

POSTER PRESENTATION

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# Efficient immune reconstitution in HIV+ naïve patients (pts) starting a first lopinavir/ritonavir-containing regimen with low CD4 counts

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## Purpose of the study

Investigate immune restoration profile, T-cell activation and microbial translocation in HIV+ naïve pts starting a first LPV/r-containing regimen with low CD4.

## Methods

40 HIV+ antiretroviral-naïve pts starting a first tenofovir/emtricitabine + LPV/r-containing ART with CD4 <350 (20 Late Presenters —LPs, CD4 <100/μL and 20 Non-Late Presenters —NLPs, CD4, 200—350/μL) were followed for 12 months (T12). Microbial translocation (MT) by plasma lipopolysaccharide (LPS) and sCD14 (LAL assay and ELISA), CD38+CD8, CD45R0+38+CD8, CD127+CD4/CD8 (flow cytometry), and plasma IL-7 (ELISA) were tested at T0 and T12. T0 and T12 differences were analyzed by Mann Whitney U test.

## Summary of results

At T12, all 40 HIV+ pts displayed a significant CD4 rise, HIV viremia reduction ( $p=0.0006$ ;  $p<0.0001$ , respectively) and a decrease in activated CD38+CD8 ( $p<0.0001$ ), with a trend to an increase in CD127+CD8 ( $p=0.07$ ). By T12, both LPs and NLPs displayed a significant CD4 increase (LPs:  $p=0.0001$ ; NLPs:  $p=0.001$ ), with LPs maintaining significantly lower CD4 at T12 ( $p=0.0001$ ). At T12, NLPs and LPs displayed a significant reduction in CD38+CD8+ ( $p=0.009$ ;  $p=0.018$ , respectively); only NLPs displayed a decreasing trend in terminally-differentiated CD45R0+CD38+CD8 ( $p=0.077$ ). Compared to LPs, NLPs featured higher CD127+CD4 proportions at all timepoints (T0,  $p=0.0001$ ; T12,  $p=0.001$ ), with a significant increase in CD127+CD8 by T12 ( $p=0.012$ ), whereas no changes were

seen in LPs. NLPs also displayed a significant rise in circulating IL-7 ( $p=0.049$ ), whereas LPs showed a decreasing trend ( $p=0.074$ ). At T0, NLPs showed higher levels of MT markers (LPS:  $p=0.01$ ; sCD14:  $p=0.007$ ). By T12, only NLPs displayed a significant reduction in LPS ( $p=0.022$ ) and in sCD14 ( $p=0.005$ ), whereas no changes were shown in LPs.

## Conclusions

In HIV+ antiretroviral-naïve pts with low CD4, LPV/r-containing regimens resulted in adequate immune reconstitution and restoration of the IL-7/IL-7R system. Interestingly, microbial translocation was efficiently controlled only in patients with less advanced HIV infection. However, LPV/r-based treatment resulted in a significant reduction of peripheral T-cell activation also in patients with late presentation. Given that T-cell activation is predictive of disease progression, our data advocate the efficacy of LPV/r regimens in broad immune reconstitution in HIV-infected pts with advanced infection.

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