A NATIONWIDE OPTIMIZATION STRATEGY USING SECOND GENERATION INSTIS IN MEXICO

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BACKGROUND

In Mexico until 2018, first line antiretroviral therapy (ART) was mainly based on either efavirenz-containing regimens (despite reports of high pre-treatment resistance levels); or on other regimens with drugs no longer considered optimal -protease inhibitors (PIs), nevirapine, maraviroc and first-generation integrase inhibitors (InSTIs)- all of them amenable to be switched to 2nd generation INSTIs as a single tablet regimen (STR). We aimed to evaluate a national optimization strategy through a rollout program using second-generation INSTI-based STR both for ART initiation and switch.

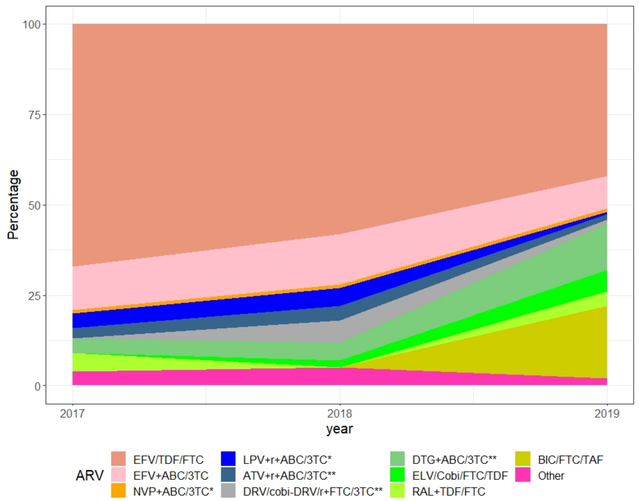


Figure 1. Percentage of patients by ARV regimen type during 2017-2019 in Mexico.
Notes: Other: unclasified in any of previous regimens. The combination could also be *FTC/TDF or ZDV/3TC , **FTC/3TC or TDF/FTC

METHODS

- We included adults registered in SALVAR database, who started on ART or switched to BIC/TAF/FTC, from June 1st 2019 to June 30th 2021. SALVAR (National System for Antiretroviral Surveillance and Administration)
- We categorized them as "started BIC/TAF/FTC" (G1), "started other than BIC/TAF/FTC" (G2) or "switched to BIC/TAF/FTC" (G3). We calculated the proportion of participants with viral suppression (VS) (< 40 copies/ml) at 6 months after ART initiation by group.
- We described VS and ART change by group at end of follow-up and fitted a Cox model to compare durability by group, sex and age. Durability was defined as maintaining VS in the same ART versus changing ART regimen, LTFU or death.

Second generation integrase inhibitors proved to be effective and durable as an option for ART initiation and switch. This strategy was carried out in all HIV care centers in the country: in the majority of them HIV care is provided by general physicians. This allowed to start and simplify an important number of PLWH to modern and well tolerated ARV regimens.

RESULTS

A total of 74,137 PLWH were included in the analysis and followed for a median of 1.6 years (IQR: 0.8 – 2.1), 23,786 (31%) were classified as G1, 5352 (7%) as G2 and 44,999 (61%) as G3 (**Table 1**). Of those classified as G2: 2543 (47%) were started on NNRTI's, 2029 (38%) on other INSTIs and 602 (11%) on PIs. The last regimen before switch in G3 group, was based on NNRTI's in 67%, PI's in 19%, other INSTIs in 10% and other regimens 4%. VS at 6 months after initiation or switch was observed in 87% individuals in G1, 80% in G2 and 98% in G3. At end of follow-up, 80% of those in G1, 56% in G2, and 87% in G3 remained with VS; < 1% of individuals changed to a different regimen in G1, 4% in G2 and 1% on G3. Durability of ART regimen by group is shown in **Figure 2.** At initial evaluation, 31% of all individuals were on a STR regimen, vs. 96% at the end of follow-up.

	G1 Started BIC/TAF/FTC	G2, Started other than BIC/TAF/ FTC	G3, Switched to BIC/TAF/FTC
Patients, n(%)	23,786 (31)	5,352 (7)	44,999 (61)
Sex at birth, n(%) Women	2570 (11)	1223 (23)	9,510 (21)
Age in years , median (IQR)	31 (26 – 38)	32 (26 – 40)	39 (31 – 48)
Patients with CD4<200, n(%)	8,088 (28)	1,760 (6)	14,613 (51)
Previous ART, n(%)			
II+2NRTI	NA	2,029 (38)	4,561(10)
PI+2NRTI		602 (11)	8,561 (19)
NNRTI+2NRTI		2,543 (47)	30,046 (67)
Unknown/Other		178 (3)	1,831 (4)

Table 1. Characteristics of participants by group.
Notes: Age and CD4 count data from starting BiC/TAF/FTC use for G1 and G3 groups, and at current ARV regimen in G2. All comparison were significantly different at p<0.05

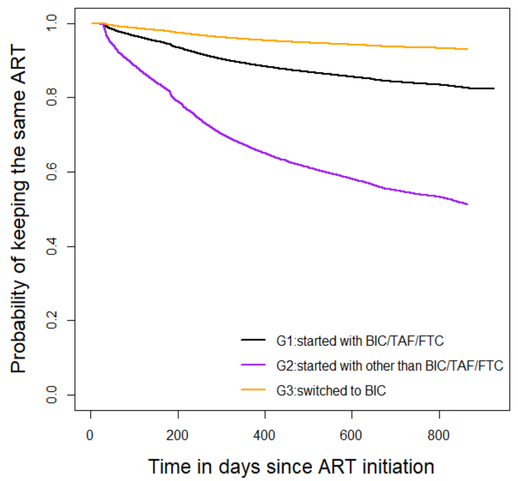


Figure 1. Durability of the same ART regimen by group.
Notes: Durability was defined as maintaining VS in the same ART versus changing ART regimen, LTFU or death.

CONCLUSIONS

In this real life analysis, we observed that the co-formulation of BIC/TAF/FTC represents an effective and durable option for both initiation and switch among Mexican population.

LIMITATIONS

Data used for this analysis were obtained from a National dataset that does not contain relevant information such as ARV adherence, specific adverse events, other clinical characteristics of the population. Additionally, the proportion of missing data regarding VS outcomes was higher in G2 group when compared to G1 and G3. However, we consider that our sample size provides strong data regarding virological outcomes and durability of treatment.

FUTURE DIRECTIONS

It is essential to conduct appropriate surveillance to constantly address the outcomes of this optimization strategy. Currently, our team is analyzing approximately 700 genotypes of individuals with viral loads over 1000 copies/ml after six months of stable ARV therapy with BIC/TAF/FTC. We consider that it is also a priority to collect information regarding metabolic outcomes among PLWH using second generation INSTIs, specially in the context of a country with a high prevalence of overweight, obesity and diabetes mellitus in the general population.

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