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Long-term effectiveness of bictegravir-emtricitabine-tenofovir alafenamide (BIC/FTC/TAF) as switch strategy in virologically suppressed people with HIV across age strata: real-life data from the ICONA-BIC Study

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PURPOSE

- The ageing of people with HIV (PWH) presents increasing challenges (comorbidities, polypharmacy and age-related fragility etc). The choice of an antiretroviral regimen both effective and well-tolerated in long-term is essential.
- Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) has demonstrated high efficacy and safety in the general adult population, however the real-world evidence in PWH aged ≥ 65 remains limited.
- We aim to confirm in an observational setting the long-term effectiveness of switching to BIC/FTC/TAF in older PWH (≥65 years old) who were already virologically suppressed

METHODS

- Study Design: Observational study in PWH enrolled in the ICONA cohort who started BIC/FTC/TAF as switching regimen while virologically suppressed from Jun2016 to Aug-2023.
- Exposure of interest: Age strata: <65 vs. ≥65 years at switch to BIC/FTC/TAF.
- Primary endpoint: time to treatment failure, TF: composite outcome of discontinuation for toxicity/intolerance or virological failure (2 consecutive HIV-RNA>200 copies/ml, or 1 >1000 copies/ml followed by ART change).
- Secondary endpoints: 1) virological failure, VF; 2) treatment discontinuation for toxicity/intolerance, TDT.
- Statistical analysis: Cumulative probabilities of endpoints were calculated by Kaplan-Meier curves till 192-weeks. Association between age strata and TF and TDT endpoints were investigated by Cox regression models adjusted for mode of HIV transmission, Italy-born, years on ART.

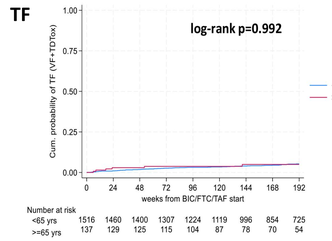
CONCLUSIONS

- BIC/FTC/TAF was effective through a median follow-up of over 4 years, both in PWH <65 and ≥65 years (TF probability of 5.3% and 4.9% at 192-weeks, respectively).
- This observational setting confirms trial data of BIC/FTC/TAF as an effective long-term option for virologically suppressed older adults ≥65 years of age, with favorable tolerability (TDT probability of 5% at 192-weeks) and optimal virological control (0% VF) in this population.

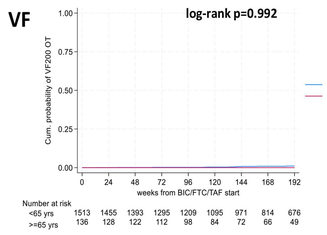
RESULTS

- 1,653 ART-experienced PWH switched to BIC/FTC/TAF:
  - <65 years: 1,516 (91.7%)
  - ≥65 years : 137 (8.3%)
- Baseline characteristics and comparison between <65 vs ≥ 65 years shown in Table 1.
- Over a median follow-up of 216 weeks (IQR 156, 244):
  - 76 PWH experienced TF (4.6%): 70 (4.6%) among <65y vs. 6 (4.4%) among ≥65y
  - 11 PWH experienced VF (0.7%): 11 (0.7%) among <65y vs. 0 (0%) among ≥65y
  - 65 PWH experienced TDT (3.9%): 59 (3.9%) among <65y vs. 6 (4.4%) among ≥65y
- Kaplan-Meier curves according to age strata with log-rank test p-values and cumulative probabilities at 48-, 96-, 144- and 192-weeks are shown in Figure1 for the 3 endpoints.
- Most frequent reasons for TDT in the <65 years group were neuropsychiatric events (n=14), lipids metabolism toxicity (n=13), gastrointestinal toxicity and weight gain (n=9); while for ≥65 years group was renal toxicity (n=3); the full list is shown in Table 2.
- Also in the adjusted analysis, we found no evidence for a different risk of TF or TDT in PWH aged ≥65 years compared to younger PWH.
  - TF: aHR ≥65y vs <65y=1.02 (95%CI 0.43-2.38)
  - TDT: aHR ≥65y vs <65y=1.13 (95%CI 0.48-2.65)

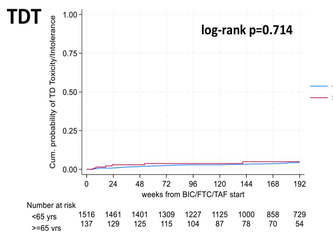
Figure 1. Kaplan-Meier curves showing cumulative probabilities of TF, VF and TFT according to age strata



Weeks	<65 years Cum. Probability [95%CI]	≥65 years Cum. Probability [95%CI]
48	1.82% [1.25-2.65]	2.95% [1.12-7.68]
96	3.15% [2.36-4.20]	3.75% [1.58-8.77]
144	3.95% [3.03-5.13]	4.95% [2.21-10.88]
192	5.31% [4.17-6.76]	4.95% [2.21-10.88]



Weeks	<65 years Cum. Probability [95%CI]	≥65 years Cum. Probability [95%CI]
48	0.14% [0.03-0.55]	0% [0.0-0.0]
96	0.21% [0.07-0.66]	0% [0.0-0.0]
144	0.79% [0.41-1.51]	0% [0.0-0.0]
192	1.04% [0.57-1.90]	0% [0.0-0.0]



Weeks	<65 years Cum. Probability [95%CI]	≥65 years Cum. Probability [95%CI]
48	1.76% [1.20-2.57]	2.95% [1.12-7.68]
96	2.93% [2.18-3.95]	3.75% [1.58-8.77]
144	3.30% [2.48-4.38]	4.95% [2.21-10.88]
192	4.44% [3.41-5.78]	4.95% [2.21-10.88]

Table 1. Characteristics of PWH switching to BIC/FTC/TAF while virologically suppressed

	<65 years (N=1516, 91.7%)	≥ 65 years (N=137, 8.3%)	p-value	Total (N=1653, 64%)
Italian, n (%)	1,256 (82.8%)	134 (97.8%)	<.001	1,390 (84.1%)
Sex at birth, Female, n (%)	293 (19.3%)	22 (16.1%)	0.351	315 (19.1%)
Age, years, median [IQR]	47 [38, 54]	70 [67, 73]	<.001	48 [39, 56]
Mode of HIV Transmission, n (%)			0.001	
Heterosexual	571 (37.7%)	71 (51.8%)		642 (38.8%)
PWID	130 (8.6%)	4 (2.9%)		134 (8.1%)
MSM	743 (49.0%)	51 (37.2%)		785 (47.5%)
Other/Unknown	72 (4.7%)	11 (8.0%)		92 (5.5%)
AIDS, n (%)	265 (17.5%)	34 (24.8%)	0.033	299 (18.1%)
Nadir CD4, cells/mm³, median [IQR]	284 [126, 427]	221 [87, 316]	<.001	277 [122, 419]
CD4 count, cells/mm³, median [IQR]	712 [512, 938]	600 [398, 807]	<.001	705 [505, 928]
eGFR, CKD-EPI, ml/min, median [IQR]	90.6 [78.4, 102.8]	68.6 [57.0, 80.4]	<.001	88.6 [76.4, 101.8]
BMI, kg/m2, median [IQR]	24.1 [22.1, 26.8]	26.0 [23.9, 28.4]	<.001	24.2 [22.2, 26.9]
Weeks follow-up after BIC/FTC/TAF start, median [IQR]	218 [114, 235]	186 [114, 235]	<.001	216 [156, 244]
At least 144-weeks follow-up	1,210 [79.8%]	90 [65.7%]	<.001	1300 (78.6%)
Previous ART-regimen			0.054	
INSTI-based	1239 (81.7%)	103 (75.2%)		1342 (81.2%)
NNRTI-based	138 (9.1%)	12 (8.8%)		150 (9.1%)
PI-based	105 (6.9%)	15 (10.9%)		120 (7.3%)
Other	34 (2.2%)	7 (5.1%)		41 (2.5%)
N. Previous ART-lines	2 [2, 4]	3 [2, 4]	0.014	2 [2, 4]
Years on ART, median [IQR]	5.2 [3.3, 8.8]	7.5 [4.2, 11.3]	<.001	5.3 [3.4, 9.0]
Years from 1st viral suppression, median [IQR]	4.5 [2.7, 7.6]	6.6 [3.5, 9.9]	<.001	4.6 [2.7, 7.8]

Abbreviations: BIC/FTC/TAF, bictegravir-emtricitabine-tenofovir alafenamide; PWID, people who inject drugs; eGFR, estimated glomerular filtration rate; BMI, body mass index; ART, antiretroviral; INSTI, Integrase strand transfer inhibitors; NNRTI, non-nucleoside reverse transcriptase inhibitors; PI, protease inhibitors;

Table 2. Detailed reasons of TDT

	n.	percent over n PWH
<65 years	60/1516	4.0%
Allergic reactions	2	0.1%
Arthro-myalgia	2	0.1%
NPEAs*	14	0.9%
Decline libido	1	0.1%
Gastro-intestinal intolerance	9	0.6%
Hepatic toxicity	1	0.1%
Lipid metabolism toxicity	13	0.9%
Osteopenia/Osteoporosis	2	0.1%
Renal toxicity	5	0.3%
Unknown	1	0.1%
Weight Gain	9	0.6%
≥65 years	6/137	4.4%
Allergic reactions	1	0.7%
NPAEs**	1	0.7%
Lipid Metabolism toxicity	1	0.7%
Renal toxicity	3	2.2%

*NPEAs (neuropsychiatric adverse events) 11 sleep disorders and 1 Depression, 1 Panic attacks, 1 Anxiety; **1 Headache*

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