BULEVIRTIDE +/- PEG-IFN IN HIV/HBV/HDV CO-INFECTED PATIENTS IN REAL-LIFE SETTINGS

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BACKGROUND

- Bulevirtide (BLV) is a lipopeptide inhibiting the HBV/HDV entry into the hepatocytes. Significant HDV RNA decline was observed in HBV/HDV patients who received 48 weeks of BLV in monotherapy or in combination with PEG-interferon α 2a (PEG-IFNα).
- Until now, no data has been presented in HIV/HBV/HDV co-infected patients treated with BLV.
- The aim of this analysis was to evaluate the efficacy and safety of BLV 2mg daily with or without PEG-IFN2a for 12 months in HIV co-infected patients treated in the French BLV early access program.

METHODS

- 21 patients with HIV/HBV/HDV in BLV early access program
  - compensated cirrhosis/severe fibrosis or
  - moderate fibrosis with elevated ALT levels
- Patients received BLV 2mg QD SC alone (N=14) or in combination with PEG-IFNα once weekly (N=7) according to physician's choice.
- HIV drugs regimen were TAF/FTC (in 100% of patients), and either rilpivirine (n=8), bictegravir (n=4), elvitegravir (n=4), raltegravir (n=2), darunavir (n=2) or dolutegravir (n=1).
- Per protocol (PP) analysis: Patients receiving treatment at evaluation. Intent To Treat (ITT) analysis: All patients (missing value = no response)

RESULTS

- Characteristics of patients were as follows: male 71%, mean age 48 years, cirrhosis 52%, median HDV-RNA 6.09 log10 IU/mL, median HIV-RNA 0 cp/mL (three patients had detectable HIV-RNA at day 0, all < 100 cp/mL), median CD4 558/mm3
- No specific adverse events related to BLV were reported and no HIV drug modification was needed (median CD4 at M12: 540/mm3). Only one patient had detectable HIV-RNA at M12 (31 cp/mL at baseline and 54 cp/mL at M12).
- 8 patients (38%) stopped treatment before M12: 2 adverse events unrelated to BLV (variceal bleeding, rectal cancer), 3 lost to follow-up or patient decision, 3 no response according to the physician).
- From baseline, mean HDV RNA (log10 IU/mL) declined overtime: M3 -2.25, M6 -4.09, M9 –3.37, and M12 -4.19.

RESULTS

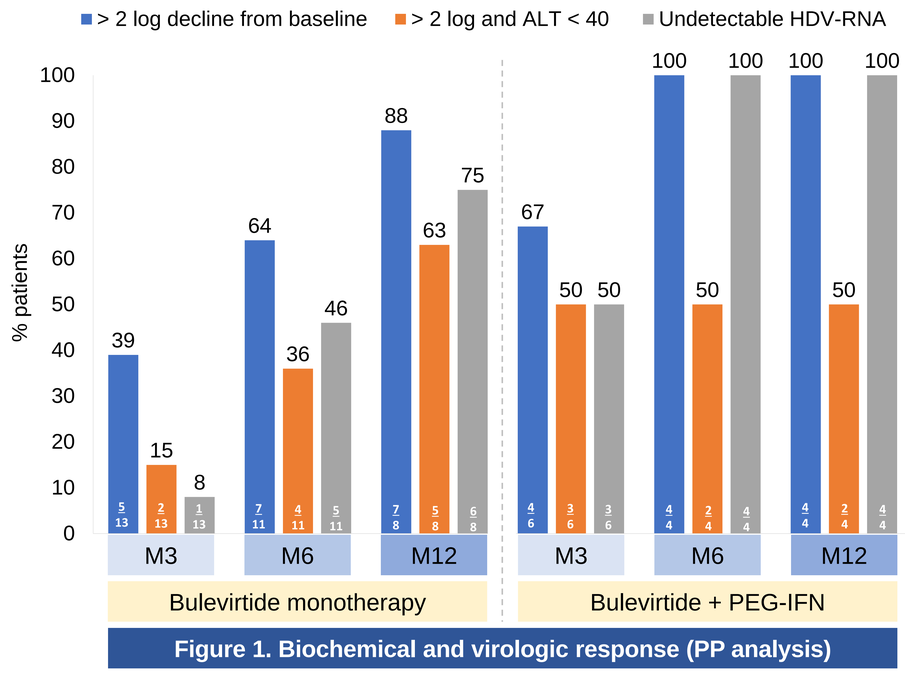


Figure 1. Biochemical and virologic response (PP analysis)

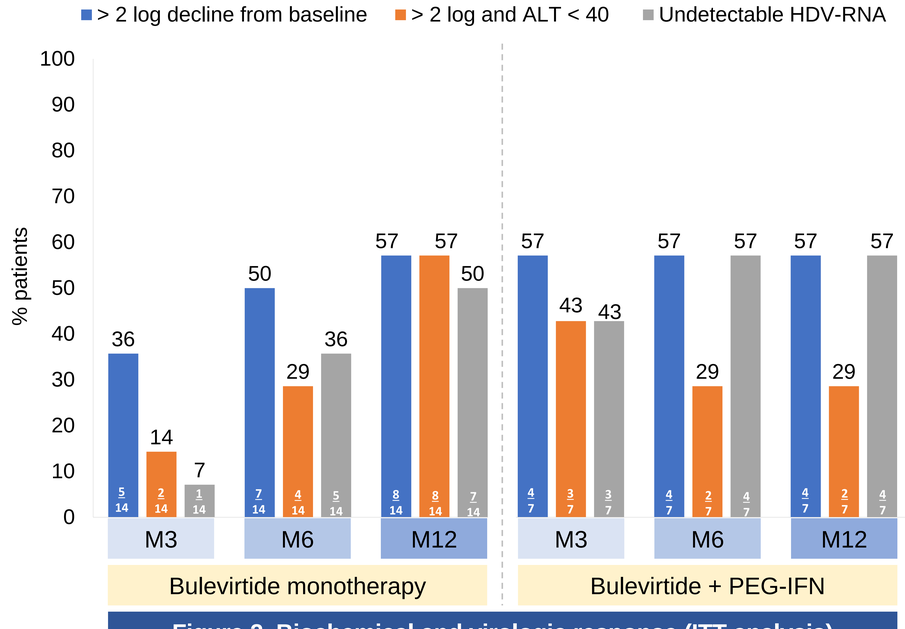


Figure 2. Biochemical and virologic response (ITT analysis)

Biochemical and virological responses gradually increased over time in patients treated by bulevirtide monotherapy.

CONCLUSIONS

- In this first real-world cohort of HIV/HBV/HDV patients, daily administration of BLV 2 mg for 12 months was safe and well tolerated with no impact on CD4, HIV viral suppression or HIV treatment regimen
- Strong HDV antiviral and biochemical responses were observed in real-life irrespective of the BLV regimen administered.

ADDITIONAL KEY INFORMATION

- Gilead collaborative study