Strong correlation between HBsAg, ALT and HDV-RNA levels in patients with chronic hepatitis D. Results of Phase 3 *D-LIVR* study.

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TAKE-HOME POINTS

- HDV RNA and HBsAg levels show positive correlation which is strongest in patients under 45 years old
- ALT levels are negatively correlated with HBsAg levels, with normal ALT levels are associated with high HBsAg levels

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1 Introduction & Aim

Several new treatments for chronic hepatitis B are focused in achieving a decline in HBsAg levels. Some of these new molecules are evaluated in patients with chronic hepatitis D (CHD). The aim of this study is to evaluate whether ALT, HBsAg and HDV-RNA levels correlate in untreated patients with CHD

2 Methods

407 patients in the on-going Phase 3 HDV *D-LIVR* trial (NCT037193139) were included .

Key inclusion criteria

- Chronic hepatitis D without or with compensated liver cirrhosis
- ALT between > ULN and < 10x ULN
- HBV DNA > 20 IU/mL
- Patients were randomized to
  - Arm 1, n=175: LNF 50 mg BID + RTV BID
  - Arm 2, n=125: LNF 50 mg BID + RTV BID + PEG IFN-alfa-2a QW
  - Arm 3, n=50: placebo LNF + placebo RTV + PEG IFN-alfa-2a QW
  - Arm 4, n=50: placebo LNF + placebo RTV

Serological markers measured at baseline

- HDV RNA, HBsAg, HBV DNA, ALT levels

Pearson correlation coefficients were computed for the following variables: ALT, HDV RNA quantification by PCR, and hepatitis B surface antigen levels. The significance level associated with the test of the null hypothesis that the correlation is zero is presented for each in correlation. Only baseline serum samples were used for this analysis.

3 Results

Baseline Characteristic	All Subjects (N=407)
Age, years	42 (18-69)
Male, n (%)	281 (69%)
Ethnicity, n (%) White Asian Black or African American	 298 (73%) 93 (23%) 6 (2%)
ALT, IU/L	78 (27 - 501)
Fibroscan, kPa	10.5 (3.7 - 48)
Liver cirrhosis, n (%)	108 (27%)
qHBsAg, IU/mL	7724 (0.11 - 56,500)
HDV-RNA, log IU/mL	5.08 (1.60 - 7.65)

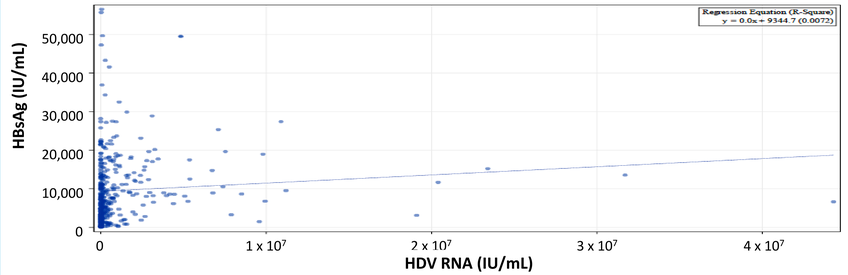
All qualitative variables are calculated as median (min-max) range

3 Results (cont)

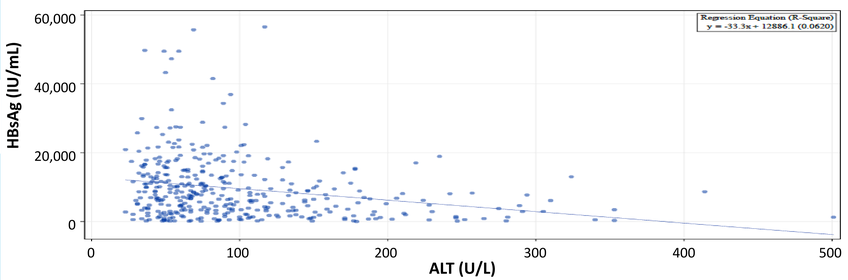
Correlation of ALT, HBsAg and HDV RNA

		Correlation Coefficient	Significance Level
All Subjects N = 407	HDV RNA - ALT	0.097	0.0499
	HBsAg – ALT	-0.248	<0.0001
	HDV RNA – HBsAg	0.154	0.0018
Subjects < 45 yo N = 261	HDV RNA - ALT	0.106	0.0862
	HBsAg – ALT	-0.242	<0.0001
	HDV RNA – HBsAg	0.162	0.0089

Correlation between baseline serum HDV RNA and HBsAg levels



Correlation between baseline serum ALT and HBsAg



4 Conclusions

In patients with chronic hepatitis D:

- HDV-RNA and HBsAg show positive correlation
- ALT levels negatively correlate with HBsAg levels
- Normal ALT levels are associated with high HBsAg levels

Poster Discussion Online

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