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Durability of doravirine/lamivudine/tenofovir disoproxil fumarate in a cohort of treatment-experienced people with HIV: a retrospective observational study

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Background

Doravirine/lamivudine/tenofovir disoproxil fumarate (DOR/3TC/TDF) is a single tablet NNRTI-based regimen approved for treatment-experienced and treatment-naive patients. Doravirine has shown a favorable resistance profile within the NNRTIs, no food restrictions, safe lipid profile and minimal drug interactions. Our study investigates the durability of DOR/3TC/FTC as a switch regimen in people with HIV (PWH) and analyzes reasons for discontinuation.

Methods

We conducted a retrospective, monocentric observational cohort study at the Infectious Disease Department of L. Sacco Hospital (Milan, Italy). The cohort includes all PWH who switched to DOR/3TC/TDF from a previous regimen until 31/12/2023 (end of observation period). Patients were followed until discontinuation of DOR/3TC/TDF due to any cause, death or until 31/12/2023, whichever came first.

Epidemiological and clinical characteristics were collected including reasons for DOR/3TC/TDF discontinuation. Durability of DOR/3TC/TDF was performed by means of Kaplan-Meier curves, and log-rank test was used to assess exposures of interest.

Results

During the study period, 83 PWH switched from a previous ARV regimen to DOR/3TC/TDF; the majority were biological males (60, 72.3%) and the median age at baseline was 49 years (IQR 43-56). The most common associated comorbidities were arterial hypertension (21.7%), obesity (13.3%), and neuropsychiatric diseases (10.8%). The median observation time was 33 months (IQR 18-38).

A total of 43 (51.8%) PLW discontinued DOR/3TC/TDF during the observation period. The estimated durability of DOR/3TC/TDF at 12, 24 and 36 months was 80.7% (95%CI 70.5%-87.7%), 63.9% (95%CI 52.6%-73.2%), and 50.6% (39.1%-61%), respectively (Figure 1).

No significant differences were observed according to biological sex in term of regimen durability (p=0.9308). The main reasons for switching to another regimen were simplification (18, 21.7% of total PWH), toxicity (16, 19.3%) and poor adherence to therapy (4, 4.8%); death occurred in 3 PWH.

No virological failure was reported. As shown in Figure 2, among patients who discontinued DOR/3TC/TDF regimen because of toxicity, the main reason was liver toxicity (3 cases), weight gain (3) followed by renal damage, osteopenia and neuropsychiatric disorders in 2 patients each. 13 patients (32.5%) switched to dual INSTI-based, 12 (30%) to a triple INSTI-based regimen, and 8 (20%) to another triple NNRTI-based regimen.

Figure 2

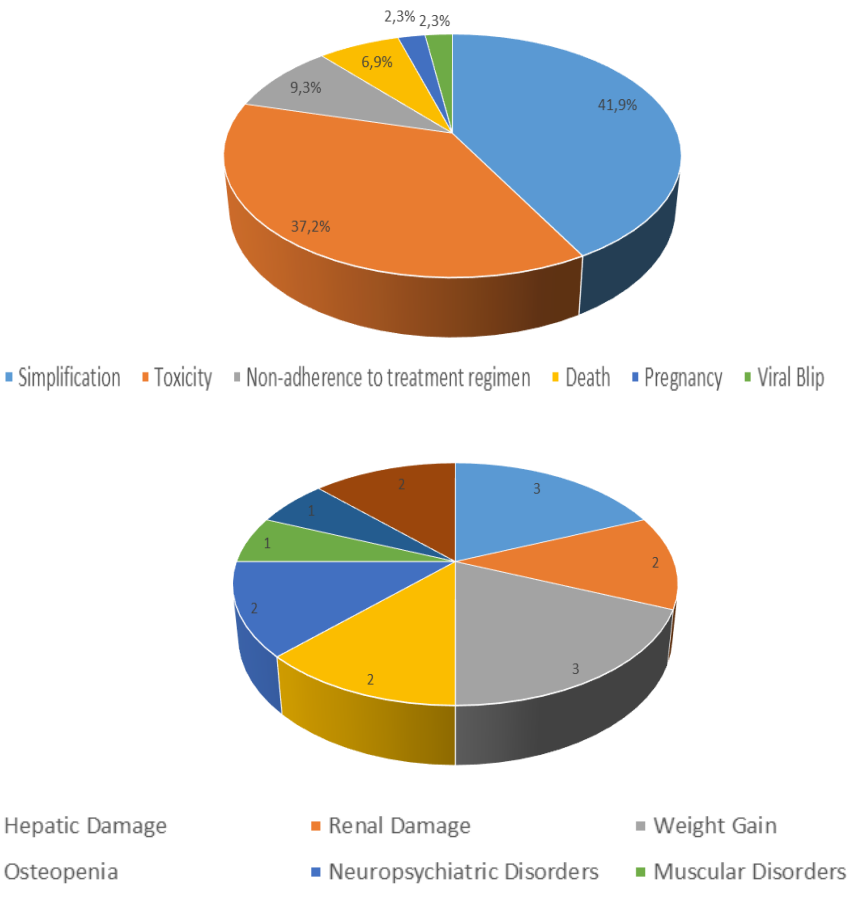
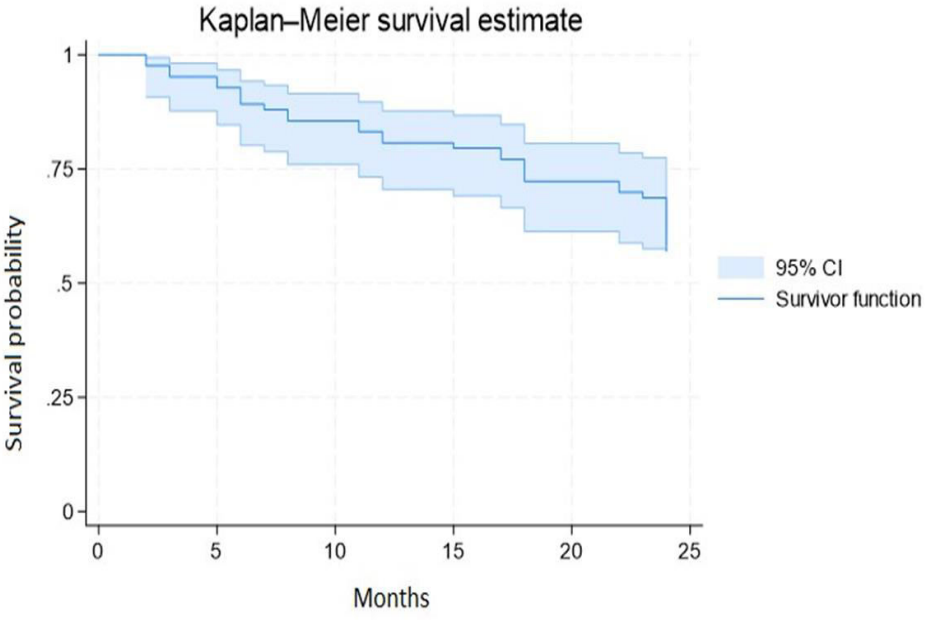


Figure 1



Conclusions

We found that most discontinuation of DOR/3TC/TDF were due to simplification although a not negligible rate of PWH experienced a toxicity potentially related to one of the components of the regimen. We confirm a favorable virological outcome of this regimen with no confirmed virological failure observed.