

Poster presentation

## Hepatic safety of tipranavir/ritonavir (TPV/r)-based antiretroviral therapy: effect of hepatitis virus co-infection and baseline liver fibrosis

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### Purpose of the study

Data on the hepatic safety of TPV/r comes mostly from clinical trials. The liver tolerability of TPV/r in real life conditions of use could be different. However, there are little data on this issue from clinical cohorts. Because of these, we evaluated the incidence and risk factors of severe liver events among HIV-infected patients treated with drug combinations including TPV/r.

### Methods

150 patients were selected because they started a regimen that included TPV/r (500/200 mg BID), and had clinical visits at least every 3 months. Patients who discontinued TPV/r before their first visit were included.

### Summary of results

Twelve (8%) individuals developed grade  $\geq 3$  transaminase elevation ( $G \geq 3TE$ ). Nine (6%) patients discontinued TPV/r due to liver events. Six (8.6%) of 70 HCV-coinfected patients and six (7.5%) of 80 subjects without HCV co-infection developed  $G \geq 3TE$  ( $p = 1$ ). Liver fibrosis was evaluable in 48 (63%) of 76 individuals with HBV and/or HCV infection. Four (13%) of 30 subjects with moderate-to-severe fibrosis and none of 18 with mild fibrosis showed  $G \geq 3TE$  ( $p = 0.3$ ). None of nine patients with cirrhosis showed  $G \geq 3TE$ .

### Conclusion

Liver tolerability of TPV/r was generally good in a cohort of patients with a high proportion of HCV co-infection, including subjects with advanced fibrosis. Monitoring of liver enzymes was not different for co-infected patients. Thus, more frequent blood testing does not seem warranted for these patients.