61	0.19-1.91	0.393	0.56	0.17-1.90	0.343

<sup>1</sup> AHR adjusted for nationality and mode of HIV transmission; <sup>2</sup> AHR adjusted for nationality; <sup>3</sup> adjusted for gender, mode of HIV transmission, HIV-RNA and nationality; <sup>4</sup> AHR adjusted for gender, mode of HIV transmission, HIV-RNA and nationality