Safety of long-term Lopinavir Plasma-levels in Patients with Liver disease

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Background: Chronic liver disease is often found in HIV infected patients. LPV as first choice drug is often used over long time periods. TDM as a tool in patient care is important but the knowledge of LPV-plasma-levels in patients with chronic liver disease remain uncertain. With this retrospective analysis we want to show if there are differences in LPV-plasma-levels between patients with and without chronic liver diseases over a long-time period.

Methods: Since 06/00 we determine LPV-plasma-levels with an HPLC-based method. The LPV-plasma-levels over the time course in patients with chronic liver disease (n=30) and patients without liver disease (n=38) was evaluated. Liver function tests, CD4-cell count and HIV-viral load was also correlated with liver disease. Statistical analysis was done by multivariate analysis with the SPSS Software.

Results: The LPV plasma-levels of totally n= 450 samples from 30 patients with liver disease (Hepatitis B: n=17, Hepatitis C: n=16, Alcoholic liver disease: n=7) and 38 patients without liver disease were determined over 18.7±16.3 months (1 - 48.5 months). A median of 10 samples per patient was eligible (2 - 50 samples). All patients received 400 mg LPV bid with various nuke-backbones. There are no significant differences according to liver disease in LPV-plasma levels (mean Ctrough without: 5917±4811 ng/ml, mean Ctrough with liver-disease: 6564±4517 ng/ml, p > 0.05). The intraindividual and interindividual variation of LPV-plasma levels, CD-4 increase, HIV-virus suppression and liver tests in patients with and without liver disease is comparable.

Conclusion: In this clinical setting no differences in LPV-plasma levels between patients with and without chronic liver disease could be demonstrated. LPV-therapy in patients with chronic liver disease is safe. TDM is a helpful tool in patients with impaired liver function for dose adjustment.

Fig. 1: LPV-plasma-levels (n=450) according to duration of therapy

Fig. 2: LPV-plasma-levels (n=450) of 68 patients up to 4.5 years

Fig. 3: LPV-plasma-levels (n=235) in 38 patients without liver disease

Fig. 4: LPV-plasma (n=215)-levels in n=30 patients with liver disease

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