# Patient-Reported Burden and Health-Related Quality of Life Among Patients With Hepatitis Delta: Results From a Real-World Study in Europe

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# Conclusions

- Although patients with chronic hepatitis delta virus (HDV) infection who received bulevirtide (BLV) monotherapy for ≥6 months were perceived by their physicians to have more severe disease at the survey date, these patients reported better disease-specific health-related quality of life (HRQoL) outcomes compared with treatment-naïve patients
- Generic and symptom-specific measures of HRQoL showed minimal differences between the groups and may not be sensitive enough to determine the health burden caused by HDV infection; thus, disease-specific HRQoL measures should be administered

# Plain Language Summary

- Chronic hepatitis delta is a disease in the liver that is caused by a virus and results in negative effects on health-related quality of life
- Previously, patients who received treatment in a clinical trial setting with the antiviral drug bulevirtide showed improvements in patient-reported health-related quality of life
- Here, in a real-world setting, patients with hepatitis delta virus infection who received bulevirtide therapy reported improved health-related quality of life compared with patients who did not receive any treatment as assessed by health-related quality of life questionnaires that measured symptoms and impacts specific for liver disease

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### Introduction

- Infection with HDV, which requires the presence of hepatitis B surface antigen for propagation, leads to the most severe form of viral hepatitis<sup>1-3</sup>
- Chronic HDV infection is associated with less favorable clinical outcomes and worse HRQoL
- BLV, a first-in-class entry inhibitor of HDV, improved HRQoL when used as a monotherapy in patients with HDV in a clinical trial setting<sup>6,7</sup>
- Evidence surrounding the impact of BLV monotherapy on HRQoL in a real-world setting is limited

treatment naïve or prescribed BLV in a real-world setting

## Methods

**Inclusion Criteria** 

hepatitis delta

≥18 years of age

**Exclusion Criteria** 

Physician-confirmed diagnosis of

Current involvement in a clinical trial

HRQoL, health-related quality of life; PROM, patient-reported outcome measure.

- 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 infection in France, Italy, Spain, and the UK8-11
- Physicians (primary care, infectious disease specialists, and hepatologists) provided data on up to 4 consecutively consulting patients with HDV infection seen during routine care, including 2 patients who were prescribed BLV and 2 regardless of treatment status
- Physicians considered patient fibrosis and cirrhosis status to report perceived
- At the time of consultation, patients were invited to complete a voluntary patient self-completion survey, which included the following patient-reported outcome measures:
- Fatigue Severity Scale, 7-item (FSS-7), a symptom-specific measure of quality of life
- Hepatitis B Quality of Life (HBQoL), a disease-specific measure of quality of life
- Descriptive analyses focused on patients who received BLV monotherapy for ≥6 months and
- Missing data were not included when calculating percentages, and missing values were not imputed

- compared with chronic hepatitis B alone<sup>4,5</sup>

# Objective

To describe the demographics and HRQoL outcomes of patients with HDV infection who were

- EuroQoL 5-Dimension (EQ-5D), a generic measure of quality of life

Figure 1. Cross-Sectional Study Design

Recorded medical

history prior to

Diagnosis date

Symptomology

Risk factors

Test results

survey date

- treatment-naïve patients

**Survey date** 

**Measurements at Survey Date** 

No follow-up data recorded

inflammation

Patient-reported

J. HRQoL via

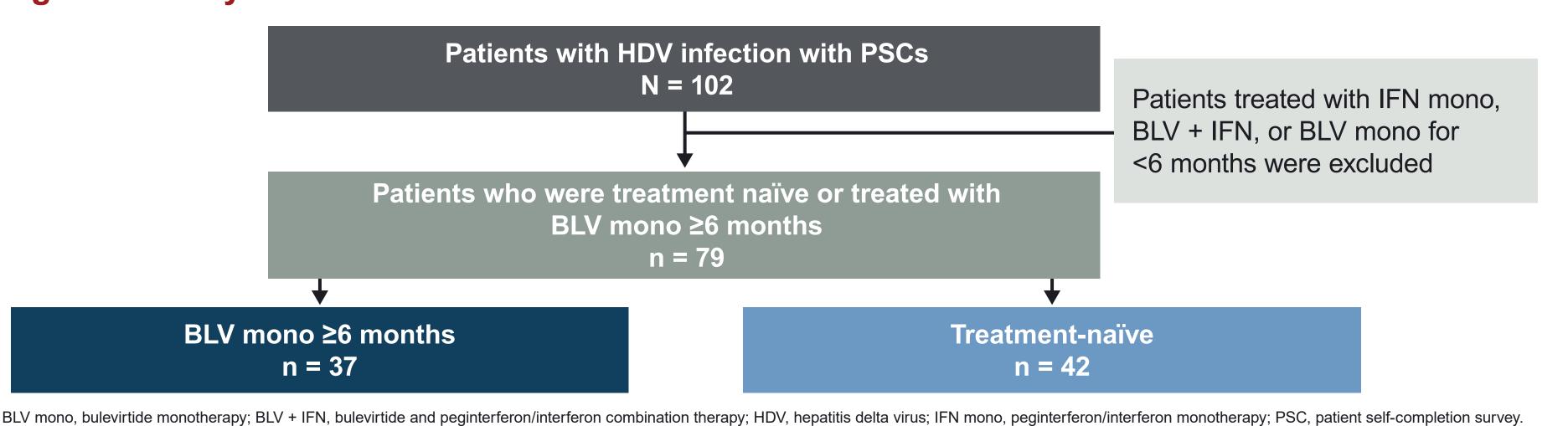
# Results

### Table 1. Physicians and Patients Per Country

Physicians N = 34	Patients N = 102
10 (29)	24 (24)
7 (21)	20 (20)
12 (35)	28 (27)
5 (15)	30 (29)
	N = 34 10 (29) 7 (21) 12 (35)

- Overall, 34 physicians reported data on 102 patients
- Each of these patients had completed a patient self-completion form

Figure 2. Study Flow Chart



• Of the 102 patients with HDV infection, 79 met treatment criteria and, of these, 42 (53%) were treatment naïve and 37 (47%) had

received BLV monotherapy for ≥6 months

### **Table 2. Physician-Reported Patient Demographics**

Patient Characteristics	BLV Mono ≥6 Months n = 37	reatment-Naive n = 42
Age, y, mean (SD)	43 (16.6)	48 (14.1)
Sex, n (%)		
Male	25 (68)	28 (67)
Female	12 (32)	14 (33)
Race, <sup>a</sup> n (%)		
White	18 (72)	31 (78)
Black African or Caribbean	3 (12)	7 (18)
Other <sup>b</sup>	4 (16)	2 (5)
Physician-stated disease severity at HDV diagnosis, n (%)		
Mild	4 (11)	19 (45)
Moderate	22 (59)	12 (29)
Severe	8 (22)	7 (17)
Physician-stated disease severity at survey date, n (%)		
Mild	18 (49)	30 (71)
Moderate	16 (43)	11 (26)
Severe	3 (8)	1 (2)
Liver fibrosis score, n (%)		
F4 (compensated cirrhosis)	5 (14)	3 (7)
F4 (decompensated cirrhosis)	2 (5)	2 (5)
Time since diagnosis of HBV, y, mean (SD)	9 (14.3)	6 (7.5)
Time since diagnosis of HDV, y, mean (SD)	6 (8.2)	3 (5.2)

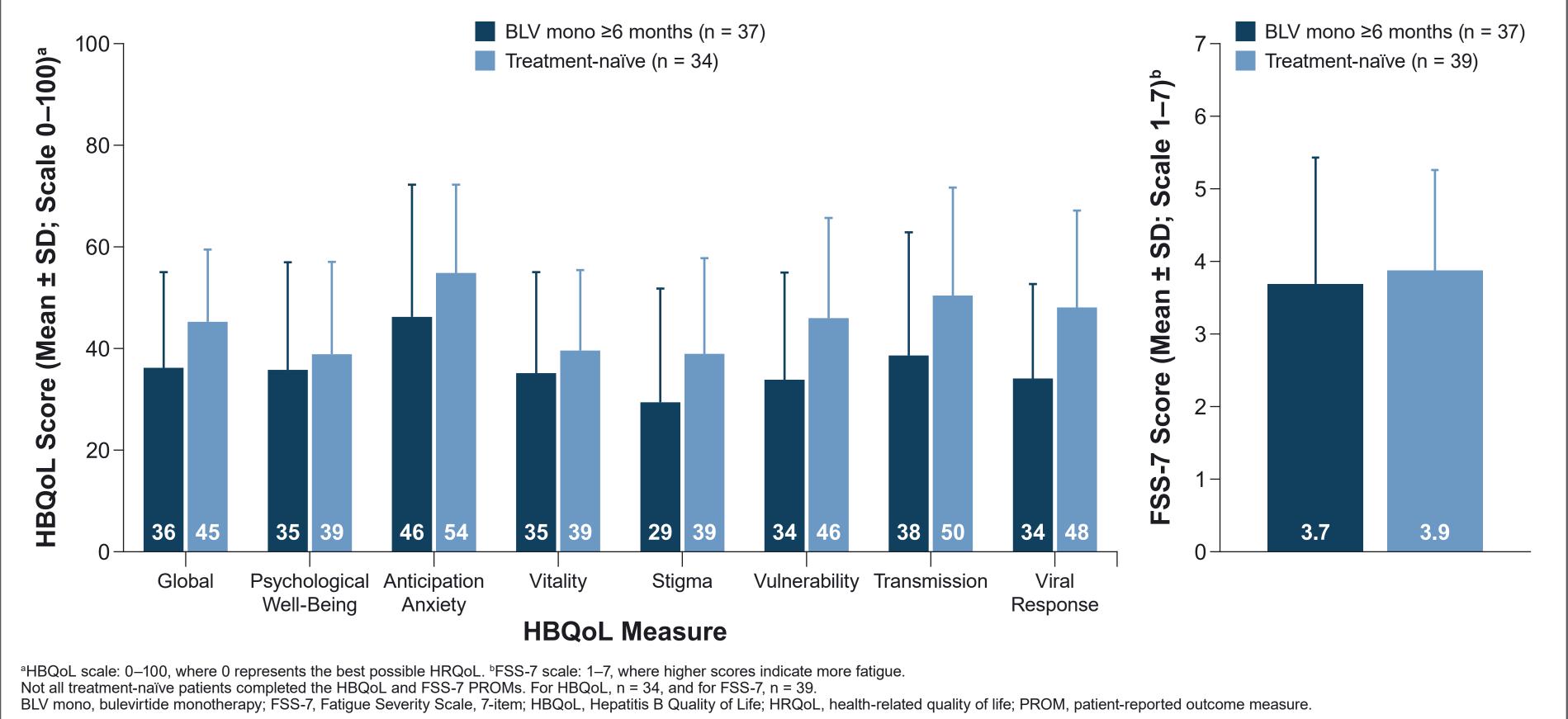
<sup>a</sup>Race data were not available for all patients (BLV mono ≥6 months, n = 25; treatment-naïve, n = 40) and respondents could select multiple race categories; physician-reported patient race was not collected in France. <sup>b</sup>Other includes East or Southeast Asian. South Asian (Indian subcontinent). Middle Eastern or North African, and other. The n values indicate the overall group size; not all data were available for all patients.

Most patients were White (75%) and male (67%)

BLV mono, bulevirtide monotherapy; HBV, hepatitis B virus; HDV, hepatitis delta virus; v, year.

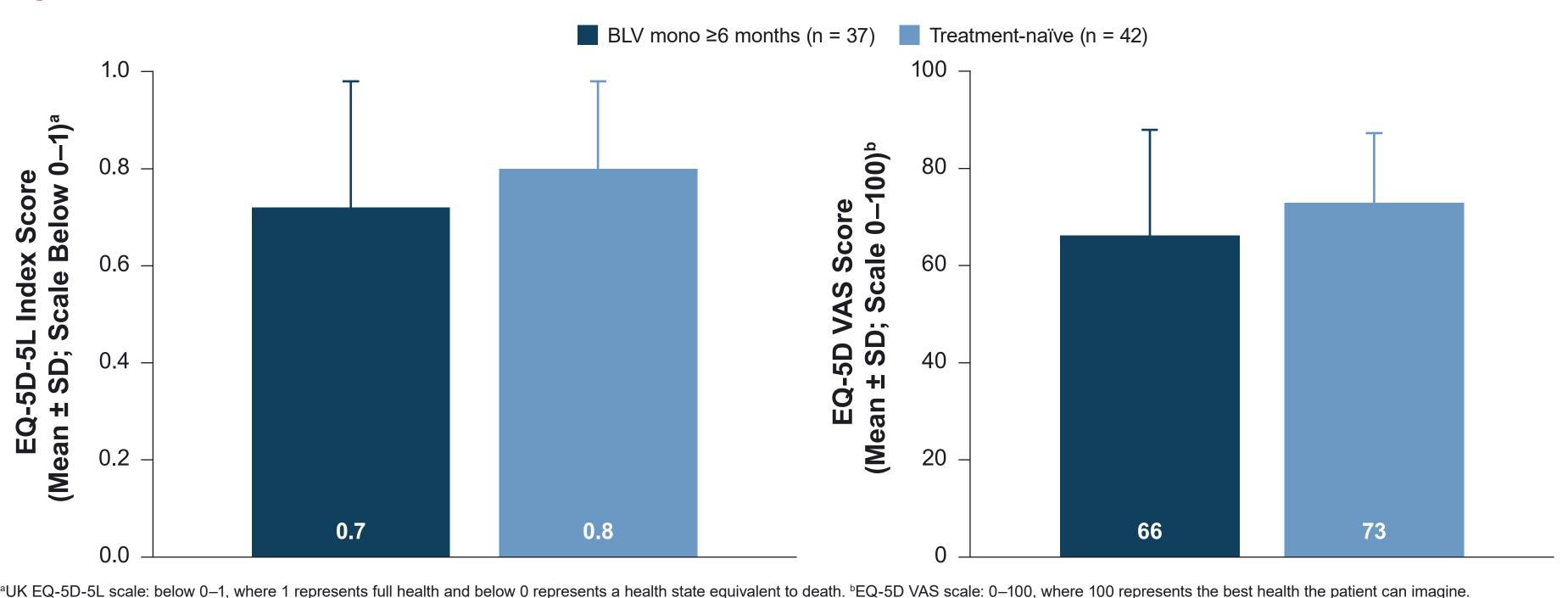
• Greater proportions of patients in the BLV monotherapy group were reported to have moderate (43%) or severe (8%) disease at the survey date compared with the treatment-naïve group (26% moderate and 2% severe)





- Patients who received BLV monotherapy reported improved HBQoL scores compared with treatment-naïve patients
- FSS-7 scores were numerically comparable between patients who received BLV monotherapy and treatment-naïve patients

### Figure 4. Generic HRQoL PROMs



BLV mono, bulevirtide monotherapy; EQ-5D-5L, EuroQoL 5-Dimension 5-Level; EQ-5D VAS, EuroQoL 5-Dimension Visual Analog Scale; HRQoL, health-related quality of life; PROM, patient-reported outcome measure.

• Generic HRQoL measure scores were numerically comparable between patients who received BLV monotherapy and treatment-naïve patients

# Limitations

- The small cohort sizes limited our ability to detect significant differences and adjust for potential confounders between the treatment groups
- Underlying baseline disease burden may vary between patients prescribed BLV and those not prescribed BLV
- Physicians and patients were recruited from 4 European countries, and results may not be generalizable to all patients with chronic hepatitis delta
- Similarly, only patients who were actively consulting with their physicians were included, and findings may not be representative of the wider patient population
- Physicians retrospectively captured patient information, introducing the potential for recall bias