BACKGROUND

• Bictegravir (BIC) is a high potent unboosted integrase strand-transfer inhibitor (INI/ITI) 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 option.

• However, there are currently few real-world evidences on efficacy, tolerability and persistence of this regimen, including populations poorly represented in clinical trials.

• The ANRS-C03 - AquilVH-NA cohort is an open, prospective hospital-based cohort of HIV-1-infected adults (≥18 years old) in care at 15 hospitals in the Nouvelle Aquitaine region of southwestern France.

• The cohort collects epidemiological, clinical, biological and therapeutic data from the medical records of PLWH and who have signed informed consent form since 1967.

• 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 copies/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

1.182 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 522 cells/mm³; 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 comorbidity 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 (13%);
  - Avoid drug-drug interactions (DDI) (6%).

• The cumulative probability of BIC-FTC/TAF discontinuation (Fig 3) was:
  - 13% [IQR: 11-15%] at M12;
  - 18% [IQR: 16-20%] at M24.

• Among the 35 patients who experienced VF:
  - 20/35 (57%) patients continued BIC-FTC/TAF;
  - 12/20 (60%) suppressed again;
  - 20 (10%) remained unsuppressed;
  - 6/20 (30%) had no follow-up data available.

• 15/35 (43%) patients discontinued BIC-FTC/TAF.

CONCLUSIONS

In this large observational cohort study, treatment persistence at M18 in patients who switched to BIC-FTC/TAF was 92%.

• 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.

METHODS

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 copies/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.


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

<table>
<thead>
<tr>
<th>Reason, N (%)</th>
<th>N= 1182 (100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any reasons for discontinuation</td>
<td>175 (14.8)</td>
</tr>
<tr>
<td>Any Side-effects</td>
<td>66 (5.6)</td>
</tr>
<tr>
<td>Physician choice / drug reducing</td>
<td>36 (3.0)</td>
</tr>
<tr>
<td>Patient choice</td>
<td>23 (1.9)</td>
</tr>
<tr>
<td>Other causes</td>
<td>18 (1.5)</td>
</tr>
<tr>
<td>Death</td>
<td>16 (1.3)</td>
</tr>
<tr>
<td>Virological Failure</td>
<td>15 (1.3)</td>
</tr>
<tr>
<td>Missing data</td>
<td>0 (0.1)</td>
</tr>
</tbody>
</table>

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