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Switch to Bictegravir in real life settings in the ANRS-CO3 - AquiVIH-NA cohort

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BACKGROUND

- Bictegravir (BIC) is a high potent unboosted integrase strand-transfer inhibitor (InSTI) with a high genetic barrier to resistance co-formulated with emtricitabine (FTC) and tenofovir alafenamide (TAF).
- BIC/FTC/TAF is a safe, effective, convenient, and well tolerated single tablet regimen for once-daily use for people living with HIV (PLWH) and currently recommended as a first line or switch options.
- However, there are currently few real-world evidences on efficacy, tolerability and persistence of this regimen, including populations poorly represented in clinical trials.

METHODS

- The **ANRS-CO3 - AquiVIH-NA cohort** is an open, prospective hospital-based cohort of HIV-1-infected adults (≥18 years old) in care in 15 hospitals **in the Nouvelle Aquitaine region of south-western France.**
- The cohort collects epidemiological, clinical, biological and therapeutic data from the medical records of PLWH and who have signed informed consent since 1987.

- We conducted a retrospective analysis to evaluate the persistence of the switch to BIC/FTC/TAF in patients included in the cohort from 2018/01/01 to 2021/12/31 with the following criteria:
  - Documented HIV-1 viral load (VL) for at least 12 months prior switching.
  - Documented CD4 count for at least 24 months prior switching.
  - A suppressed VL (HIV-1 RNA ≤ 50 cp/ml) at the time of switching.
- Virological failure (VF) was defined by one HIV-1 RNA >1000 cp/ml VL or two consecutive HIV RNA >50 cp/ml VL and <1000 cp/ml VL during the follow-up period.

RESULTS

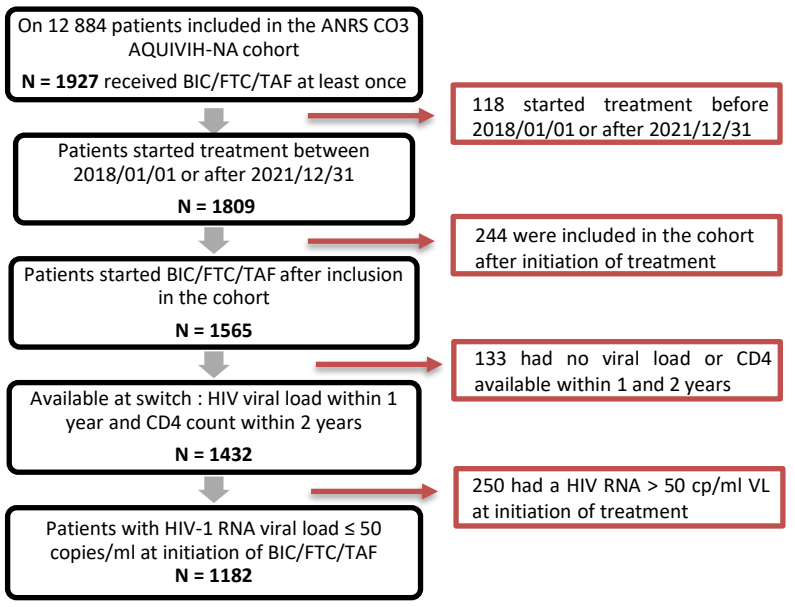

Figure 1. Flow chart of the cohort study.

Characteristics	Patients with available data (PWAD)	N*	IQR or %
Age (year),	1182		
Median (IQR)		53,1	(45.2;60.1)
Gender,	1182		
Male **(%)**		869	(73.5)
Group of contamination,	1182		
MSM , n (%)		537	(45.4)
Heterosexual , n (%)		445	(37.6)
Toxicomanes IV , n (%)		109	(9.2)
Other , n (%)		91	(7.7)
Time since first positive serology (in year),	1182		
Median (IQR)		17,9	(8.8;26.3)
Stage of infection,	1182		
C (AIDS) , n (%)		236	(20.0)
BMI (kg.m^{-2}),	1019		
Median (n IQR)		24,2	(21.6;27.2)
Missing data		163	
Origin by geographical area,	1182		
France and Europe , n (%)		1007	(82.7)
Sub-Saharan Africa , n (%)		148	(12.5)
other , n (%)		57	(4.8)
Measure of CD4 (en cells/mm^3),	1182		
Median (IQR)		692	(491;910)
Number of virological failure before switch ,	1182		
0 , n (%)		780	(66.0)
1 , n (%)		206	(17.4)
2 and more n (%)		196	(16.6)
Number of previous line of treatment,	1182		
Median (IQR)		5,0	(3.0;8.0)
End-stage renal disease,	975		
Yes		141	(14.5)
Cardiovascular event,	1182		
Yes		144	(12.2)
Diabetes mellitus,	908		
Yes		136	(15.0)
Hypertension,	942		
Yes		537	(57.0)
Cancer,	1182		
Yes		162	(13.7)
Number of comorbidity,	870		
0		252	(29.0)
1		303	(34.8)
2		172	(19.8)
3 and more		143	(16.5)

Table 1. Demographic, clinical, and HIV-related characteristics of patients switching to BIC/FTC/TAF in the cohort study

***** *Data are shown in median (IQR, Interquartile range) or frequencies and percentages, n (%).*

- 1182 PLWH were switched to BIC/FTC/TAF. Median follow-up of patients treated was 18 months [IQR: 9-18]; 26.5% were women; median age was 53 years; median BMI was 24; median CD4 count was 692 cells/mm^3; 402 PLWH (34%) had a history of at least one virologic failure; the median number of previous treatment lines was 5; > 70% of patients had ≥ 1 comorbid condition (Table 1).
- The most frequent prior regimens before switching to BIC/FTC/TAF are presented in Table 2. A previous TDF-based regimen was identified in 37% of PLWH.
- The most frequent reasons for switching to BIC/FTC/TAF were:
  - Simplification or drug reducing (52%);
  - Avoid side effects (12%);
  - Physician's choice (12%);
  - Avoid drug-drug interactions (DDIs) (6%).
- The cumulative probability of BIC/FTC/TAF discontinuation (Fig 3) was :
  - 13% [IQR: 11-15%] at M12;
  - 18% [IQR: 16-20%] at M18.
- 175/1182 (14.8%) patients discontinued BIC/FTC/TAF at M18 (Table 3). Reasons for discontinuations were:
  - Any side-effects (n=66/1182, 5.6%), including:
    - neurological toxicity (1.3%);
    - general sign (0.9%);
    - digestive toxicity (0.7%);
    - weight gain (0.7%);
    - others (2.1%).
  - physician choice / drug reducing (3.0%);
  - patient's choice (1.9%);
  - death (1.3%).
- The cumulative probability of BIC/FTC/TAF VF (Fig 4) was:
  - 3% [IQR: 2.1-4.3] at M12;
  - 3.7% [IQR: 2.6-5.1] at M18.
  - Among the 35 patients who experienced VF;
    - 20/35 (57%) patients continued BIC/FTC/TAF
      - 12/20 (60%) suppressed again;
      - 2/20 (10%) remained unsuppressed;
      - 6/20 (30%) had no follow-up data available.
    - 15/35 (43%) patients discontinued BIC/FTC/TAF.

Regimen, N (%)	N= 1182 (100)	
EVG/COBI/FTC/TAF	424	(35.9)
DRV + RTV + FTC/TDF	110	(9.3)
DTG + FTC/TDF	88	(7.4)
DTG/3TC/ABC	70	(5.9)
RPV/FTC/TAF	65	(5.5)
Other combinations	425	(36.0)

Table 2. Most frequent regimens before switching to BIC/FTC/TAF in the cohort study

Reason, N (%)	N= 1182 (100)	
Any reasons for discontinuation	175	(14.8)
Any Side-effects	66	(5.6)
Physician choice / drug reducing	36	(3.0)
Patient choice	23	(1.9)
Other causes	18	(1.5)
Death	16	(1.3)
Virological Failure	15	(1.3)
Missing data	1	(0.1)

Table 3. Most frequent reasons for BIC/FTC/TAF discontinuation at 18 months in the cohort study

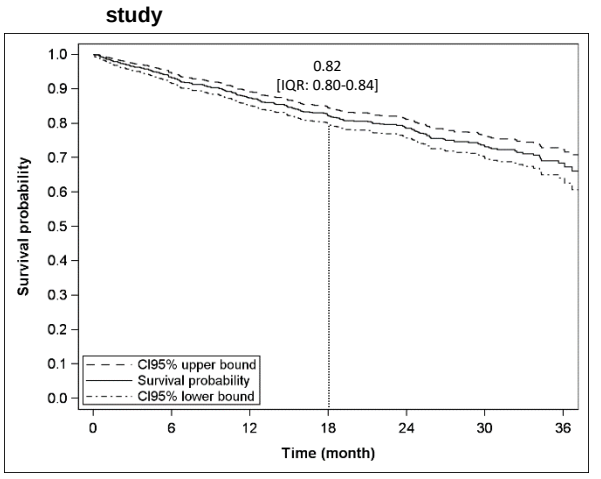

Figure 3. Survival curve of BIC/FTC/TAF switch persistence – Any reasons for discontinuation in the cohort study

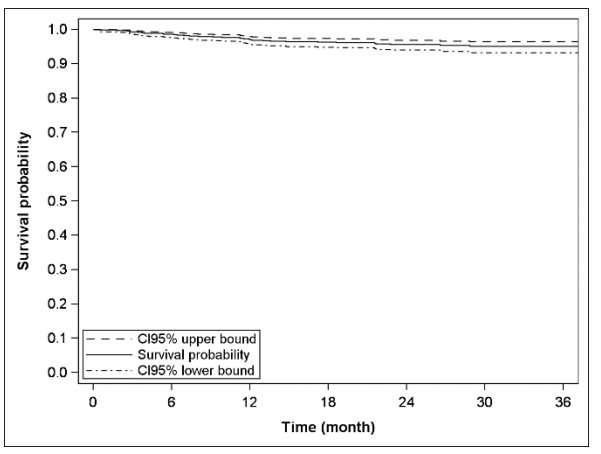

Figure 4. Survival curve of virologic failure in patients switching to BIC/FTC/TAF in the cohort study

CONCLUSIONS

In this large observational cohort study, treatment persistence at M18 in patients who switched to BIC/FTC/TAF was 82%.

- **VF was observed in 3.7% at M18, but BIC/FTC/TAF was maintained in more than half of the cases of VF.**
- **BIC/FTC/TAF was well tolerated at M18 with discontinuations related to any adverse event occurring in 5.6% of PLWH.**

Switching to BIC/FTC/TAF in virologically suppressed patients with comorbid conditions is a safe and effective strategy.

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