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Efficacy of switching from darunavir ritonavir to darunavir cobicistat in HIV infected patients treated with less drug regimen

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Background: Boosted PI monotherapy with lopinavir or darunavir (DRV) has proven efficacy in clinical trials and real-life cohort studies when applied in selected patients. Dual therapy that includes DRV/r can be a useful switch strategy in HIV-infected patients whose viral replication is controlled over time. There are few data on the use of DRV/cobicistat (DRV/c) in LDR

Material/methods: An Observational, retrospective cohort study including HIV-infected patients treated with DRV/r containing in a LDR who switch to DRV/c maintaining the same LDR. 3 Spanish Hospitals participated in the study. All patients included were over 18 years, had HIV-RNA < 50 copies/ml when switched and were followed every 12 weeks. Epidemiological and clinical data, treatment exposure and reasons for LDR prescription were recorded. During follow-up, virological and immunological data were collected. Adverse events were categorized via the standardized toxicity-

grade scale used by the AIDS Clinical Trials Group. A resistance study was carried in patients with VF. The primary endpoint was the proportion of participants without virological failure at week 24, in the intent-to-treat analysis (non-complete/missing = failure). Changes in CD4 cells count, cholesterol, lipids and creatinine were analyzed from basal to week 24.

Continuous variables were reported using means ± standard deviations (SD) or median (range), as indicated. For categorical variables, absolute numbers and percentages were computed. Changes in continuous measures from baseline to week 24 were analyzed with the Wilcoxon signed rank test. The primary endpoint was expressed including two-sided 95% confidence interval (95%CI).

Results: from 157 patients selected, 148 were included in the primary end-point analysis (nine patients continued with DRV/c but did not reach 24 weeks after switching). 68.8% men with 47±13 years old; 43.9% of patients were treated with DRV/r monotherapy and 45.2% with DRV/r plus lamivudine. The reasons for LDR use were NRTI toxicity (36.9%), simplification strategy (33.8%), patient's wishes (19.7%) and other reasons (9.6%).The efficacy at week 24, in the intent-to-treat analysis was 95.3% (95%CI: 90.6%-97.7%) and 98.6% (95.0%-99.6%) in the on-treatment analysis. Seven patients discontinued the DRV/c-based LDR. Two were considered to have VF and the other five discontinued for other reasons The virological failures were documented without resistance mutations development. No significant changes were found in the lipid profile. Creatinine increased significantly (0.06 mg/dl, 95%CI: 0.03-0.10, P<0.001).

Conclusions: We found no significant changes in the lipid profile up to 6 months after switching. Creatinine concentration increased slightly in our patients during the first weeks after switching and plateaued during the following weeks. In conclusion, switching from DRV/r to DRV/c in patients under an LDR was shown to be safe and effective. However, these results should be considered with caution until pharmacokinetics or larger cohorts studies with longer follow-up were performed.