

**BACKGROUND**

Double-PI regimens are a reliable therapeutic option in salvage therapy. However, double PI-therapy has not yet been examined as an option for treatment naïve patients. In the LORAN study, a 72-week, randomized trial among HAART-naïve patients, LPV/r is combined with either CBV (ATZ+3TC) or ATV. Primary endpoints are metabolic side effects and QOL, secondary endpoints are virological and immunological response.

**METHODS**

Treatment-naïve HIV-1-infected patients started on HAART were randomly assigned to either treatment arm. We analysed virological failure in both groups, defined as VL ≥50 copies/mL at week 24.

**RESULTS**

We present 24-week data of 77 patients focusing on virological response. 27/36 patients in the CBV-LPV/r arm show virological response vs. 20/41 in the ATV-LPV/r arm. Referring to non completion equals failure, the intent-to-treat analysis revealed significant differences for virological failure in the LPV/r-ATV arm compared to the control group: Fisher’s Exact Test p=0.037. With regard to 64 on-study subjects (“as treated” analysis) in week 24, we observed 12 failures in the ATV-LPV/r arm vs. 4 failures in the CBV-LPV/r arm (Fisher’s Exact test: p=0.043). ATV-LPV/r failures were on low level (9/10 virological failures <400 copies/mL) (Fig. 1). The time to viral suppression was delayed in the double-PI-arm (Fig. 3). Pharmacokinetic measuring showed reduced LPV concentrations in 1/7 tested subjects in the double-PI failures (Data not shown).

Referring to the immunological response, the increase of the CD4+ T cells is significantly higher in the ATV-LPV/r arm (Mann-Whitney test p<0.01) (Fig. 4).

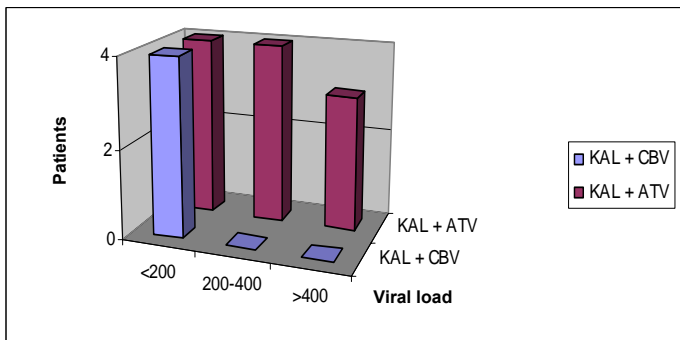


Figure 1: Treatment failures were mostly on low levels of plasma viremia.

	#Patients (week 24)	Viral load <50 (cop/ml)
KAL+CBV	30	26
KAL+ATV	31	20

Figure 3: Virological response (viral load <50 cop/ml in week 24).

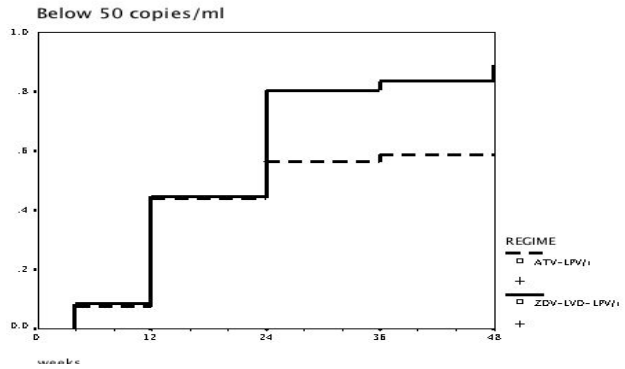


Figure 3: Kaplan-Meier-Analysis: Time to viral suppression <50 cop/ml.

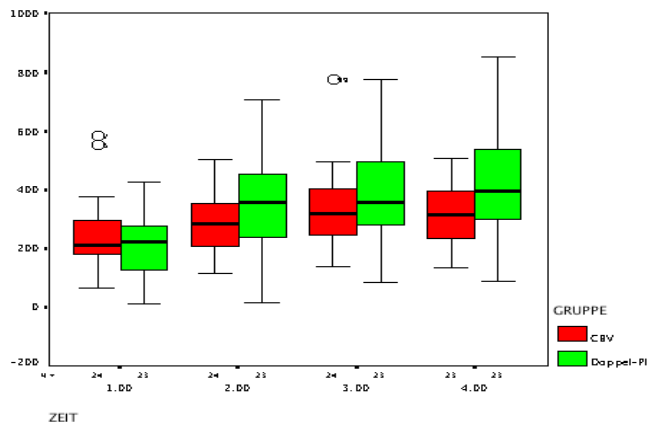


Figure 4: CD4+ T Cell Course. No significant difference in the initial T cell count in both treatment groups. The increase is significantly higher in the ATV-LPV/r-group.

**CONCLUSIONS**

This is the first report of a first line double-PI first line therapy. In this interim analysis, patients in the double-PI-arm had a significantly higher rate of mostly low level virological failure. ATV and LPV/r are less effective than the conventional RTI-based LPV/r regimen. These findings are underlined by recently published MONARK-study, where Therapy-naïve patients treated with Mono-PI-strategy had a reduced virological response compared to PI plus conventional NRTI backbone.

Due to these data, we stopped recruitment for patient’s safety. Nevertheless, further exploration of early RTI-sparing therapy with regard to metabolic side effects and QOL is still warranted.

**References**

Delfraissy JF, Flandre P, Delaugerre C et al. (2008): Lopinavir/ritonavir monotherapy or plus zidovudine and lamivudine in antiretroviral-naïve HIV-infected patients. AIDS 30;22:385-93

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