Oral Communication **Session/Topic:** **Antiretroviral trials and observational studies**

N. **Title:**

OC 63 **Response to first-line ritonavir-boosted protease inhibitors (PI/r) based regimens in late presenting patients enrolled in a large cohort of HIV-infected individuals**

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Abstract:

Background: Ritonavir boosted protease inhibitors (PI/r)-based regimens are frequently used in late presenters (LP) due to their high genetic barrier and virological potency. There are no data from clinical trial or the observational setting comparing the response to currently recommended PI/r-based regimens in LP.

Aim: To compare the response to LPV/r- or DRV/r- or ATV/r-based cART regimens in LP initiating cART from ART-naive.

Patients and methods: LP were defined as people enrolled in Icona with a diagnosis of AIDS and either i) a CD4 count ≤350 cells/mm3 (LP) or ii) a CD4 count ≤200 cells/mm3 (advanced LP- ALP). The main analysisis focussed on LP in the Icona Foundation Study cohort who started their first PI/r-based regimen from ART-naive after 2008. Initial regimens were compared using an intention-to-treat analysis with respect to a number of outcomes: 1. time to virological suppression (VS), defined at time of the first viral load (VL) ≤50 copies/mL; 2. time to viral failure (VF) defined at time of the first of 2 consecutive VL>200 copies/mL after ≥6 months of ART; 3. treatment failure (TF) defined as time to VF or to discontinuation of the PI/r component of the regimen. Standard survival analysis by Kaplan-Meier curves and Cox regression models was used; unadjusted and adjusted relative hazards (RH) were computed.

Results: 1,140 LP were included (DRV/r 443; ATV/r 474; LPV/r 223); of these, 659 were ALP (DRV/r 292; ATV/r 225; LPV/r 142). Women and non-Italians were more represented in the LPV/r group (women: 35% LPV/r, 23% ATV/r, 20% DRV/r, p<.001; non-Italians: 31% LPV/r, 25% ATV/r, 22% DRV/r, p<.001); DRV/r group initiated cART more recently (2012 vs. 2011 for ATV/r and LPV/r; p<.001). There were differences between the groups in CD4 count [CD4 cells/mm3, median (IQR): 171 (70-263) LPV/r; 220 (116-288) ATV/r; 147 (48-260) DRV/r; p<.001] but not in VL at starting cART (median log10 copies/ml 4.94, IQR:4.30-5.95 in all groups). Over a median follow-up of 18 months (IQR:8-31), the 1-year probability of VS, VF and TF were 82% (95% CI: 71-84), 3% (2-4) and 20% (18-23), respectively. In the adjusted analysis (see footnote of Table for list of considered potential confounding factors), compared to participants starting LPV/r, those on ATV/r were 22% more likely to achieve VS but had a 2.7-fold higher risk of VF. People receiving DRV/r and ATV/r showed lower risk of TF than those on LPV/r. Results were similar after excluding patients on bid DRV/r-regimens (n=61) and when restricting the analysis to ALP.

Conclusions: Our population of LP responded well to first-line PI/r-based treatment with high chance of viral success by 1 year and small differences among the specific PI/r used. However, larger differences have been detected when comparing longer-term endpoints such as virological or treatment failure. These results are important to help designing clinical trials in the setting of HIV-infected people presenting late for care.