**BACKGROUND**

- BIC/FTC/TAF co-formulation showed excellent efficacy and tolerability in randomized clinical trials as switch strategy in people living with HIV (PLWH) virologically suppressed, but in real-life setting effectiveness need to be further investigated especially among some sub-groups:

  - Older PLWH is a growing population among PLWH, with increased levels of comorbidities, polypharmacy and drug–drug interactions.
  - Sex-related factors influence ART outcomes and wellbeing of PLWH. Women are historically differentially affected by ART side effects.

**AIM**

Evaluate the effectiveness of BIC/FTC/TAF in ART-experienced virologically suppressed (VS) people living with HIV (PLWH)

**STUDY DESIGN AND METHODS**

Study Design: Observational study including ART-experienced VS PLWH from the Icona cohort who switched, for the first time to BIC/FTC/TAF from April 2018 to Dec 2021.

**EXPOSURE**

- Age (≥50 years old);
- Sex (Female);
- Switching from NNRTI-based regimen

**Primary Endpoint**

Time to treatment failure (TF) i.e. virological failure (VF): 2 HIV RNA>200 copies/ml or 1>1000 copies/ml or treatment discontinuation (TD) for any reason.

**Secondary Endpoints**: (1) Time to TD for any reason; (2) Time to TD for toxicity/intolerance; (3) Time to VF in intention to treat; (4) Changes in CD4, CD4/CD8 and weight at 12 to 18 months from switch.

**Statistical Analysis**: Standard survival analysis (Kaplan-Meier curves (KM) and log-rank test), the probability of different endpoints has been estimated at 1-year from BIC/FTC/TAF start according to the different exposures of interest.

- Unadjusted and adjusted hazard ratios (HR) of the primary endpoint TF of and of TD, TDT, TDS and VF have been estimated by fitting Cox regression models according to main exposures of interest.

**RESULTS**

In the adjusted Cox regression models, age ≥50 years and NNRTI class in the previous regimens were not with a higher risk of TF (Table 3).

**Table 3 - Hazard Ratios (HR) and Adjusted HR of TF from fitting 4 Cox regression models**

<table>
<thead>
<tr>
<th>ART-experienced</th>
<th>HR (95%CI) p</th>
<th>Adjusted HR (95%CI) p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, ≥50 years</td>
<td>0.73 (0.50-1.0)</td>
<td>0.011</td>
</tr>
<tr>
<td>Female (vs. male)</td>
<td>1.01</td>
<td>(1.03-1.0)</td>
</tr>
<tr>
<td>Previous NNRTI-based regimen</td>
<td>0.56 (0.25-1.28)</td>
<td>0.67</td>
</tr>
</tbody>
</table>

**Secondary Endpoints**

Overall 15 VF and 10 TD (8.1%) occurred: 4 simplifications (3.3%), 3 toxicity/intolerance (2.4%), 3 failures (0.2%), 3 patient’s decision (0.2%) and 23 (1.9%) other reasons (including 6 pregnancies). KM 1-year cumulative probabilities are shown in Table 4.

**Table 4 - KM 1-year cumulative probability of TD, TD toxicity/intolerance and VF**

<table>
<thead>
<tr>
<th>Treatment Discontinuation</th>
<th>4.1% (3.1-5.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Discontinuation for toxicity/intolerance</td>
<td>2.6% (1.8-3.7)</td>
</tr>
<tr>
<td>Virological Failure</td>
<td>0.7% (0.3-1.4)</td>
</tr>
</tbody>
</table>

Mean CD4 increase at 1-year was +36 cells/mmc (95%CI 22.51; p<0.001)
Mean CD4/CD8 ratio change was +0.06% (95%CI 0.04,0.08; p<0.001).

**CONCLUSIONS**

- BIC/FTC/TAF as switch strategy demonstrated high effectiveness in real-life with 4.6% TF and 0.7% VF at 1-year.
- Higher risk of TF in women seems mainly related to discontinuation of BIC/FTC/TAF for pregnancy concerns.
- 4.1% of TD at 1-year, main cause of discontinuation was simplification
- Limits: These data should be confirmed with long-term follow-up
- Few numbers on weight at 12 to 18 months from switch

**ACKNOWLEDGMENTS – Icona Foundation Study Group**

**Funding**

This study was funded by a Gilead Sciences Inc. unrestricted grant. ICONA Foundation is supported by unrestricted grants from Gilead Sciences, Merck Sharp & Dohme, Thera Technologies and VIIV Healthcare.