Dettaglio abstract

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Title: BIC/FTC/TAF is effective on PLWH with low CD4 counts: real-life data from the Icona cohort

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Abstract

Methods: Observational study of patients enrolled in the Icona cohort starting BIC/FTC/TAF as first line or switch ART. Naïve PLWH were defined as late presenters (LP) with CD4 200 copies/ml or 1 HIV-RNA >1000 copies/mL after 6 months for ART-naïve). Statistical analyses included descriptive statistics, and standard survival analysis. Cox-regression models were used to investigate the role of LP/VLP (ART-naïve) and the role of CD4 at switch (ART-experienced) on the risk of TF.

Results: 310 ART-naïve and 1115 virologically controlled ART-experienced patients included (Table1). ART-Naïve PLWH: median HIV-RNA 4.96-log10 copies/ml (4.39-5.56), median CD4 290 cells/mmc (103-496), 178 subjects LP (57.4%) and 124 VLP (40.0%). In median follow-up of 7.5 months, 38 patients underwent TF (12.2%). TF occurred in 21 LP (11.8%) vs 17 non-LP (12.9%) p=0.77 and in 16 VLP (12.9%) vs 22 non-VLP (11.8%), p=0.78 Out of 38 TF, 4 were VF and 34 were TD; main reasons for TD are showed in Table2A.The overall 1-year probability of TF was 13.2% (95%CI 9.1-19.0). In the Cox regression models after adjusting for HIV-RNA, sex, Italian and mode of HIV transmission there were no significant differences in the risk of TF both for LP (vs non-LP aHR=1.24; 95%CI: 0.61-2.50) and VLP (vs non-VLP aHR=1.76; 95%CI: 0.87-3.56).

ART-experienced PLWH: median CD4 703 cells/mmc (505-933), 120 PLWH had CD4 =350 cells/mmc, p=0.61. Out of 89 TF, 12 were VF and 77 as TD, main reasons for TD are showed in Table2B. Overall the 1-year probability of TF was 4.9% (3.7-6.5). In the Cox regression models after adjusting for calendar year of first cART, CD4 nadir and duration of viral suppression, having a CD4 cell count

Table 1. Main patients' characteristics

	ART-naive N=310		ART-experienced N=1,115	
Italian, n(%)	217	70	939	84.2
Gender, Female, n(%)	51	16.4	209	18.7
Year of BIC start, median (IQR)	2020	2019-2020	2019	2019-2020
Year HIV diagnosis, median (IQR)	2020	2019-2020	2013	2008-2016
Year cART start, median (IQR)	2020	2019-2020	2015	2011-2017
Age, years, median (IQR)	41	31-51	47	38-55
Age, >50 years, n(%)	86	27.7	472	42.3
Italian Geo Zone, n(%)				
Northern	192	61.9	696	62.4
Central	85	27.4	345	30.9
Southern/Islands	33	10.6	74	6.6
Mode of HIV Transmission, n(%)				
Heterosexual	119	38.4	405	36.3
IVDU	15	4.8	87	7.8
MSM	157	50.6	572	51.3
Other/Unknown	19	6.1	51	4.6
HCVAb positive status, n(%)	16	5.2	110	9.9
HBsAg positive status, n(%)	1	2.3	41	3.7
Smoker, Yes, n(%)	108	34.8	474	42.5
CDC C-stage, n(%)	39	12.6	176	15.8
CD4, cells/mmc, median (IQR)	290	103-496	703	505-933
CD4<200 cells/mmc, n(%)	120	38.7	22	2
CD4<350 cells/mmc, n(%)	177	57.1	120	10.8
HIV-RNA, log10 copies/mL, median (IQR)	4.96	4.39-5.56	1.00	0.00-1.43
HIV-RNA >5 log10 copies/mL, median (IQR)	152	49	0	0
Total Cholesterol, median (IQR)	159	138-187	193	169-218
LDL cholesterol, median (IQR)	103	81-124	120	100-144
HDL cholesterol, median (IQR)	41	33-49	49	41-58
Triglycerides, median (IQR)	98	72-142	116	83-169
Serum Glucose, median (IQR)	87	80-94	87	80-94
eGFR, CKD-EPI, ml/min/1.73m2, median (IQR)	106	92.2-117.4	89.5	77.3-101.8
BMI, Kg/m2, median (IQR)	23	20.9-24.8	24.2	22.1-26.8
Diabetes diagnosis, n(%)	11	3.5	59	5.3
CVD diagnosis, n(%)	3	1	18	1.3
NADM diagnosis, n(%)	8	2.6	33	3
CKD diagnosis, n(%)	10	3.2	151	13.5
ESRD diagnosis, n(%)	0	0	1	0.1
ESLD diagnosis, n(%)	0	0	2	0.2
Follow-up on BIC, years, median (IQR)	0.62	0.32-1.08	1.11	0.80-1.38
Years of VS before switch, median (IQR)	.	.	4.3	2.4-7.5
Class previous regimen, n (%)				
INSTI-based	.	.	958	85.9
NNRTI-based	.	.	83	7.4
bPI –based	.	.	56	5.0
other/dual	.	.	18	1.6

Table 2. Reasons for BIC/FTC/TAF discontinuation in (A) ART-naïve and (B) ART-experienced virologically controlled PLWH who underwent TF

(A) ART-NAIVE	n	percent
VIROLOGICAL FAILURE	2	5.9%
DEATH	1	2.9%
OTHER	7	20.6%
SIMPLIFICATION	11	32.3%
PATIENT'S DECISION	0	0.0%
TOXICITY	13	38.2%
Other toxicities	3	
Clinical contraindications	1	
DDI	3	
GI intolerance	2	
Allergic reactions	2	
CNS symptoms	1	
Liver Toxicity	1	

(B) ART-EXPERIENCED	n	percent
VIROLOGICAL FAILURE	3	3.9%
OTHER	19	24.7%
SIMPLIFICATION	31	40.3%
PATIENT'S DECISION	1	1.3%
TOXICITY	23	29.9%
Arthro-myalgia	1	
Clinical contra-indications	1	
Other toxicities	2	
DDI	1	
GI intolerance	2	
Allergic reactions	4	
CNS symptoms	4	
PNS symptoms	3	
Renal toxicity	3	
Lipidic Metabolism toxicity	2	