Abstracts of the HIV Drug Therapy Glasgow Congress 2014
Neukam K et al. *Journal of the International AIDS Society* 2014, **17(Suppl 3)**:19631
http://www.jiasociety.org/index.php/jias/article/view/19631 | http://dx.doi.org/10.7448/IAS.17.4.19631

Hepatic safety of RPV/FTC/TDF single tablet regimen in HIV/HCV-coinfected patients. Preliminary results of the hEPAtic Study

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Introduction: Although hepatotoxicity related to antiretroviral treatment (ART) has become less frequent, hepatotoxic events, such as transaminase elevations (TE), are still a matter of concern. RPV/FTC/TDF (EPA) is a new single tablet regimen which is widely used in real life practice. Clinical trials showed an adequate profile of liver safety in the sub-population of HIV/HCV-coinfected patients receiving rilpivirine. However, the number of individuals included in these analyses is low [1]. The aim of this ongoing study is to evaluate the incidence of TE and total bilirubin elevations (TBE) during the first 48 weeks of EPA-based therapy in a large population of HIV/HCV-coinfected subjects outside of clinical trials.
Patients and Methods: This is a retrospective analysis of HIV/HCV-coinfected subjects who started EPA at the infectious diseases units of 14 centres throughout Spain, included as cases. Subjects who started an ART different to EPA during the study period at the same hospitals were selected as controls. The primary outcome variables were grade 3 or 4 TE and grade 4 TBE.
Results: Of the 191 patients included, 31 (16.2%) subjects were naïve to ART. Eighty-seven individuals started EPA and the remaining ones were controls. The most common NRTI backbone among the controls was TDF/FTC [59 (56.7%) patients] followed by NRTI-sparing regimens [24 (23.1%) individuals] and ABC/3TC [17 (16.3%) subjects]. Among controls, 67 (64.4%) started a ritonavir-boosted protease inhibitor, mainly DRV/r [41 (39.4%) patients] followed by ATV/r [16 (15.4%) subjects]. EFV, ETV and RAL were started in 16 (15.4%), 12 (11.5%) and 13 (12.5%) subjects, respectively. The median (Q1–Q3) follow-up was 5.79 (3.65–8.61) months for the cases and 11.44 (5.8–12.88) months for the controls. TE was observed in two (2.3%) cases versus five (4.8%) controls ($p = 0.358$), accounting for a density of incidence of 4.32/100 person-years versus 5.51/100 person-years [incidence rate difference (95% confidence interval): -1.88 (-9.95–6.2), $p = 0.354$]. All TE were grade 3 and no patient discontinued ART due to TE. None of the cases developed TBE versus four (3.8%) controls, all of them receiving ATV/r.
Conclusions: The frequency of grade 3–4 TE associated with EPA in HIV/HCV-coinfected patients under real life conditions is very low. In addition, TE in HIV/HCV-coinfected patients treated with EPA are usually mild and do not lead to treatment discontinuation. TBE was not seen in patients taking EPA. All these data confirm that EPA is safe in this particular subpopulation.

Reference

1. Nelson M, Amaya G, Clumeck N, et al. Efficacy and safety of rilpivirine in treatment-naive, HIV-1-infected patients with hepatitis B virus/hepatitis C virus coinfection enrolled in the Phase III randomized, double-blind ECHO and THRIVE trials. J Antimicrob Chemother. 2012;67:2020–8.

Published 2 November 2014