Monotherapy with boosted protease inhibitors as antiretroviral treatment simplification strategy in the clinical setting

Santos, J1; Berrio, D2; Miranda, C1; Bravo, I1; Pérez, S3; Llibre, J1; Paredes, R3; Clotet, B3 and Moltó, J1

1Lluita contra la SIDA Foundation, Hospital Universitari Germans Trias i Pujol, HIV Unit, Barcelona, Spain. 2Universidad Autónoma de Barcelona, Barcelona, Spain. 3IrsiCaixa Foundation, Barcelona, Spain.

Antiretroviral treatment simplification with darunavir/ritonavir or lopinavir/ritonavir monotherapy maintains sustained HIV viremia suppression in clinical trials. However, data about the efficacy of this strategy in routine clinical practice is still limited, and no direct comparison between darunavir/ritonavir and lopinavir/ritonavir has been performed to date. We retrospectively studied all HIV-1-infected subjects who initiated monotherapy with darunavir/ritonavir or lopinavir/ritonavir while having plasma VL < 50 c/mL, and had at least 1 subsequent follow-up visit in our clinic. When two consecutive PI-monotherapy regimens were used, each regimen was considered separately. The primary endpoint was the percentage of patients who maintained virological suppression (HIV-1 VL < 50 c/mL) through follow-up. Virological failure was defined as at least two consecutive HIV-1 VL > 50 c/mL. We also evaluated other reasons for treatment discontinuation. Analyses were performed considering all regimens (full dataset analysis) either as “on treatment” or as “treatment switch equals failure”. Five hundred and seventy-three PI-monotherapy regimens corresponding to 520 subjects were included, 262 with darunavir/ritonavir and 311 with lopinavir/ritonavir. Medians (IQR) follow-up were 50 (26.3–107.6) and 85.6 (36.9–179.1) weeks for subjects on darunavir/ritonavir and lopinavir/ritonavir, respectively (p < 0.001). Overall, 67 (11.7%) subjects experienced virological failure, 23 (8.7%) were on darunavir/ritonavir and 42 (13.5%) were on lopinavir/ritonavir (p = 0.796). Two hundred and three (77.5%) patients on darunavir/ritonavir and 154 (49.5%) on lopinavir/ritonavir maintained virological suppression in the “treatment switch equals failure” (p = 0.002). Other reasons for treatment discontinuation were gastrointestinal toxicity and dyslipidemia in 7.2% and 5.9% of cases, respectively. Gastrointestinal toxicities and dyslipidemia leading to treatment discontinuation were more frequent in patients on lopinavir/ritonavir (10.6% and 10.3%, respectively) than in patients on darunavir/ritonavir (3.1% and 0.8%, respectively). Monotherapy with darunavir/ritonavir or lopinavir/ritonavir as simplification strategy appears to be effective and safe in subjects with virological suppression in clinical practice. Virological efficacy seems to be similar between regimens. However, rates of discontinuation due to toxicities were higher in subjects on lopinavir/ritonavir than darunavir/ritonavir.