associated with improved renal function over TT continuation, but also with increased total cholesterol and bilirubin levels.

O122

Dual therapy with a boosted protease inhibitor plus lamivudine is an effective maintenance strategy in patients on second-line antiretroviral therapy in Africa: the ANRS 12286/MOBIDIP trial

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Introduction: Second-line ART regimens with ritonavir-boosted protease inhibitor (PI/r) plus nucleoside reverse-transcriptase inhibitors (NRTIs) have shown good efficacy in resource-limited settings [1–3]. But issues of costs, toxicity and future options make a simplified maintenance treatment a strategy of interest. We aimed to compare two maintenance treatments with PI/r in mono- or dual therapy [plus lamivudine (3TC)] in a group of virally suppressed patients on second-line ART.

Material and methods: A randomized, open-label, multicentre clinical trial was conducted in Cameroon, Senegal and Burkina Faso. HIV-1 positive patients followed in the ANRS 12186 2LADY trial [3] on stable PI plus NRTIs second-line ART with HIV-1 RNA [viral load (VL)] below 200 copies/mL, CD4 above 100 cells/mm^3 and adherence $\geq$90%, were included in a two arms trial comparing monotherapy with the ongoing PI/r: darunavir (DRV/r) or lopinavir (LPV/r) – mono arm – with the same PI/r associated with 3TC 300 mg – dual arm. The primary outcome was failure rate at 96 weeks. Treatment failure was defined as 1) a confirmed VL above 500 copies/mL, 2) reintroduction of the NRTI backbone or 3) the interruption of PI.

Results: From March 2014 to January 2015, 265 patients were randomized (133 in mono arm and 132 in dual arm). Included patients were mainly women (73%), with a median age of 42 years [interquartile range (IQR) 36–50]; median CD4 was 475 cells/mm^3 (IQR 379–652) and median time on second line was 37 months (IQR 30–47). At the failure of first line, 96% had the M184V mutation. For the Data Safety Board meeting in March 2016, week 48 data were analyzed. The Board advised for the interruption of the mono arm. In the ITT analysis, 3.0% (95% CI 0.8–7.6) and 22.6% (95% CI 15.8–30.6) of patients failed in the dual and mono arm respectively ($p < 0.001$). Median time to failure was 24 weeks. All failing patients, except one, resuppressed to less than 200 copies/mL in a median time of 12 weeks after reintroduction of the NRTI backbone. Increase in CD4 was significantly higher in the dual arm (48 vs. 7 cells/mm^3). No differences in adverse events were observed. Neither adherence, nor nadir CD4 count, nor PI drug were associated with failure.

Conclusions: After viral suppression with PI plus NRTIs in second-line therapy, maintenance with PI/r plus 3TC is associated with a high rate of success despite the presence of M184V while PI/r monotherapy cannot be recommended.

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O123

Resistance profile analysis of treatment-experienced HIV-1-infected patients switching to elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) plus darunavir (DRV)

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Introduction: In study GS-US-292-0119, virologically suppressed, treatment-experienced patients on complex multi-tablet regimens [1] were switched to a simpler, more convenient antiretroviral regimen. After 48 weeks, viral suppression was maintained in 94.4% of patients who switched to E/C/F/TAF + DRV compared to 76.1% in the DRV-containing "Stay on Baseline Regimen" arm. All patients had documented resistance to >2 classes of antiretroviral (ARV) agents at baseline. Detailed ARV regimens and the resistance profile of the study population are described.

Methods: Historical genotypic reports were analyzed for resistance-associated mutations (RAMs) to ARVs. The Stanford HIVdb algorithm version 8.01 was used to calculate genotypic susceptibility scores (GSS). For each drug, a 5-point scale was used: susceptible, potential low-level resistance, low-level resistance, intermediate-level resistance and high-level resistance were scored as 1, 0.75, 0.5, 0.25 and 0, respectively. The total GSS for a given regimen was calculated as the sum of the scores for each individual drug.

Results: A total of 94.8% had documented resistance to >2 classes of ARVs, including protease inhibitors (PIs; 34.8%), non-nucleoside RT inhibitors (NNRTIs; 88.1%) and NRTIs (94.8%). The most common PI-RAMs were L90M (15.6%) and V82A/F/L/S/T (14.8%), the most common NNRTI-RAMs were K103N/S (63%) and Y181C/I/V (19.3%) and the most common NRTI-RAMs were M184V/I (83%) and K65R (23.7%). Thymidine analog mutations (TAMs) were present in 42.2% of patients (59.6% with one or two TAMs and 40.4% with three TAMs). The distribution of GSS at study entry was similar across treatment groups. Patients in the E/C/F/TAF + DRV arm maintained virologic suppression similarly, regardless of the DRV dosage received before switching (33/33 and 51/56 with treatment success in the 600 mg BID and 800 mg QD groups, respectively). In the E/C/F/TAF + DRV arm, 11/89 patients (12.4%) had GSS <2, 51/89 patients (57.3%) had GSS ≥2 and <3, and 27/89 patients (30.3%) had GSS ≥3.