Journal of the International AIDS Society

Poster presentation

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Hepatic tolerability of fosamprenavir/ritonavir (FPV/RTV) in HIV/hepatitis C co-infected subjects with severe hepatic fibrosis

P Nasta*, F Gatti, G Cologni, A Matti, M Monia and G Carosi

Address: Institute of Infectious and Tropical Diseases, Brescia, Italy
* Corresponding author

from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P282 doi:10.1186/1758-2652-11-S1-P282

This abstract is available from: http://www.jiasociety.org/content/11/S1/P282

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Background

Few data are available in HIV/hepatitis C co-infected subjects with severe hepatic fibrosis or cirrhosis. Liver enzymes elevation (LEE) in HIV/HCV co-infected patients with or without cirrhosis on fosamprenavir/ritonavir (700/100 mg BID)-containing HAART regimen has been assessed.

Methods

HIV/HCV-RNA positive co-infected subjects, treated with FPV/rtv for at least 6 months have been enrolled in a retrospective observational study. Baseline socio-demographic characteristics, data on HIV, HCV and antiretroviral treatments history, immuno-virologic data, and renal and liver function parameters have been recorded at baseline and every 6 months. Liver enzymes (LE) level at baseline has been categorized as normal (LE-N) or abnormal (LE-AN) using the local laboratory cut-off of 45 IU/l for females and 50 IU/l for males. The stiffness >14 Kpascal by Fibroscan® and/or a FIB-4 score >3.25 [calculated by: age ([yr] × AST [U/L])/((PLT [109/L]) × (ALT [U/L])1/2)] have been used to define the cirrhosis. LEE after 6 months of treatment has been compared between groups of patients with LE-N or LE-AN and with or without cirrhosis using a Student's t-test for normal distribution parameters or the Mann-Whitney U test. A Kaplan Meier analysis has been used to assess the risk of developing a grade 1–2 LEE.

Summary of results

A total of 13 HIV/HCV co-infected subjects on HAART containing FPV/rtv have been enrolled [median age 44 years (IQR 29–68); 25 females; mean time on HAART: 9.3 years; mean time on FPV/rtv: 28 months; pts with LE-AN: 70 (53%); with cirrhosis: 51(38.6%)]. Subjects with LE-AN had a significant decrease of AST/ALT from baseline through 6th month (mean ALT: 136 (DS 95) UI/l to 86 (+90) UI/l, $p < 0.001$; mean AST: 106 (DS 57) UI/l to 64 (DS 62) UI/l, $p < 0.001$). No difference in LEE was observed in subjects with or without cirrhosis. At the Kaplan Meier analysis, the risk to develop a grade 1–2 LEE in patients with or without cirrhosis was similar (Log Rank $p = 0.42$).

Conclusion

In HIV/HCV co-infected patients, LEE is frequent and it is related with liver disease progression and death. In co-infected subjects FPV/rtv at standard dose represents a safe opportunity also in cirrhotic patients.