Dolutegravir Plus 3TC In Antiretroviral Experienced Adults: Immunovirological Outcomes In a Multicenter Retrospective Cohort In Spain

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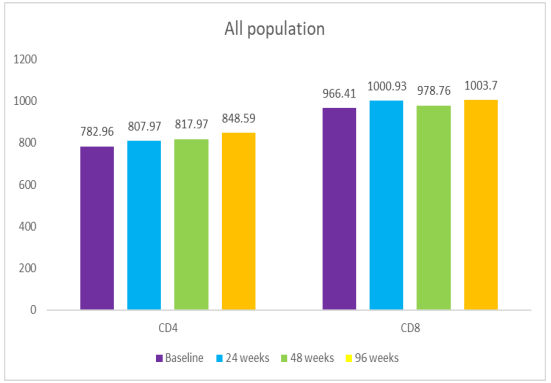
Background: Dolutegravir-based dual therapies for treating people living with HIV (PLHIV) are strategies strongly recommended in several practice guidelines. The safety and efficacy combination of Dolutegravir (DTG) plus 3TC as a switching strategy in virologically suppressed patients was demonstrated in the TANGO study. Wide multicenter real-life data supporting this treatment is needed. The aim of the current study was to describe the efficacy in terms of immunovirological outcomes in patients treated with this antiretroviral combination.

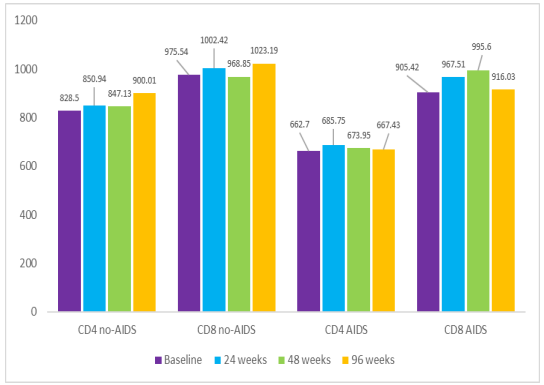
Methods: From November 1st, 2020 to August 1st, 2021, data from 1002 PLHIV collected from 13 Spanish institutions were recorded in a multicenter, retrospective study. Inclusion criteria were age>18 years, and to receive treatment with DTG/3TC as a switching strategy. Immunovirological impact of this strategy (CD4+, CD8+ lymphocyte cell count and CD4+/CD8+, as well as HIV plasma viral load through weeks 24, 48, and 96 of follow-up) was evaluated using multivariable mixed models where the individual was considered as a random effect. Sex and age were added as demographic covariables.

DEMOGRAPHICS	
Age mean (sd)	48.67 (12.28)
Male sex n (%)	790/1002 (78.8)
Spanish nationality n (%)	739/967 (76.4)
COMORBIDITIES n (%)	
Arterial hypertension	119/1002 (11.9)
Diabetes	50/1002 (5.0)
Dyslipemia	208/1002 (20.8)
Heart Disease	29/1002 (2.9)
Cerebrovascular disease	9/1002 (0.9)
Peripheral vascular disease	11/1002 (1.1)
Kidney failure	39/1002 (3.9)
Osteoporosis/Osteopenia	29/1002 (2.9)
Chronic pulmonary disease	47/1002 (4.7)
Psychiatric disorders	78/1002 (7.8)
Cancer	14/1002 (1.4)
Chronic liver disease	105/1002 (10.5)
HIV INFECTION	
Transmission pathways n (%)	
Sexual intercourse	673/982 (68.5)
Intravenous drug injectors	175/982 (17.8)
Immune status mean (sd)	
Baseline CD4 (cells/mm³)	782.96 (334.34)
Baseline CD8 (cells/mm³)	966.41 (483.20)
Baseline CD4/CD8 ratio	1.04 (1.46)
AIDS diagnosis n (%)	117/746 (15.7)
Age of diagnosis mean (sd)	
Global cohort	36.24 (14.61)
AIDS patients	42.70 (14.17)
Non-AIDS patients	34.00 (14.75)
Previous treatments n (%)	
- ABC/3TC	384/1002 (38.3)
- FTC/TDF	459/1002 (45.8)
- FTC/TAF	149/1002 (14.9)
- PI	271/1002 (27.0)
- INSTI	475/1002 (47.4)
- NNRTI	340/1002 (33.9)
Reasons for switching n (%)	
Simplification	587/1002 (58.16)
Toxicity	168/1002 (16.8)
Transition therapy to injectable drugs	9/1002(0.9)
Drug interaction	61/1002 (6.1)
Simplicity	33/1002 (3.3)
Cost	26/1002 (2.6)
COINFECTIONS n(%)	
HBV diagnosis	192/685 (28.0)
HBsAg positive	10/189 (5.3)
HCV positive ELISA	160/693 (23.1)
HCV positive PCR	52/150 (34.7)

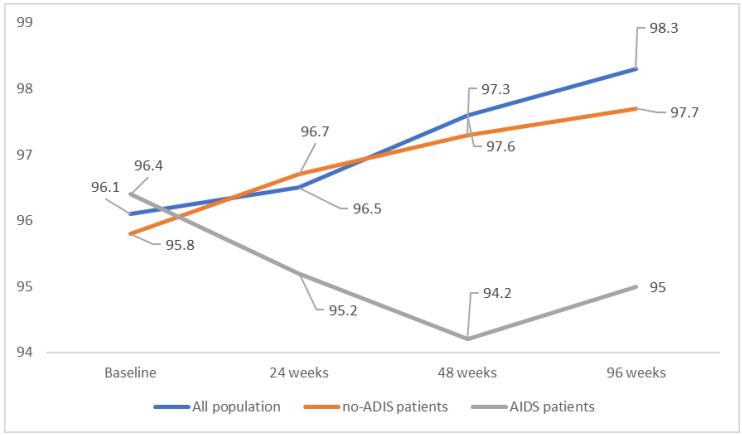
Main Characteristics of Spanish Cohort



Absolute CD4 and CD8 values for all population at baseline, 24, 48 and 96 weeks



Absolute CD4 and CD8 values at baseline, 24, 48, and 96 by the presence of AIDS.



Percentage of patients with a viral load < 50 copies/mL in the whole population and according to the presence of AIDS in patients at baseline, 24, 48, and 96 weeks of treatment.

Results: 78.8% of patients were men, and 15.7% had been previously diagnosed with AIDS. The mean age was 48.67 years old. The mean CD4 T cell count nadir was 300 cells/ml (160-480). We found a significant increase in CD4+ counts at 24, 48, and 96 weeks after switching drug strategies. We also detected a small increase in the CD4+/CD8+ count rate at 48 and 96 weeks. No significant change was found in the CD8+ count. No differences were found on behalf of sex, between backbone drugs (45.8% switched from a TDF/FTC backbone, 14.9% to an FTC/TAF, and 38.3% from ABC/3TC) or amongst the different third agents used (47.4% switched from integrase inhibitors). We identified a strong and negative effect of having AIDS in the CD4+ count. However, this effect did not interact with the effect of switching drug strategies.

Conclusions: PLHIV who, being virologically suppressed, switched to dual therapy based on DTG/3TC, experienced a statistically significant increase of CD4+ T cell count at weeks 24, 48 and 96, as well as an increase in CD4/CD8 T cell ratio, as well as high efficacy in terms of viral suppression, independently of the stage of HIV infection.