

## Abstract 142

### ***Efficacy and tolerability of switching to a dual therapy with darunavir/r+raltegravir in HIV-infected patients with HIV-1 RNA $\leq$ 50 cp/mL***

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**Background:** Nucleos(t)ide reverse transcriptase inhibitors (NRTI) toxicity may represent a threat for long term success of cART. Although little data is available, NRTI sparing regimens are often used in clinical practice. We aimed to explore the risk of virological failure (VF) and durability after a switch to dual therapy with darunavir/r (DRV/r) and raltegravir (RAL) while with viral load (VL)  $\leq$ 50 copies/mL in the clinical setting.

**Methodology:** Treatment experienced HIV 1-infected patients enrolled in the Icona Foundation Study cohort were included in this analysis if they underwent a switch from a three-drug containing regimen to dual therapy with DRV/r+RAL with a HIV-RNA  $\leq$ 50 copies/mL (baseline). A number of definitions of VF were employed including a confirmed HIV-RNA  $>$ 50 copies/mL (two consecutive values), a single HIV-RNA  $>$ 200 copies/mL and others (Table). We also investigated the risk of treatment failure (TF) defined as VF or discontinuation of DRV/r+RAL for any reason. We performed time to event analyses using Kaplan-Meier curves and Cox regression models (covariates in the final model: number of PI previously virologically failed, gender, mode of HIV transmission, HBV/HCV co-infection, calendar year of switch, age, CD4 nadir count, CD4 count at cART initiation, viral load at cART initiation and duration of suppression  $<$ 50 copies/mL).

**Results:** 99 patients were included, 21 (21.2%) female, 50 (51%) MSM, 16 (16.2%) had hepatitis coinfections (12 with HCV, 3 with HBV and 1 with HBV/HCV). Median baseline characteristics were: age 42 (IQR 34-51) years, CD4 cell count 439/mm<sup>3</sup> (300-554); HIV-RNA at initiation of cART was 4.95 (1.60-6.54) log<sub>10</sub> copies/mL, median time from starting last cART to baseline was 1 year (0-10), time from first starting a NRTI was 134 months (31-157), and duration of HIV-RNA  $<$ 50 copies/mL was 2 months (1-36). Twentyfive (25.3%) patients failed virologically a PI-based cART before baseline. The table shows the number of patients experiencing VF and TF and the Kaplan-Meier estimates by 12 and 24 months respectively, for each of the endpoints. VL at starting cART (adjusted relative hazard -ARH=1.79 per log<sub>10</sub> higher copies/mL; 95%CI 0.97, 3.31, p=0.06) was the only factor showing a trend towards an association with the risk of TF. Mean (SD) CD4 count were 357 (187) cells/mm<sup>3</sup> by 3 months, 418 (243) 6 months, 453 (203) 9 months, and 398 (231) by 12 months.

**Conclusions:** Switching to DRV/r+RAL in clinical practice is a promising NRTI-sparing strategy, with relatively low risk of VF (8-11%) and good tolerability (15-18% discontinued due to adverse events) by 2 years from baseline. However, patients who started cART with high VL might be at higher risk of failing this strategy.