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Poster for you

Real-World Patient Profile for Individuals With Hepatitis Delta Virus Infection Treated With Bulevirtide 2 mg in Europe

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Conclusions

- In this narrative review, we describe patients profiled from 6 real-world cohorts with chronic hepatitis delta virus (HDV) infection treated with bulevirtide (BLV) 2 mg in Europe
- The characteristics of patients who have chronic hepatitis delta include
  - Mean age between 40 and 50 years
  - Diverse racial and ethnic profiles
  - Advanced disease with evidence of cirrhosis at treatment initiation in approximately 58% of patients
  - Less than 10% were hepatitis B e antigen positive
- Country of origin, race, and ethnicity reporting varied greatly by study (eg, one study had a predominantly immigrant population)
- The limited real-world data indicate a need for enhanced efforts to characterise patient sociocultural profiles to enhance understanding of patients living with HDV, to increase screening of HDV infection, and to improve access to BLV for those most in need

Plain Language Summary

- Bulevirtide is the only medicine approved in Europe to treat chronic hepatitis delta virus infection
- The safety and benefit of bulevirtide have been shown in clinical trials, but real-world data shine light on how doctors and patients use this treatment and reveal the demographic and clinical profiles of patients who have had access to treatment
- In this study, we found that the characteristics of patients, in 4 countries, who had chronic hepatitis delta virus infection treated with bulevirtide include
  - An average age between 40 and 50 years old
  - A high likelihood of having cirrhosis when they start treatment
  - A low likelihood (less than 10%) of having high levels of hepatitis B virus present in their blood
- The real-world data highlight the need for increased efforts around better understanding patients with hepatitis delta virus and their social and cultural backgrounds; the enhanced understanding will benefit more people suffering with chronic hepatitis delta infection by increased screening/diagnosis and access to treatment

Introduction

- Hepatitis delta virus (HDV) is considered the most severe form of viral hepatitis and is associated with high rates of cirrhosis and increased risk of hepatocellular carcinoma[1]
- Bulevirtide (BLV) is the only medication approved by the European Medicines Agency for the treatment of chronic hepatitis delta (CHD)[2]
- BLV has demonstrated efficacy and safety in treating HDV infection in clinical trials and in real-world studies[2-6]
- Real-world data describing the profile of patients treated with BLV are limited

Objective

- This review aims to describe the patient profile of people with CHD treated with BLV 2 mg in real-world studies

Methods

- We conducted a narrative review of the demographic and baseline clinical characteristics from published studies that reported on BLV 2 mg prescribed in routine clinical practice to people with CHD for up to 48 weeks in Europe

Figure 1 **Narrative Review Criteria**

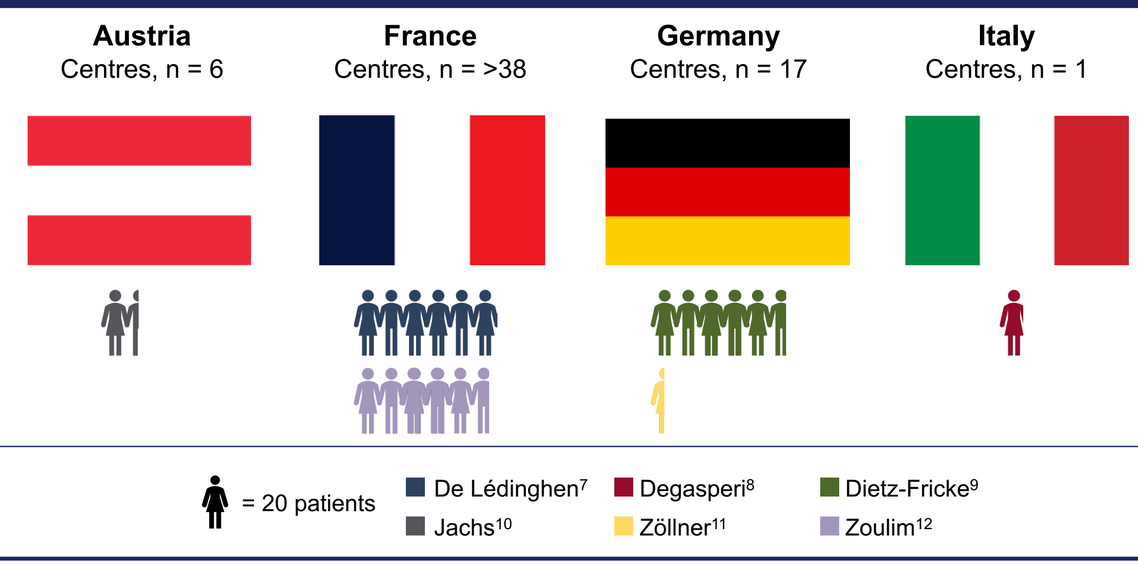
Inclusion Criteria	Exclusion Criteria
Real-world data of patients with CHD infection	Randomised, controlled studies
Patients treated with on-label BLV 2 mg	Published protocols
Reported virologic and biochemical outcomes	Review articles
Articles and congress abstracts published in English from groups in countries in the EU	Publications from groups outside the EU

BLV, bulevirtide; CHD, chronic hepatitis delta; EU, European Union.

Results

- We identified 6 studies that reported real-world use of BLV in cohorts from European countries[7-12]

Figure 2 **Real-World Data Studies in Europe**



- Individuals in these studies had a mean age of 40 to 50 years and were more likely to be male (44%–89%)

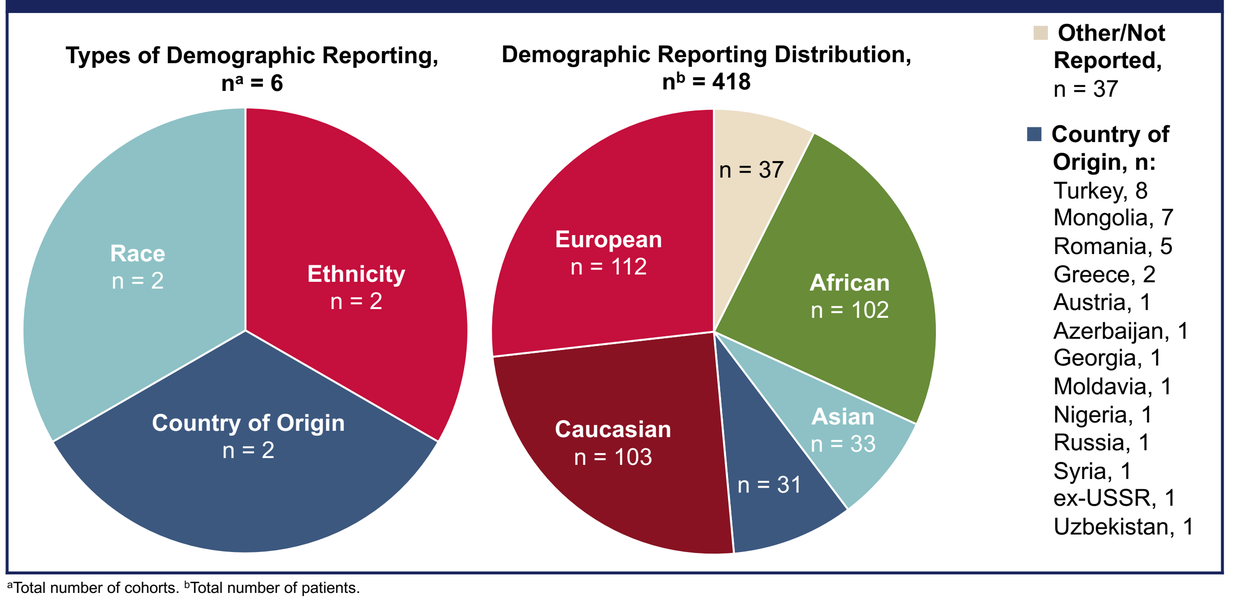
Table 1 **Patient Demographics**

	De Lédinghen[7]	Degasperi[8]	Dietz-Fricke[9]	Jachs[10]	Zöllner[11]	Zoulim[12]	Summary
Patients, (n)	139	18	114	23	9	115	9–139 (418 total)
Age, mean	41	48[a]	47	48	46[a]	42	40–50
Sex, male, %	68	67	70	44	89	70	44–89
Location	France early-access programme	Italy 1 centre	Germany 16 centres/clinics	Austria 6 hospitals	Germany 1 clinic	France >38 centres	4 countries >62 centres

[a]Median age reported.

- Data on country of origin, ethnicity, and language spoken were varied and limited across all publications
  - Across all studies, 37 (9%) patients had unspecified “other” or no country of origin, ethnicity, or race data available
  - In the Italian cohort and 1 German cohort, most people were Caucasian
  - The other cohorts (from Austria, France, and 1 from Germany) reported populations of diverse origins, including people from Africa, Asia, Europe, and the Middle East

Figure 3 **Reported Patient Country of Origin and Ethnicity Distribution**



[a]Total number of cohorts. [b]Total number of patients.
USSR, Union of Soviet Socialist Republics.

- Baseline cirrhosis was common, affecting more than half the patients among the study populations (range: 44%–78%)
- Alanine aminotransferase was elevated in all populations, with the mean/median in each above the normal range
- Four of the 6 studies reported hepatitis B e antigen (HBeAg) status
  - Less than 10% of patients had HBeAg-positive status
- The majority of individuals had ongoing or previous HBV treatment at baseline

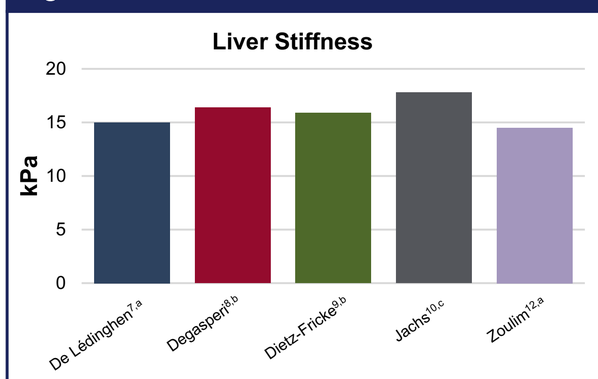
Table 1 **Patient Baseline Characteristics**

	De Lédinghen[7] n = 139	Degasperi[8] n = 18	Dietz-Fricke[9] n = 144	Jachs[10] n = 23	Zöllner[1] n = 9	Zoulim[12] n = 115
Cirrhosis, n (%)	86 (62)	18 (100)[a]	59 (52)	16 (70)	3 (38)[b]	64 (56)
HBV DNA below LLOQ, n (%)	86 (62)	4	-	19	8 (89)	76 (67)
HDV RNA, $\log_{10}$ IU/mL, median	6.52	4.9	-	2.0 × 10^{5} [c]	1.3 × 10^{7} [c]	6.3
HBeAg positive, n (%)	13 (9)	1	-	2	0	-
Reported treatment, n	NA: 107[d]	IFN: 12	ETV: 16 PegIFNα: 55	ETV: 3 TDF: 16 TAF: 2[d]	ETV: 3 TDF: 6 IFN: 6	NA: 93[d]
HIV coinfection, n (%)	19 (14)	-	-	-	-	13 (13)
Oesophageal varices, n (%)	-	14 (78)	31 (22)	-	-	-
ALT, IU/mL, mean	109	106 (32–222)[e]	115	71 (21–341)[e]	94.75	116.4

Data are presented as n (%) where available. [a]Including both compensated cirrhosis and clinically significant portal hypertension. [b]One patient did not complete 48 weeks of treatment and did not have their cirrhosis status listed. [c]Reported as copies/mL. [d]Current NA treatment at baseline. [e]Median value and range.
ALT, alanine aminotransferase; ETV, entecavir; HBeAg, hepatitis B e antigen; HBV, hepatitis B virus; HDV, hepatitis delta virus; IFN, interferon; LLOQ, lower limit of quantitation; NA, nucleos(t)ide analogue; PegIFNα, pegylated interferon alpha; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

- Fibrosis was common among patients in all studies

Figure 4 **Real-World Liver Health Status**



Fibrosis and Cirrhosis Status		
Reference	**Reporting**	**Grade, n**
Degasperi[8]	Child-Pugh grade	A5, 13 A6, 5
Dietz-Fricke[9]	Child-Pugh grade	A, 54 B, 4 C, 1
Dietz-Fricke[9]	FIB-4, median	2.9
Zöllner[11]	Fibrosis stage	F2, 2 F3, 3 F4 Child A, 4

[a]Mean FibroScan, kPa. [b]Median FibroScan, kPa. [c]Mean VCTE-LSM, kPa.
FIB-4, Fibrosis-4 Index; VCTE-LSM, vibration-confirmed transient elastography–liver stiffness measurement.

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References: **1**. Stockdale AJ, et al. *J Hepatol*. 2020;73:523-32. **2**. Hepcludex prescribing information. European Medicines Agency. 2023. **3**. Asselah T, et al. *N Engl J Med*. 2024;391(2):133-43. **4**. Wedemeyer H, et al. *Lancet Infect Dis*. 2023;23:117-29. **5**. Wedemeyer H, et al. *J Hepatol*. 2024. https://doi.org/10.1016/j.jhep.2024.05.001. **6**. Degasperi E, et al. *Sex Transm Infect*. 2024;0:1-8. **7**. De Lédinghen V, et al. *Hepatology*. 2022;76:S26-7. **8**. Degasperi E, et al. *J Hepatol*. 2022;77:1523-31. **9**. Dietz-Fricke C, et al. *JHEP Rep*. 2023;5:100686. **10**. Jachs M, et al. *Aliment Pharmacol Ther*. 2022;56:144-54. **11**. Zöllner C, et al. *Liver Int*. 2022;42:2403-7. **12**. Zoulim F, et al. *J Hepatol*. 2022;77:S72.