

# High frequency of liver cirrhosis in European patients with hepatitis D: Data from a large multicentre study (D-SOLVE and HDV-1000 consortia)

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## Background:

- Infection with the **hepatitis D virus (HDV)** can lead to hepatitis delta, which is associated with a **high risk of developing liver-related complications**.
- The global epidemiology and disease severity is **highly heterogeneous**.
- There is **limited knowledge** on disease pathophysiology and host-virus interactions explaining the large inter-individual variability in the disease course.

## Aim:

- To screen a **large multicentre cohort** of well-defined HDV-infected patients from different European countries to better understand the **epidemiology** and to identify **individual factors** that determine infection outcome, thus providing the basis for an **individualised treatment approach**.

## Methods:

- Observational, non-interventional, cross-sectional multicentre cohort.
- Inclusion criteria: detectable anti-HDV for at least 6 months.
- Participating centers: England, France, Italy, Germany, Romania and Sweden.
- Retrospective data from databases and patient records for each patient's most recent visit (index visit).
- Biosample collection for virological and immunological analyses

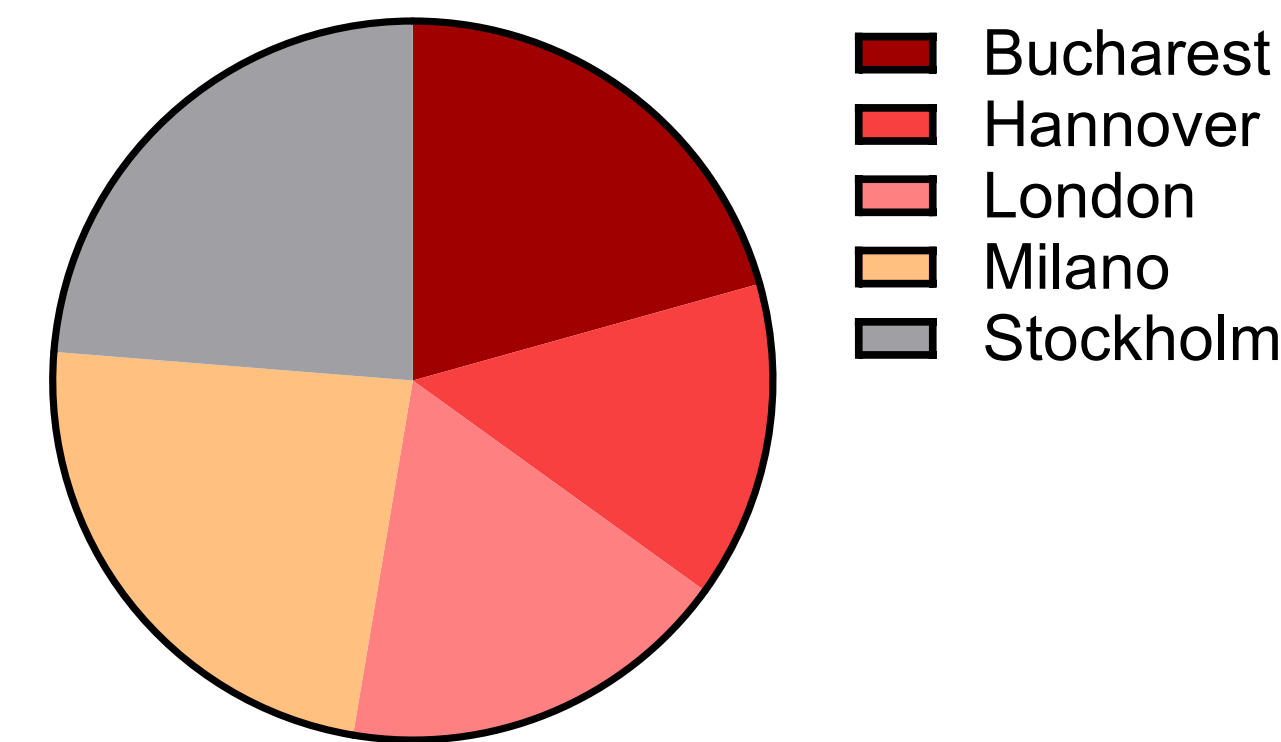
## Results:

	Index visit	Total n = 847
Demographics	Age, years	49 (20-66)
	Sex, male	467/847 (55.1)
	BMI, kg/m <sup>2</sup>	24.9 (17.2-43)
	Smoking	133/707 (18.8)
	Harmful alcohol intake	44/721 (13.2)
	Diabetes	51/847 (6.0)
Laboratory parameters	AST (U/L)	42 (19-274)
	ALT (U/L)	40 (8-600)
	GGT (U/L)	31 (7-245)
	AP (U/L)	97 (47-469)
	Bilirubin (µmol/L)	12 (5-104)
	Albumin (g/L)	41 (31-49)
	Sodium (mmol/L)	140 (135-144)
	Serum Creatinine (mg/dL)	0.82 (0.43-1.42)
	Hemoglobin (g/dL)	13.6 (9.5-16.7)
	Platelets (x1000/µl)	117 (24-267)
	INR	1.1 (0.8-3)
	AFP (ng/ml)	3 (1-373)
Liver disease	<b>Liver cirrhosis</b>	<b>351/840 (41.8)</b>
	Previous liver decompensation	104/822 (12.7)
	HCC	53/834 (6.4)
	Splenomegaly	196/588 (33.3)
	Esophageal varices	120/691 (17.4)
	Ascites	
	No	652/708 (92.1)
	Mild	29/708 (4.1)
	Moderate-severe	27/708 (3.8)
	Hepatic encephalopathy	
	Absent	703/717 (98.0)
	West Haven I-II	8/717 (1.1)
	West Haven III-IV	6/717 (0.8)
	Child Pugh Score	
	A	237/544 (78.2)
	B	55/544 (18.2)
	C	10/544 (3.3)
	MELD	7 (7-19.9)
Virology	Fibroscan	7.1 (2.3-73.6)
	HDV RNA pos	308/585 (52.6)
	HBV DNA pos	248/649 (38.2)
	HBsAg pos	744/807 (92.2)
	HBsAg neg	63/807 (7.8)
	Anti-HBs pos	43/455 (9.5)
	Anti-HBe pos	529/602 (87.9)
	Coinfections	
	HCV	84/847 (9.9)
	HIV	15/847 (1.8)
Treatment	Ongoing therapy	480/847 (56.7)
	Bulevirtide	104 (21.7)
	Nucleos(t)ide analog	452 (94.2)
	Pegylated interferon	26 (5.4)
	Ongoing trial	41 (8.5)

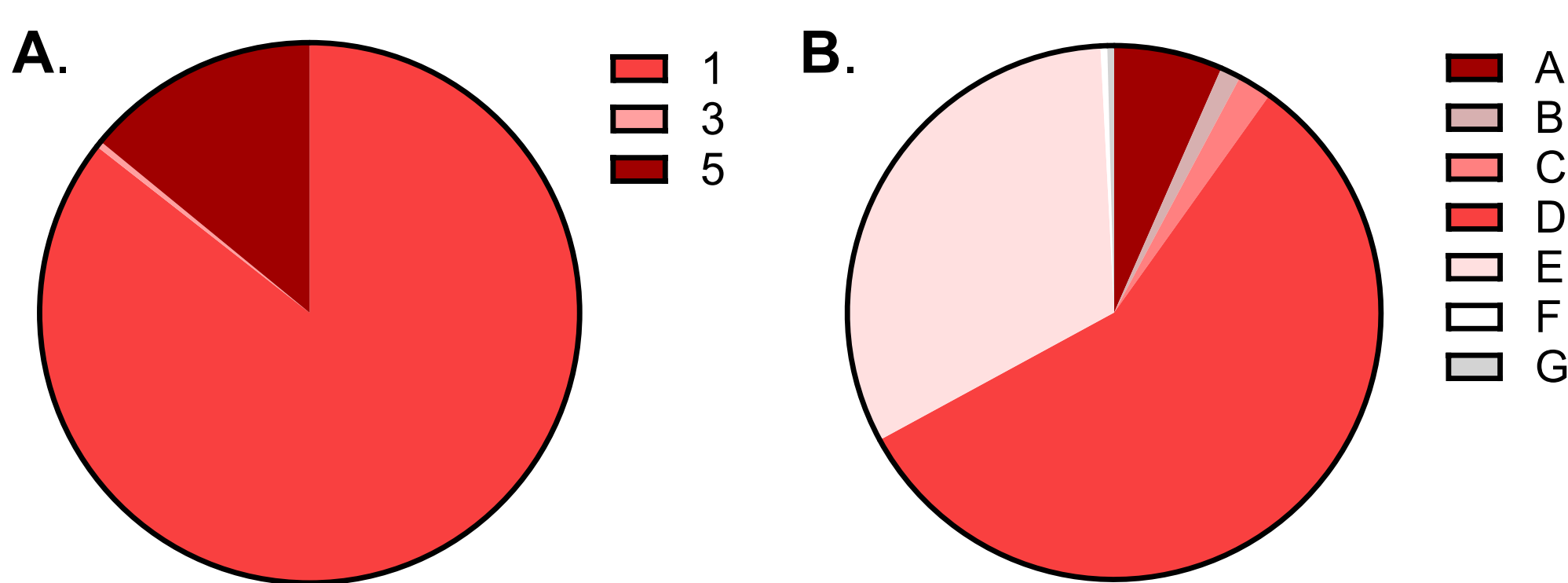
**Table 1:** Baseline characteristics. Quantitative parameters are depicted as median with range (min-max), qualitative parameters as numbers / total valid cases and percentages.

## Funding

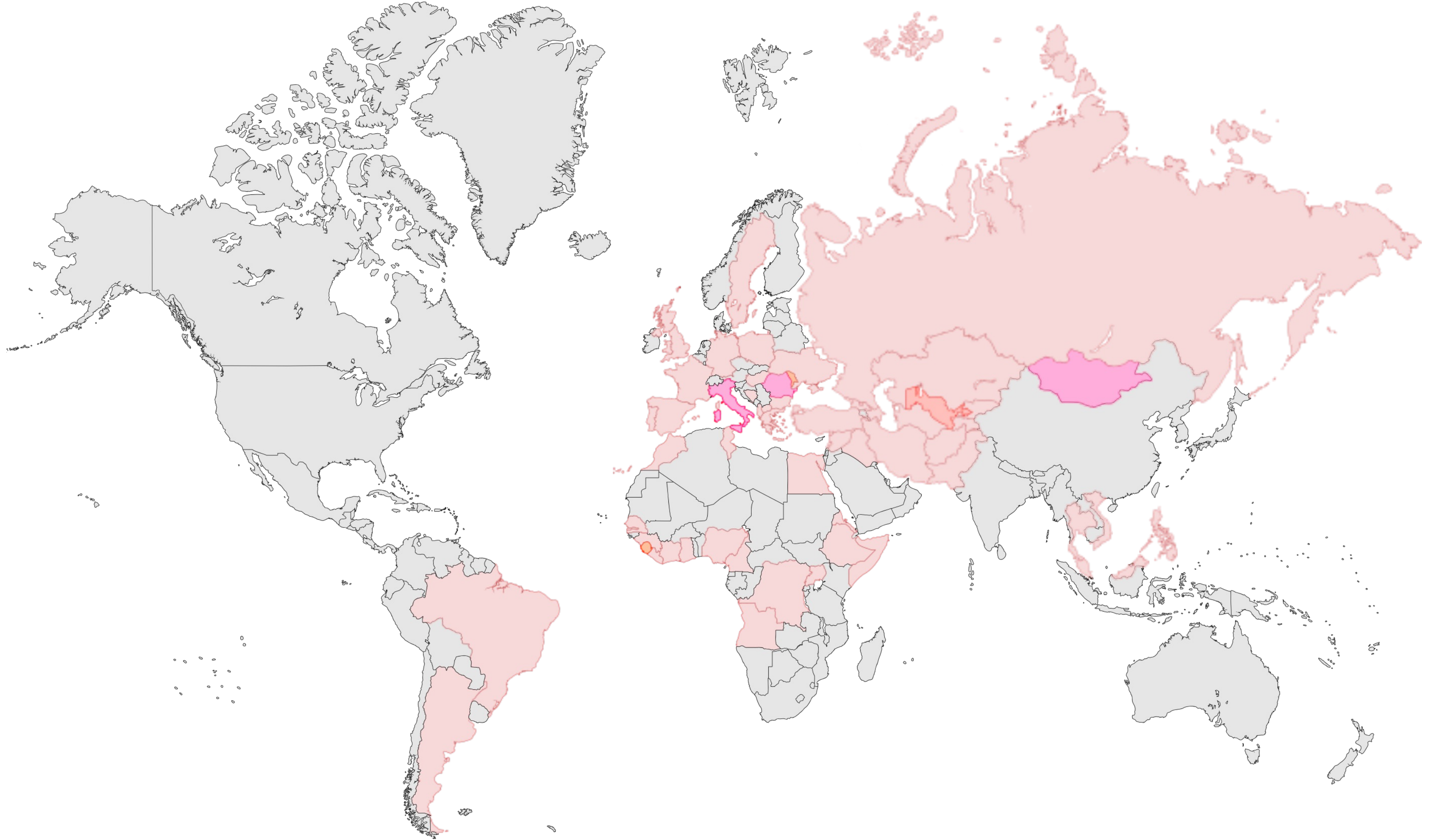
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**Figure 1:** Overview of the participating centers.



**Figure 2:** Genotype distribution of HDV (A) and HBV (B).



**Figure 3:** Country of birth of patients included in the cohort. pink: >10% (Romania, Italy, Mongolia), red: 3-10% (Moldova, Sierra Leone, Uzbekistan), light red: <3%.

## Conclusion:

- Two out of five patients were classified as having liver cirrhosis at the index visit.
- The majority of patients showed detectable HDV RNA and undetectable HBV DNA levels.
- The most prevalent genotypes were HDV genotype 1 and HBV genotype D.
- Only 3% of the patients were treated with pegylated interferon, while 53% received nucleos(t)ide analog treatment. Bulevirtide treatment was present in 12% of patients.

Place of first diagnosis	HBV (n=724)	HDV (n=729)	p-value
General practitioner	289 (39.9)	101 (13.9)	<0.001
Specialist	64 (8.8)	119 (16.3)	<0.001
Clinical center	346 (47.8)	493 (67.6)	<0.001
Other	25 (3.5)	16 (2.2)	0.148

**Table 2:** Place of first diagnosis of HBV or HDV infection.