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Experienced PWH switching to 3TC/TDF/DOR in outpatient setting: real-life data on Lipid changes and ASCVD risk from an Italian multicenter cohort

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Introduction

- The burden of cardiovascular disease in persons living with HIV (PWH), requires clinicians to seek safe ARV regimens with low metabolic impact. Doravirine (DOR) showed long-term safety, tolerability, and a favorable lipid profile, which placed it among the most suitable treatment options in dyslipidemic PWH with high CVD risk. We present out data on multicenter cohort on the effects of 3TC/TDF/DOR on ASCVD risk and lipid profile at 24 weeks of follow-up.

Methods

- We enrolled treatments experienced PWH from seven outpatient settings in Italy (Rome, Milan, Siena, Florence, Perugia, Pesaro, Sassari) switching to 3TC/TDF/DOR (baseline, BL). We collected viro-immunological parameters, lipid profiles and calculated the ASCVD risk score at BL and after 24 weeks (24W) of follow-up.Reported adverse events during follow-up were recorded. Student t-test for paired samples and multivariable linear regression were used to assess changes in lipid profile and predictors of those changes, respectively.

TABLE 1. Full population characteristics at baseline.

VARIABLE	N= 309
Male sex n (%)	227 (73)
Age, mean (SD)	51 (10)
Ethnicity, n (%) -Caucasian -Afro-Americans -Latin-Americans -Other	 236 (76.3) 38 (12.3) 33 (10.6) 2 (0.6)
RF HIV, n (%) -Heterosexual -MSM -PWID	 121 (42.0) 127 (44.1) 28 (9.7)
Comorbidities, n (%) -Diabetes -Hypertension -Dyslipidemia -Known cardiac disease at BL	 18 (5.83) 58 (18.8) 100 (34.9) 11 (5.14)
HIV-RNA>50 cps/mL, n (%)	26 (8.5%)
CD4+ cell/L, mean (SD)	725 (322)
CD4/CD8 ratio, mean (SD)	0.9 (0.4)

RF: Risk Factor;
MSM: Men who have sex with men;PWID: Persons who inject drugs;
CDC: Centers for Disease Control and Prevention;

Results

- We enrolled 309 individuals, with a mean duration of HIV infection of 16y (± 9) and a mean time of antiretroviral therapy of 13y (±7.8). At BL most of PWH (67%) switched from a 3-drug regimen, while a smaller percentage (7.4%) from a 2-drug regimen (NRTI+ INI 4.85%, other dual 2.59%); 132 (43%) were on a TAF-based regimen vs 52 (17%) on a TDF-based one).
- The major reason for switching to 3TC/TDF/DOR was regimen optimization (32%). Population characteristics at BL are shown in Table 1.
- Regarding to the lipid profile, at 24 W, we observed a significant improvement in total cholesterol (TC) (mean difference -17.80 mg/dl, 95% CI -22/-14, p<0.001), HDL/LDL (0.03 95% CI, 0.004/0.05, p= 0.019), triglycerides (-28 mg/dl, 95% CI -42/-14, p<0.001), TC/HDL (-0.3 95% CI, -0.4/-0.2, p< 0.001). However, upon stratification by pre-switch therapy (TDF-based regimens versus all others), mean reduction in total cholesterol (-21 mg/dL; p<0.001) and triglycerides (-34 mg/dL; p<0.001) and mean increase in HDL/LDL (+0.03; p=0.028), were only observed in PWH who switched from non-TDF-based regimen, whereas reduction in TC/HDL was seen independently from pre-switch regimen (-0.28; p<0.001).
- Multivariable regression analysis confirmed the association with pre-switch TDF for TC/HDL and triglycerides. Greater lipid improvements over time were associated with higher respective BL levels (all p-values <0.001). No significant change was observed in either ASCVD risk score or BMI at 24 W. At 24W, 37 PLWH discontinued 3TC/TDF/DOR (37/309, 12%) mainly for gastrointestinal toxicity (2.3%) and for simplification to a 2DR (2.3%).

Conclusion

- In this national multicenter cohort of PWH, the main driver of the improvement in TC, HDL/LDL, and triglycerides appears to be a non TDF- based prior antiretroviral regimen.However, based on the TC/HDL ratio amelioration observed in overall population, 3TC/TDF/DOR could represent a suitable antiretroviral treatment option for dysplipidemic PWH.

References

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