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Oral Abstract – O333

Prolonged treatment with boosted protease inhibitor monotherapy is not associated with a higher rate of neurocognitive impairment than triple drug ART

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Purpose of the study

To investigate if boosted protease inhibitor monotherapy is associated with a higher risk of neurocognitive impairment (NCI).

Methods

HIV-infected patients from two hospitals in Madrid (Spain) without concomitant major neurocognitive confounders, currently receiving for ≥1 year lopinavir/ritonavir (LPV) or darunavir/ritonavir (DRV) as monotherapy or with two N(t)RTIs were included if they had prolonged (≥1 year) plasma viral suppression (<50 c/mL, single blip allowed). Patients underwent full neurocognitive assessment (7 domains) by two psychologists blinded to the treatment group. NCI was defined as per 2007 Frascati criteria using demographically adjusted normative scores. Rates of NCI and the association between NCI and boosted protease inhibitor monotherapy, adjusted by significant confounders, were analyzed. Two categories of monotherapy duration were considered: short-term (1–2 years) and long-term (2–9 years). We evaluated as potential confounding variables: demographics, HIV risk factor, AIDS, CD4 (nadir/current), smoking, alcohol/illicit drug use, prior medical, neurological and psychiatric disease, HCV coinfection, years of ART, prior blips, time with HIV viral suppression, type of protease inhibitor, lipids and HOMA index.

Summary of results

191 patients (89.5% Caucasian) were included (Table 1).

	Triple therapy (n = 95)	Monotherapy (n = 96)	p value
Male. n (%)	70 (73.7)	70 (72.9)	0.91
Former IVDU. n (%)	30 (31.6)	34 (35.4)	0.85
MSM. n (%)	29 (30.5)	30 (31.3)	0.85
Age. Median (IQR)	44.7 (40.6–48.4)	47.4 (44.8–51.4)	<0.01
Years of education. Mean (SD)	11.3 (4.1)	10.4 (4.4)	0.13
Prior neurologic disease. N (%)	12 (12.6)	10 (10.4)	0.63
Prior psychiatric disease. n (%)	19 (20.0)	24 (25.0)	0.44
Current or past use of illicit drugs. n (%)	49 (53.6)	46 (47.9)	0.66
HCV coinfection (past or active)	43 (47.3)	43 (45.3)	0.54
Years of ART. Median (IQR)	10.7 (4.8–15.7)	14.1 (10.7–15.9)	0.01
Years of monotherapy. Median (IQR)	Not applicable	2.3 (1.7–3.2)	Not applicable
Years suppressed (<50 c/mL). Median (IQR)	4.8 (2.9–8.9)	7.5 (4.5–10.0)	<0.01
No prior blip	63 (66.3)	61 (63.5)	0.17
Currently on LPV. n (%)	70 (73.7)	53 (55.2)	<0.01
Currently on DRV. n (%)	25 (26.3)	43 (44.8)	<0.01
CPE score (2010). Median (IQR)	7 (7–7)	3 (3–3)	Not applicable

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CD4 cell nadir. Median (IQR)	153 (49–255)	182 (76–288)	0.11
CD4 cell current. Median (IQR)	560 (440–754)	629.5 (476–845.5)	<0.05

Proportion (95% CI) with NCI: Overall: 27.2% (20.9–33.6, all asymptomatic or mild). Triple therapy: 31.6 (22.1–41.0). 1–2 years of monotherapy (n = 40): 25.0 (11.3–38.7). 2–9 years of monotherapy (n = 56): 21.4 (10.5–32.3) No differences in rates of NCI were found by treatment group (p = 0.38). In our regression model confounding variables for NCI were years on ART, ethnicity, years of education, transmission category and the HOMA index. Adjusted by those variables the odds ratio (95% CI) for NCI of patients receiving boosted protease inhibitor monotherapy monotherapy during 1–2 years was 0.85 (0.29–2.50) and for 2–9 years was 0.40 (0.14–1.15).

Conclusions

Boosted protease inhibitor monotherapy, regardless of duration, was not associated with a higher rate of neurocognitive impairment than triple drug ART. These results call into question the ability of neuropenetrance scores to predict the neuroefficacy of antiretroviral regimens in HIV-infected patients with adequate blood viral suppression.