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Durability and effectiveness of dual versus triple INSTI-based antiretroviral therapy in a real-world cohort in Palermo

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Background

Integrase Strand Transfer Inhibitor (INSTI) are oral antiretroviral agents with a high efficacy and safety rate[1]. Our aim is to describe treatment durability and virological outcomes in people living with HIV (PLWH) using two of the most commons INSTI-based regimens, BIC/TAF/FTC or DTG/3TC, respectively a three-drug (3-DR) and two-drug (2-DR) regimen.

Material and methods

We performed an observational retrospective single center study that included all treatment-naïve (TN) and treatment-experienced (TE) PLWH, who started 3-DR or 2-DR between 01 March 2019 and 29 February 2024. PLWH were followed up from the date of start of antiretroviral therapy to the date of treatment discontinuation for any reason or censoring. Exclusion criteria were: multidrug regimens, documented resistance to INSTI or Non-Nucleoside Reverse Transcriptase Inhibitor, PLWH who started study treatment or were followed up in another clinical centre. The purpose was to establish the durability of the two regimens; secondary endpoints were the reasons for discontinuation and the rate of virological suppression, defined as viral load (VL)<50 copies/mL after starting or switching to 2-DR or 3-DR at 48 and 96 weeks +/- 24 weeks.

Results

According to the exclusion criteria, 440 PLWH were identified: 293 (67%) in the 3-DR group (228 TE and 65 TN) and 147 (33%) in the 2-DR group (142 TE and 5 TN). The median follow-up was 99 weeks (Q1-Q3:52-197) in the 3-DR group and 99 weeks (Q1-Q3:50-142) in the 2-DR group.
Durability of the two regimens was analyzed using Kaplan-Meier survival analysis and showed no statistically significant difference (log rank p=0,467) (Figure 1).
65 (14%) PLWH discontinued treatment. Eleven (15%) TN PLWH discontinued 3-DR due to drug interactions (4), lost to follow-up (4), switch to long-acting antiretroviral treatment (LA-ART) (2) and death due to AIDS (1).

No TN PLWH discontinued 2-DR (although one was excluded from this study for documented resistance to INSTI). In the TE group, 38 (10%) PLWH suspended 3-DR due to treatment simplification (13), toxicity (11), lost to follow-up (6), switch to LA-ART (5), pregnancy (1), switch to crushable drug (1) and kidney failure (1). 17 (12%) TE discontinued 2-DR due to switch to LA-ARV (9), toxicity (6), lost to follow-up (1) and kidney failure (1).

292 (79%) TE PLWH reported outcomes for VL at 48 weeks and 223 (60%) at 96 weeks after switch. Percentage of TN with VL<50 copies/ml at 48 weeks was 93.3% in 3-DR group and 97.3% in 2-DR group. After 96 weeks, 95.2% PLWH in 3-DR group and 97.4% in 2-DR group achieved virological suppression. In both cases, the rate of viral suppression was similar between the two groups (p>0,05).

Conclusions

3-DR and 2-DR showed a similar risk of treatment discontinuation. Additionally, virological suppression in TE using 2-DR was comparable to 3-DR. Concerning TN PLWH, a more appropriate evaluation of virological suppression needs a larger sample and a longer observation period.

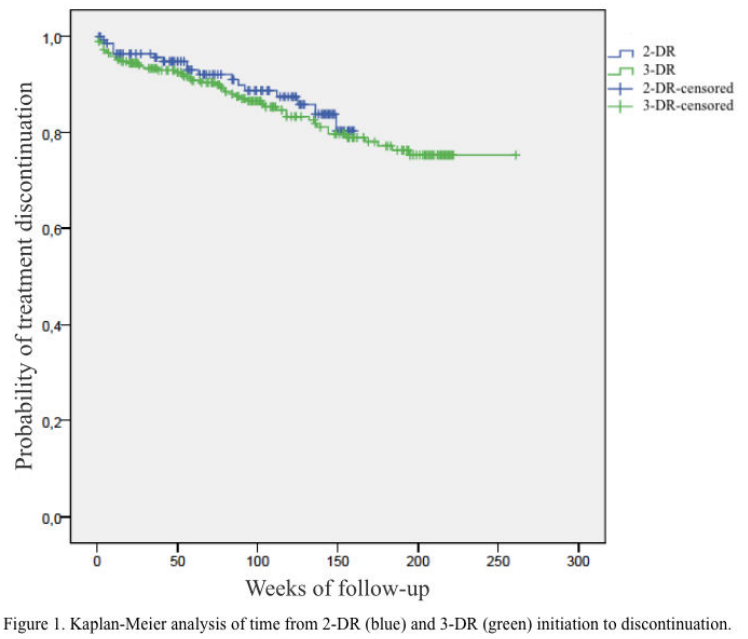

Figure 1. Kaplan-Meier analysis of time from 2-DR (blue) and 3-DR (green) initiation to discontinuation.

Reference

1. Zhao AV, Crutchley RD, Guduru RC, Ton K, Lam T, Min AC. A clinical review of HIV integrase strand transfer inhibitors (INSTIs) for the prevention and treatment of HIV-1 infection. Retrovirology. 2022 Oct 22;19(1):22.