







EFFICACY AND SAFETY OF DORAVIRINE/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE IN PEOPLE LIVING WITH HIV-1 AGED OVER 60 YEARS

L. Calza, M. Giglia, V. Colangeli, F. Baldasso, M. Cantini, I. Grassi, A. Poma, S. Cretella, P. Viale
Unit of Infectious Diseases, IRCCS S.Orsola Hospital, University of Bologna

Introduction

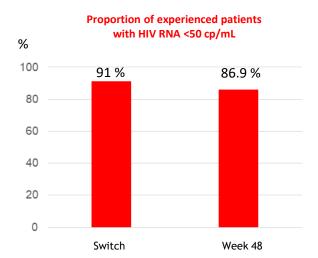
A significant percentage of people living with HIV (PLWH) in the European countries and United States are ≥60 years, and this percentage will increase in next years.

Methods

Retrospective cohort study evaluating records from PLWH aged ≥60 years at our HIV Clinic who started doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) between January 2020 and December 2022. Eligible patients were antiretroviral therapy-naive or experienced PLWH with 48 weeks of follow-up data and no known resistance mutations for doravirine, lamivudine and tenofovir.

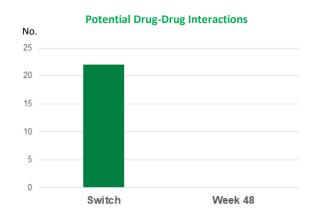
Results

- Inclusion criteria were met by 32 patients: 9 naive and 23 experienced. Mean age was 64.2 years (range, 60-72), 88% were men, and one or more comorbidities were present in 25 subjects (78%). In naive patients, mean log₁₀ HIV RNA was 4.46, and two (6%) had an AIDS diagnosis. In experienced patients, mean CD4+ T lymphocyte count was 617 cells/mm3, 21 (91%) had HIV RNA <50 copies/mL, 3 (13%), and previous antiretroviral regimen included two nucleoside/nucleotide analogues (NRTIs) plus one boosted protease inhibitor (PI) in 5 patients (22%), two NRTIs plus one non-nucleoside reverse transcriptase inhibitor in 13 (56%), and two NRTIs plus one integrase inhibitor in 5 patients (22%).
- At week 48, 28 patients (87.5%) had HIV RNA <50 copies/mL: 8 (88.8%) naive and 20 (86.9%) experienced. Four patients discontinued DOR/3TC/TDF: one for virological failure and three for adverse events. A genotype resistance testing was performed in patient with virological failure (HIV RNA 1400 copies/mL) and no resistance mutations were detected. Twenty-two potential DDIs were identified in 16 (50%) patients at baseline and were resolved after switching to DOR/3TC/TDF. Treatment-related adverse events occurred in 11 (34%) patients (all grade 1-2) but there were only three cases (9.3%) of treatment discontinuation because of gastrointestinal symptoms. At week 48, mean change (+ SD) in CD4+ T lymphocyte count was +156 (±101) cells/mm3 in naive patients and +59 (±32) cells/mm3 in experienced patients. Overall, mean variations (±SD) in creatinine, total cholesterol and triglycerides were +0.19 (+0.11) mg/dL, -34 (±18) mg/dL, and -46 (±25) mg/dL, respectively. Reductions in total and LDL cholesterol were statistically significant in experienced patients switched from a PI-based and/or a tenofovir alafenamide (TAF)-based regimen. At week 48, mean change (±SD) in body weight was +1.81 (±0.92) Kg in naive patients and +0.87 (± 0.51) Kg in experienced patients.



At week 48:

- 1 patient with virological failure (HIV RNA 1400 cp/mL)
- No resistance mutations



Conclusions

In this real-world cohort, DOR/3TC/TDF was associated with high virological efficacy, good tolerability profile, favourable metabolic impact, and avoidance of DDIs among antiretroviral therapy-naive or experienced PLWH aged over 60 years. These data support use of DOR/3TC/TDF as a treatment option in older patients with HIV infection.