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# Lipid-profile of Lopinavir/ritonavir (LPV/r) in an 18-month French observational prospective cohort (Kaleobs cohort)

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## Background

Kaletra®, (lopinavir/ritonavir, LPV/r) has been extensively studied in both anti-retroviral naïve and experienced HIV-infected patients.
Long-term data are available and show a potent antiviral effect and a good tolerance in clinical trials.
In order to assess the use of Kaletra® in routine practice, a large observational cohort, KALEOBS, has been set up to study short and long term tolerance, as well as antiviral activity.
This poster presents the analysis focused on the lipid-profile through 18 months.

## Objectives

To assess the long-term lipid profile of LPV/r-containing regimens in routine practice.

## Methods

### Study Design

Large observational cohort of 1315 adult HIV-infected patients treated for the first time by LPV/r and conducted in France in 181 investigating centers. Follow-up was scheduled up to 18 months. Patients were included between September 2002 and November 2003.

### Patients

HIV-1 positive patients, currently treated by Kaletra® (lopinavir/ritonavir) Soft Gel Capsules (SGC) for at least 1 month and no more than 3 months, and :

- either naïve of ARV (ARV-Naïve)
- or pre-treated without PI (PI-Naïve)
- or pre-treated with a first line PI (PI-Exp).

### Follow-up

After an inclusion visit (M0), visit frequency was determined by standard of care (M1, M3, then every 3 months). Due to the observational character of this survey, data collection and follow-up were left to the judgment of each physician within the 18-month period.
Data collection for this analysis at baseline and during follow-up includes demographic data, current ARV medications and laboratory results (total cholesterol, HDL and LDL-cholesterol, triglycerides, glycemia). Plasma lipid levels were measured per standard of care and under fasting conditions.

### Statistical analysis

Description is based on mean and standard deviation for quantitative values.
Baseline characteristics are presented for the total number of patients included in the cohort.
Follow-up data are only presented for patients with M18 data (n=127).
Changes in laboratory parameters are compared during time and between the 3 groups using two factor analysis of variance for paired series.

## Results

### Baseline Cohort Characteristics

**Patient Distribution and Baseline Characteristics**

Figure 1: Patients Distribution (all patients)

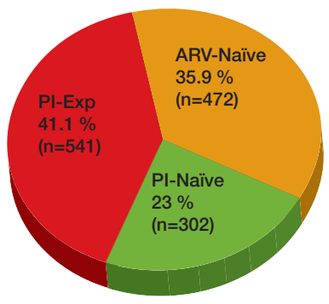



Table 1: Demographic and Baseline Lipids Characteristics (all patients)

| Value at Baseline | ARV-Naïve | PI-Naïve | PI-Exp |
|---|---|---|---|
| Mean age (years) | 40 | 41 | 42 |
| Gender (% male) | 71.4% | 68.9% | 74.9% |
| Total Cholesterol (mg/dL) | 172 (+/-40) | 186 (+/-98) | 197 (+/-120) |
| Mean (+/-SD) | n=359 | n=252 | n=461 |
| Triglycerides (mg/dL) | 121 (+/-76) | 146 (+/-117) | 160 (+/-106) |
| Mean (+/-SD) | n=359 | n=250 | n=484 |
| HDL-c (mg/dL) | 43 (+/-19) | 47 (+/-34) | 58 (+/-180) |
| Mean (+/-SD) | n=174 | n=105 | n=198 |
| LDL-c (mg/dL) | 106 (+/-33) | 113 (+/-41) | 116 (+/-42) |
| Mean (+/-SD) | n=159 | n=84 | n=177 |

**Antiretroviral Regimens Combined with LPV/r (all patients)**

For the 3 populations, AZT+3TC are the most frequently antiretroviral drugs combined with LPV/r at inclusion : in 66.7% of the cases for ARV-Naïve, 21.1% for PI-Naïve and 21.5% for PI-Exp.

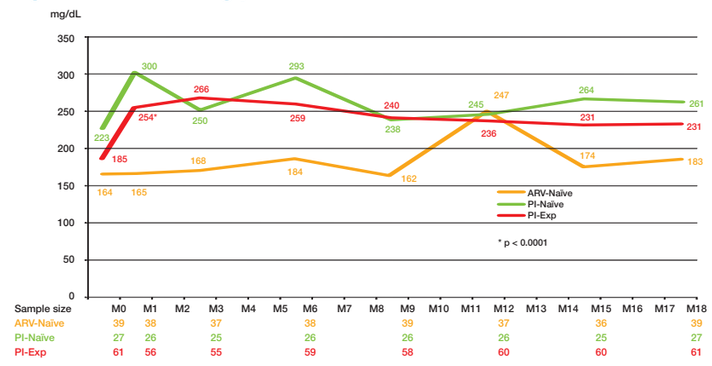
### Biological safety: total cholesterol, triglycerides, HDL-c and LDL-c

*(Patient who completed the 18-month follow up, n=127)*

Figure 2. Mean Total Cholesterol Evolution


Mean changes in TC from baseline to M1: +13; +9; +21 mg/dL in the 3 populations (n=39; n=30; n=58).

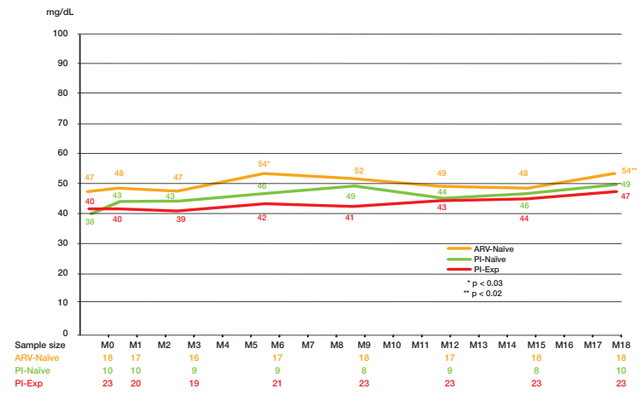
Figure 3. Mean Triglycerides Evolution




Mean changes in TG from baseline to M1: +1; +77; +69 mg/dL in the 3 populations (n=39; n=27; n=61).

After a significant increase in TC (in ARV-Naïve and PI-Exp only) and TG (in PI-Exp only) within the first month, TC and TG remained stable up to M18.

Figure 4. Mean HDL-c Evolution




Mean values of HDL-cholesterol were normal at baseline. No significant decrease was observed in the 3 groups from M0 to M18.

Figure 5. Mean LDL-c Evolution


Mean values of LDL-cholesterol were normal at baseline. No significant increase was observed in the 3 groups from M0 to M18.

Table 2. Distribution of Total Cholesterol and Triglycerides Values at M0, M3 and M18

| | ARV-Naïve | | | PI-Naïve | | | PI-Exp | | |
|---|---|---|---|---|---|---|---|---|---|
| | M0 | M3 | M18 | M0 | M3 | M18 | M0 | M3 | M18 |
| CT (mg/dL) | n=39 | n=38 | n=39 | n=30 | n=29 | n=30 | n=58 | n=53 | n=58 |
| < 250 | 92.3% | 91.9% | 84.6% | 90% | 86.2% | 86.7% | 86.2% | 83% | 79,3% |
| 250-300 | 5.1% | 5.4% | 15.4% | 10% | 13.8% | 13.3% | 12.1% | 7.6% | 17.2% |
| > 300 | 2.6% | 2.7% | 0% | 0% | 0% | 0% | 1.7% | 9.4% | 3.4% |
| TG (mg/dL) | n=39 | n=37 | n=39 | n=27 | n=25 | n=27 | n=61 | n=55 | n=61 |
| < 200 | 79.5% | 67.6% | 71.8% | 63% | 48% | 55.6% | 67.2% | 43.6% | 59% |
| 200-400 | 12.8% | 32.4% | 25.6% | 29.6% | 32% | 29.6% | 24.6% | 40% | 31.2% |
| > 400 | 7.7% | 0% | 2.6% | 7.4% | 20% | 14.8% | 8.2% | 16.4% | 8.8% |

High value of TC and TG, when present, appears within the 3 first Month and concern only a minority of patients. Prevalences of high value of TC and TG are low (less than 3.5 % for TC and less than 15% for TG for the 3 groups).
The percentage of patients with high values of TC and TG remains stable through 18 month follow up.

## Conclusion

As previously reported after a M9 follow-up in this cohort, the impact of LPV/r on lipids, when it exists, occurs early after treatment initiation.
Changes in TC and TG are moderate and remain stable up to M18.

## References

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## Aknowledgments

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