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Abstract (poster session)

Quantifying the incidence and magnitude of liver injury among HIV-infected patients receiving raltegravir-containing antiretroviral therapy

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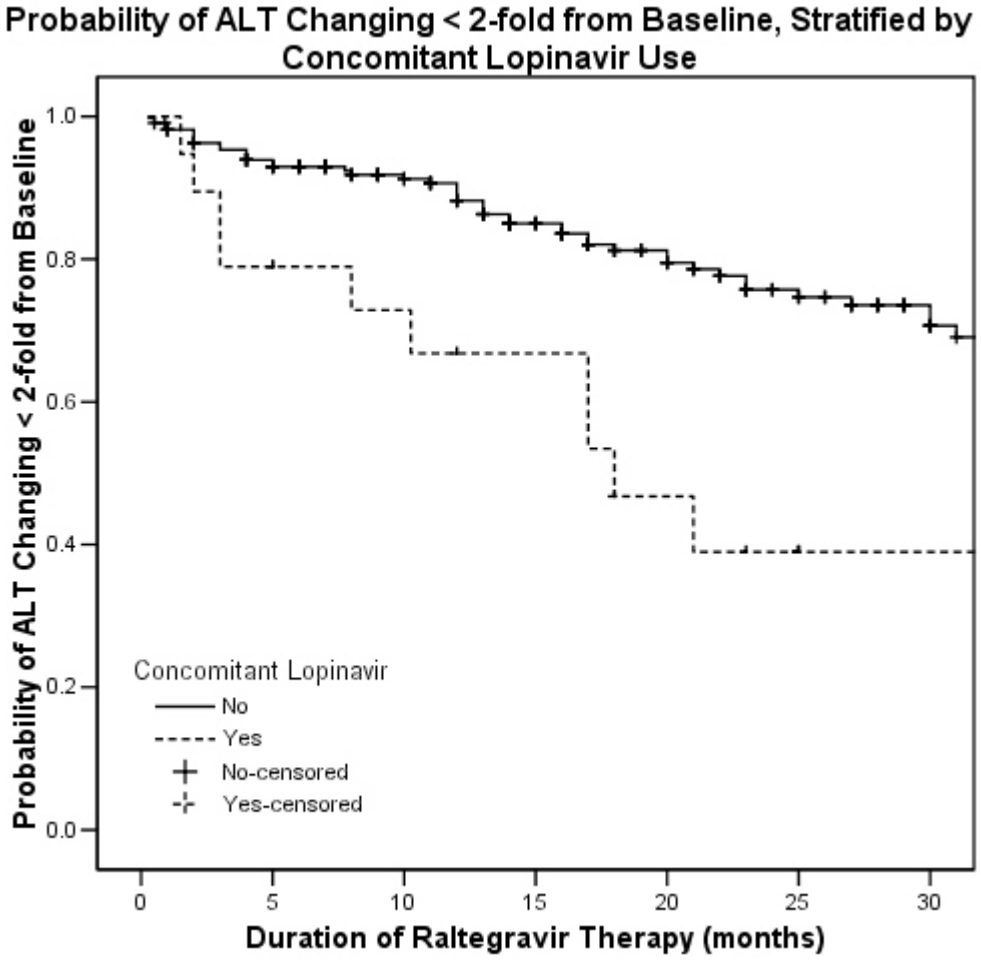
Objectives: 1) Quantify the incidence of liver injury among patients receiving raltegravir (RAL) and 2) characterize the magnitude of liver injury associated with raltegravir (RAL) use. Methods: A retrospective cohort study was performed at the Albany Medical Center between Jan 2007 and Jul 2011. Inclusion criteria were: i) age >= 18 years, ii) HIV-infection, iii) availability of alanine aminotransferase (ALT) values in the medical chart and iv) RAL use >= 1 month. The following were extracted from the patients' medical records: demographics, co-morbid conditions, medication histories and laboratory values. Liver injury was defined in 2 ways: 1) ALT increase 3x the upper limit of normal (ULN) from baseline ALT value and 2) a relative change in ALT from baseline, calculated as the most extreme ALT value divided by the baseline ALT. For this second outcome, liver injury was defined as a 2-fold increase in ALT from baseline. Descriptive statistics were used to quantify the incidence and magnitude of liver injury. Kaplan Meier plot was generated and survival distributions were compared using log-rank test. Results: There were 238 patients included. The mean (SD) age of the patients was 48.6 (9.0) years. The median (IQR) baseline ALT was 27.5 (20.0 - 41.0) IU/L. The median (IQR) value of the most extreme ALT value on RAL therapy was 43 (28 - 72.3) IU/L, occurring after a median (IQR) of 7 (2 - 15.3) months. Concomitant hepatotoxic drugs were used by 214 (89.9%) patients. Among these patients, the mean (SD) number of concomitant hepatotoxic drugs was 2.5 (1.4). Absolute ALT increases 3x the ULN were observed in 8 (3.9%) patients. Concomitant lopinavir use was the only covariate associated with this outcome and was more frequent among patients that experienced an ALT increase 3x ULN than those that did not, 37.5% vs 6.6%, respectively. There were 60 (25.2%) patients that experienced a doubling (2-fold increase) in ALT from baseline. The covariates associated with a doubling ALT were alcoholism, baseline ALT, concomitant lopinavir use and duration of RAL therapy. Time-to-event distribution of the probability of ALT changing < 2-fold from baseline, stratified by concomitant lopinavir is displayed in the figure. Survival distributions differed significantly ($p = 0.001$) and was most pronounced for patients using concomitant lopinavir. Conclusion: The incidence of ALT increases 3x ULN was low among patients receiving RAL. Doubling ALT was more common and modified by concomitant lopinavir use.


Probability of ALT Changing < 2-fold from Baseline, Stratified by Concomitant Lopinavir Use
Probability of ALT Changing < 2-fold from Baseline
1.0
0.8
0.6
0.4
0.2
0.0
Concomitant Lopinavir
No
Yes
No-censored
Yes-censored
0
5
10
15
20
25
30
Duration of Raltegravir Therapy (months)