P1843 EFFICACY OF SWITCHING FROM DARUNAVIR RITONAVIR TO DARUNAVIR COBICISTAT IN HIV INFECTED PATIENTS TREATED WITH LESS DRUG REGIMEN (LDR)

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BACKGROUND:

Boosted PI monotherapy with lopinavir or darunavir (DRV) has proven efficacy in clinical trials and real-life cohort studies. 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 in 3 Spanish Hospitals
- 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, immunological data and adverse events were collected.
- 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.

RESULTS: (table 1):

- 148 patients were included in the analysis (nine patients continued with DRV/c but did not reach 24 weeks after switching).
- 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%)
  - 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 (Fig 1).
- Seven patients discontinued the DRV/c-based LDR. Two have VF 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).

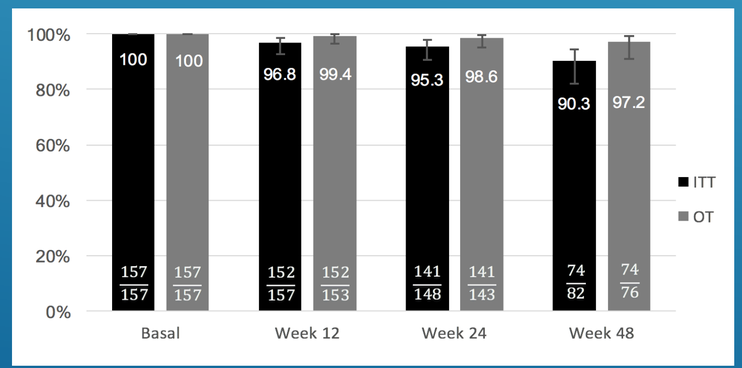

Figure 1. Percentage of patients with HIV viral load (<50 copies/ml) in treatment with DRV /r (basal) and after switching to DRV/c. Intent-to-treat (ITT) and on treatment (OT) analysis, with the 95% CI.

Table 1. Main characteristics of the study population and laboratory parameters during the follow-up.

	Basal[1]	Week 12	Week 24	Week 48	$\Delta_{basal-w24}$*	P value
Number of patients	157	157	148	82		
Age (years)	47±13					
Sex, male (%)	108 (68.8)					
Transmission route:						
IDU (%)	35 (22.3)					
Sexual (%)	118 (75.2)					
CD4 nadir (cells/µL)	184±92					
CDC C Category	40 (25.5)					
Length of HIV infection (years)	13 (7-20)					
HCV coinfection	32 (20.4)					
Time on ART (years)	9.8±4.1					
Time on LDR (years)	2.6±1.4					
Treatment:						
DRV/c monotherapy	69 (43.9)					
DRV/c+3TC	71 (45.2)					
DRV/c+NNRTI	7 (4.5)					
DRV/c+INI	10 (6.4)					
Adherence >90% (%)	148 (94.3)	147 (93.6)	139 (95.9)	79 (96.3)	-	-
CD4 (cells/µL)	682±312	661±305	701±336	694±314	+19 (-54,+92)	0.612
Total cholesterol (mg/dl)	192±33	190±30	188±30	190±35	-4 (-11,+3)	0.278
LDL-cholesterol (mg/dl)	126±24	122±23	125±28	124±30	-1 (-7,+5)	0.738
HDL-cholesterol (mg/dl)	45±15	46±15	42±14	44±16	-3 (-6,+1)	0.073
Triglycerides (mg/dl)	166±94	160±84	162±98	158±100	-4 (-25,+18)	0.716
Creatinine (mg/dl)	1.02±0.12	1.09±0.14	1.08±0.17	1.06±0.20	0.06 (0.03,0.10)	<0.001

IDU, intravenous drug use; ART, antiretroviral treatment; LDR, less drugs regimen; DRV/c, darunavir/cobicistat; 3TC, lamivudine; NNRTI, non-nucleoside reverse transcriptase inhibitor; INI, integrase inhibitor. [1] Last determination before switching. * Change from basal to week 24, expressed with the 95%CI.

CONCLUSIONS:

- No significant changes in the lipid profile up to 6 months after switching were found
- 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.
- These results should be considered with caution until pharmacokinetics or larger cohorts studies with longer follow-up were performed.