Patient Characteristics and Treatment Patterns Amongst Hepatitis Delta Patients: Results From a Real-World Survey in Europe

THU-258

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Conclusions

- Half of patients with chronic hepatitis delta (CHD) experienced a high comorbidity burden
- According to physicians, most patients for whom they prescribed bulevirtide (BLV) received treatment as a monotherapy and were adherent to their regimen
- Reduction in hepatitis delta virus (HDV) transmission was shown to be an important consideration when prescribing BLV in clinical settings, alongside its long-term efficacy and reduction in viral shedding
- One-third of patients with CHD were not on HDV treatment, yet nearly one-fifth of these patients had cirrhosis and/or moderate or severe liver disease
- Real-world evidence on HDV treatment options may complement current and future treatment outcomes among patients prescribed BLV as monotherapy

Plain Language Summary

- Chronic hepatitis delta is a disease in the liver caused by a virus, which can be treated with an antiviral drug called bulevirtide
- Patients with chronic hepatitis delta also frequently experience co-occurring problems with anxiety and depression
- Doctors chose bulevirtide because the treatment can work in the long term
- Most patients took the correct dose of bulevirtide at the correct times, as instructed by their doctors

References: **1.** Netter HJ, et al. *Front Microbiol*. 2021;12:652962. **2.** Da BL, et al. *Gastroenterol Rep (Oxf)*. 2019;7(4):231-45. **3.** Hepcludex. Summary of product characteristics. European Medicines Agency. Gilead Sciences, Inc.; 2023. **4.** Anderson P, et al. *Curr Med Res Opin*. 2008;24:3063-72. **5.** Anderson P, et al. *Curr Med Res Opin*. 2023;39:1707-15. **6.** Babineaux SM, et al. *BMJ Open*. 2016;6:e010352. **7.** Higgins V, et al. *Diabetes Metab Syndr Obes*. 2016;9:371-80.

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INTRODUCTION

- HDV, which requires the presence of hepatitis B virus (HBV) for transmission, results in the most severe form of viral hepatitis[1,2]
- CHD infection is associated with rapid progression to cirrhosis, hepatic decompensation, and hepatocellular carcinoma, and is associated with increased morbidity and mortality compared with HBV monoinfection[2]
- BLV, an entry inhibitor of HDV, is approved in the European Union, Great Britain, Switzerland, the Russian Federation, and Australia at 2 mg/day for the treatment of CHD[3]
- BLV has been shown to reduce the likelihood of transmitting HDV by clearing its RNA from the blood[3]
- Although data are readily available on antiviral drugs treating HBV, real-world evidence on BLV for the treatment of HDV is lacking

OBJECTIVE

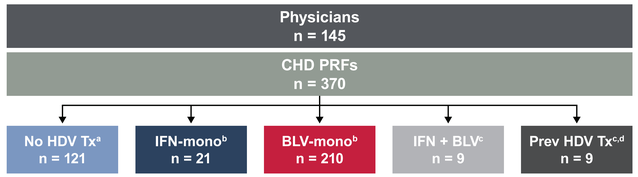
- To describe the demographics, clinical characteristics, and physician-perceived treatment adherence of patients with CHD who were prescribed antiviral treatments, including BLV

METHODS

- Data were drawn from the Adelphi Real World Hepatitis Disease Specific Programme,™ a cross-sectional survey with retrospective data collection of physicians and their patients with HDV in France, Italy, Spain, and the UK from May 2024 to Nov 2024[4-7]
- Primary care physicians, infectious disease specialists, gastroenterologists, and hepatologists provided data on patient demographics, clinical characteristics, and adherence through patient record forms for up to four consecutively consulting patients with HDV, two of whom were prescribed BLV
  - Analyses were descriptive
- Physicians who saw ≥2 patients with HDV in a typical month were eligible for inclusion in the study
- Physicians reported on patients ≥18 years of age with a physician-confirmed diagnosis of HDV. Patients involved in a clinical trial for any condition at the time of consultation were not eligible for inclusion

RESULTS

Figure 1. Study Flow Chart



[a]Never treated with bulevirtide or peginterferon/interferon. [b]With or without prescription of entecavir, tenofovir, lamivudine, adefovir, or telbivudine. [c]Patients on combination therapy or patients who had discontinued HDV treatment were not included in stratifications in the analyses due to small sample size. [d]Patients who had discontinued HDV treatment.
BLV-mono, bulevirtide monotherapy; CHD, chronic hepatitis delta; HDV, hepatitis delta virus; IFN + BLV, peginterferon/interferon and bulevirtide combination therapy; IFN-mono, peginterferon/interferon monotherapy; Prev, previous; PRF, patient record form; Tx, treatment.

- Overall, 145 physicians reported data on 370 patients with CHD

Table 1. Physician Characteristics

Physician Characteristics	Physicians n = 145
Physician specialty, n (%)	
Hepatologists	66 (46)
Infectious disease specialists	52 (36)
Primary care physicians	25 (17)
Gastroenterologists	2 (1)
Average patient distribution across each setting, %	
Academic hospital	58
Community hospital	20
Office	16
Community clinic	5
Other	<1

RESULTS

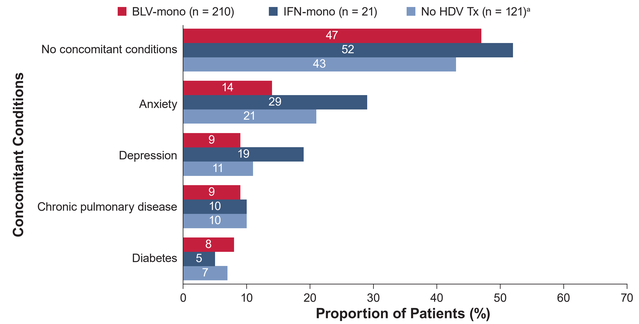
Table 2. Physician-Reported Patient Demographics and Disease Characteristics

Patient Characteristics	BLV-Mono Patients n = 210	IFN-Mono Patients n = 21	No HDV Tx Patients[a] n = 121	All Patients With CHD N = 370
Age, years	**n = 209**	**n = 21**	**n = 121**	**n = 369**
Mean (SD)	45.4 (12.66)	43.6 (11.66)	46.7 (12.90)	45.9 (12.95)
Sex, n (%)	**n = 210**	**n = 21**	**n = 121**	**n = 370**
Male	141 (67)	14 (67)	77 (64)	245 (66)
Ethnicity,[b,c] n (%)	**n = 137**	**n = 17**	**n = 106**	**n = 270**
White	97 (71)	9 (53)	73 (69)	188 (70)
Black African or Caribbean	16 (12)	6 (35)	15 (14)	37 (14)
East or Southeast Asian	21 (15)	2 (12)	6 (6)	29 (11)
Other	3 (2)	0 (0)	12 (11)	16 (6)
High-risk HBV region,[c] n (%)	**n = 210**	**n = 21**	**n = 121**	**n = 370**
Born in high-risk region	86 (41)	9 (43)	44 (36)	148 (40)
Lived in high-risk region	48 (23)	3 (14)	33 (27)	88 (24)
Time since diagnosis of HBV, years	**n = 156**	**n = 13**	**n = 88**	**n = 271**
Mean (SD)	6.0 (8.14)	8.8 (12.11)	7.2 (9.92)	6.8 (9.10)
Time since diagnosis of HDV, years	**n = 177**	**n = 17**	**n = 98**	**n = 307**
Mean (SD)	4.0 (5.12)	5.3 (9.62)	5.2 (7.97)	4.7 (6.70)
Physician-stated severity at survey date, n (%)	**n = 210**	**n = 21**	**n = 121**	**n = 370**
Mild	136 (65)	14 (67)	80 (66)	240 (65)
Moderate	65 (31)	6 (29)	30 (25)	107 (29)
Severe	9 (4)	1 (5)	11 (9)	23 (6)
Liver fibrosis score, n (%)	**n = 210**	**n = 21**	**n = 121**	**n = 370**
F4 (compensated or decompensated cirrhosis)	31 (15)	4 (19)	21 (17)	61 (16)
Liver disease, n (%)	**n = 210**	**n = 21**	**n = 121**	**n = 370**
Moderate or severe	16 (8)	1 (5)	23 (19)	43 (12)
Time receiving HDV treatment line, months	**n = 193**	**n = 16**	**–**	**n = 306**
Mean (SD)	18.3 (31.19)	46.2 (87.22)	–	28.7 (47.98)

[a]Never treated with bulevirtide or peginterferon/interferon. [b]Ethnicity data not collected in France. [c]Respondents were able to select multiple responses.
BLV-mono, bulevirtide monotherapy; CHD, chronic hepatitis delta; HBV, hepatitis B virus; HDV, hepatitis delta virus; IFN-mono, peginterferon/interferon monotherapy; Tx, treatment.

- Among all patients with CHD, mean (SD) age was 45.9 (13.0) years; 70% were White, and 66% were male
- Almost one-fifth (19%) of No HDV Tx patients had moderate or severe liver disease (BLV monotherapy [BLV-mono]: 8%; IFN monotherapy [IFN-mono]: 5%)

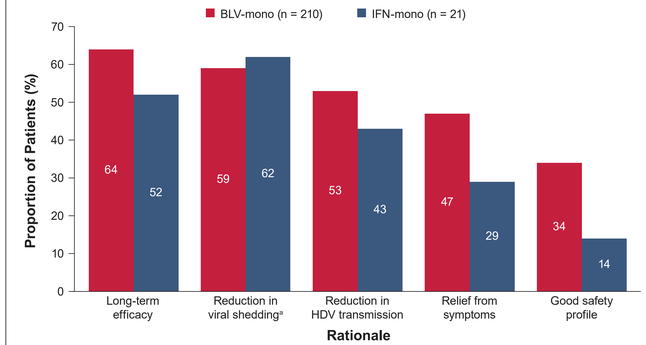
Figure 2. Concomitant Disease Burden



[a]Never treated with bulevirtide or peginterferon/interferon.
BLV-mono, bulevirtide monotherapy; HDV, hepatitis delta virus; IFN-mono, peginterferon/interferon monotherapy; Tx, treatment.

- For patients who were never prescribed HDV antiviral treatment (No HDV Tx; n = 37), the top physician-reported reasons were patient's choice not to use treatment (51%), the patient did not want to take a daily medication (27%), and the physician thought treatment was not needed (16%)

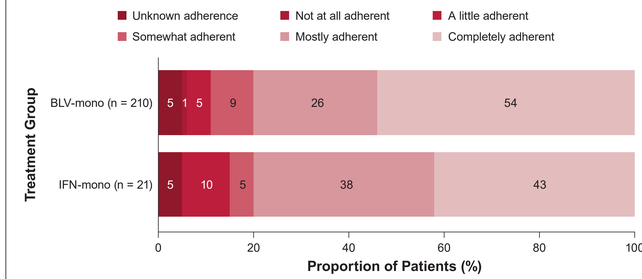
Figure 3. Primary Reasons Physicians Prescribed the Current HDV Treatment Regimen



[a]The definition of 'viral shedding' was not included in the questionnaire; it was up to the physicians' interpretation.
BLV-mono, bulevirtide monotherapy; HDV, hepatitis delta virus; IFN-mono, peginterferon/interferon monotherapy.

- Physicians reported that increased likelihood of a functional cure (37%), longer-acting medication (24%), and less-frequent administration (23%) were the most common areas where treatment could be improved for BLV-mono patients
- Drug adverse events/side effect profile (38%), reduction in transmission (29%) and increased likelihood of a functional cure (24%) were common areas where treatment could be improved for IFN-mono patients

Figure 4. Physician-Perceived Treatment Adherence



The surveys defined adherence as, "taking medication exactly as agreed with their physician, for example, taking the prescribed amount at the time of day recommended."
BLV-mono, bulevirtide monotherapy; IFN-mono, peginterferon/interferon monotherapy.

- Across both groups, physicians reported that patients were either completely or mostly adherent to their current treatment regimen (BLV-mono: 80%; IFN-mono: 81%)
- Of those who were not completely adherent (n = 86), physicians reported that difficulties integrating into daily routine (23%) and forgetting to take medication (21%) were the most common reasons for nonadherence among BLV-mono patients

LIMITATIONS

- Physicians and their patients were recruited from four European countries; therefore, results may not be generalisable to all patients with CHD
- Because data were captured for patients actively consulting with their physicians, findings may not be representative of the wider patient population, including nonconsulting patients
- Physicians were requested to capture patient information retrospectively, which may introduce recall bias
- Data on BLV use in Spain were not collected due to a lack of reimbursement at the time of data collection

European Association for the Study of the Liver; 7–10 May 2025; Amsterdam, the Netherlands