Poster # 74

Long-term Hepatic Safety of Protease Inhibitors Including Lopinavir/Ritonavir Containing Regimens in the Treatment of HIV-HBV Co-Infected Patients

Homayoon Khanlou[1], Ashwaq Hermes[2], Richard A Rode[2], Rick A Stryker[2], Charles Farthing[1]

[1] AIDS Healthcare Foundation, Los Angeles, CA, United States; [2] Abbott Laboratories, Abbott Park, IL, United States

ACTHIV
May 31 – June 3, 2007
Dallas, Texas

Introduction:

- Hepatitis B virus (HBV) is a major source of morbidity outside of United States. There is limited data regarding the liver toxicity of antiretroviral therapy in HIV-HBV co-infected patients.
- Some clinicians have avoided the use of boosted protease inhibitors to decrease risk of hepatotoxicity in these patients.

Methods :

- Our objective was to compare the incidence of hepatotoxicity, defined as ALT/AST >5 x upper-limit of normal if ALT/AST normal at baseline OR 3.6 x baseline if ALT/AST elevated at baseline (last on-treatment measurement during observation period) between HAART combinations and boosted HIV-protease inhibitors, including lopinavir/ritonavir (LPV/r).
- We retrospectively assessed all HIV-HBV co-infected patients at our institution followed for more than 1 year.

Results:

- We identified 107 co-infected patients.
- 6 were excluded from analysis due to concomitant PI+NNRTI therapy.
- Median age of remaining pts was 42 [24-68] years.
- 93% were male, 7% were female.
- Ethnicity/Race: White (41%), Black (36%), Hispanic (16%), Native-American (1%) and Asian (2%).
- 5 Treatment arms:
  - No ART (control): n=10
  - NRTIs alone (3 agents): n=5
  - NNRTI: n=21
  - LPV/r: n=19
  - other RTV-boosted PIs (fosAPV and ATV): n=46
- Fisher's exact test (discrete) and a one-way ANOVA model (continuous) were used for comparison among different arms.

Incidence of ALT and/or AST elevations per treatment arm:

	No ART (Controls)	NRTIs	NNRTIs	LPV/r	Other PI/r
ALT ↑ (IU/L)	0/10	0/5*	1/21**	0/19*	0/46*
AST ↑ (IU/L)	0/10	0/5*	0/21*	0/19*	0/46*
ALT/AST ↑ (IU/L)	0/10	0/5*	1/21**	0/19*	0/46*

p-value (for comparison with No ART): *=0.999, ** p=0.677

	No ART	NRTIs	NNRTI	LPV/r	Other PI/r
Duration of Follow up (months)					
Mean ± SD	41 ± 24	43 ± 25	38 ± 21	33 ± 21	41 ± 21
Median	45.5	43.0	34.0	34.0	39.5

Baseline Viral Load ($\log_{10}$ c/mL)					
Mean ± SD	3.7 ± 1.1	2.9 ± 1.6	3.2 ± 1.2	3.6 ± 1.5	4.1 ± 1.4
Median	3.7	2.1	2.7	4.0	4.4
P-value (Compared to No ART)	N/A	0.278	0.358	0.905	0.320

Viral Load Change ($\log_{10}$ c/mL)					
Mean ± SD	0.6 ± 1.2	-0.1 ± 2.2	-0.5 ± 1.1	-0.8 ± 1.8	-1.1 ± 1.9
Median	0.3	0.4	-0.4	-0.9	-1.3
P-value (Compared to No ART)	N/A	0.441	0.098	0.037	0.005

Baseline CD4 Count (cells/mm^3)					
Mean ± SD	676 ± 209	578 ± 339	332 ± 178	205 ± 201	243 ± 180
Median	670.5	620.0	286.0	189.0	212.5
P-value (Compared to No ART)	N/A	0.362	<0.001	<0.001	<0.001

CD4 Count Change (cells/mm^3)					
Mean ± SD	-172 ±217	-84 ±207	80 ±166	124 ±188	80 ±140
Median	-117.5	-43.0	60.0	95.0	71.0
P-value (Compared to No ART)	N/A	0.341	0.002	<0.001	<0.001

Corresponding Author:

Homayoon Khanlou, MD
AIDS Healthcare Foundation
4835 Van Nuys Blvd, suite 200
Sherman Oaks, CA 91403
Tel: (818) 380-2626
Fax: (818) 380-2620
E-mail: homayoon.khanlou@aidshealth.org

Conclusions:

- In our cohort, HAART combinations appeared equally safe in HIV-HBV co-infected patients.
- Clinicians should not be reluctant to use regimens containing RTV-boosted HIV-protease inhibitors in HIV-HBV co infected patients.