OCTOBER 11-12, 2024 MILAN, ITALY
DeltaCure 3rd International Meeting
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Poster for you

Treatment of chronic hepatitis delta with bulevirtide in Portugal: data from a real-life cohort

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Introduction

- Hepatitis delta virus (HDV) infection is considered the most severe form of viral hepatitis[1-3].
- Treatment with bulevirtide (BLV) for adult patients with chronic hepatitis delta (CHD) and compensated liver disease became available in Portugal in 2022, through an early access program.
- Patients were eligible for treatment if they presented at least advanced fibrosis, and either previous exposure or a contraindication to interferon (IFN).

Methods

- We performed a multicentric observational study of patients who started BLV treatment for CHD between January 2022 and January 2024.
- All patients were treated with BLV monotherapy 2 mg SC per day.
- Follow-up visits were scheduled at the physician's discretion, usually every 8-12 weeks.
- HDV RNA was determined locally.
- We collected epidemiological, clinical and virological variables at baseline and during follow-up.
- Virological response was defined as undetectable HDV RNA or ≥ 2 log10 decline from baseline, biochemical response as ALT < 40 IU/L, and complete response as both virological and biochemical responses.

Results

POPULATION

- We included **14 patients** from **7 centres.**
- The geographical distribution of patients is shown in **Fig. 1.**
- Median follow-up on treatment was 59 weeks.

Figure 1 **Geographical distribution of patients who started treatment with bulevirtide for chronic hepatitis delta in Portugal between January 2022 and January 2024**

Results of 2

POPULATION

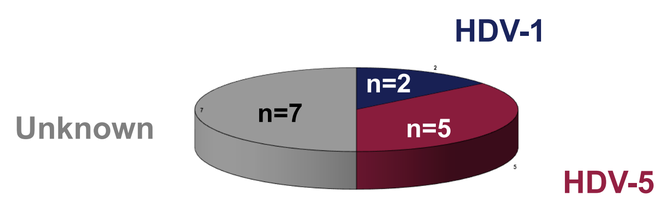
- The clinical and epidemiological characteristics of the patients are shown in **Table 1**.
- HDV genotype distribution is depicted in **Fig. 2**.

Table 1 **Clinical and epidemiological characteristics of the patients**

Female – n (%)	8 (57%)
Age – M ± SD [min-max]	40 ± 10 [21-57]
Country of origin – n (%)	
Portugal	4 (29%)
Africa	7 (50%) [Guinea-Bissau: 5]
Eastern Europe	3 (21%)
Intravenous drug use – n (%)	3 (21%)
HBeAg-negative – n (%)	11 (79%)
Treatment with nucleos(t)ide analogs – n (%)	13 (93%)
HIV coinfection – n (%)	5 (36%)
Liver stiffness (Md)	17.3 kPa
Cirrhosis (Child-Pugh A) – n (%)*	10 (71%)
Hepatocellular carcinoma – n (%)**	1 (7%)
Previous treatment with interferon	7 (50%)
Contraindication to interferon	9 (64%)

* Including 3 patients with varices and 1 with previous ascites (resolved at the time of BLV initiation) ** Previously treated with transarterial chemoembolization and non-viable at the time of BLV initiation

Figure 2 **HDV genotype distribution**



HDV RNA TESTING

- HDV RNA tests were performed in different laboratories.
- The characteristics of the tests are described in **Table 2.**

Table 2 **Type of HDV RNA tests**

Type of test	Number of patients
Quantitative WHO standardized tests[4] (EurobioPlex)	n=8
Quantitative non-standardized tests	n=5
Qualitative test	n=1

ADHERENCE TO TREATMENT

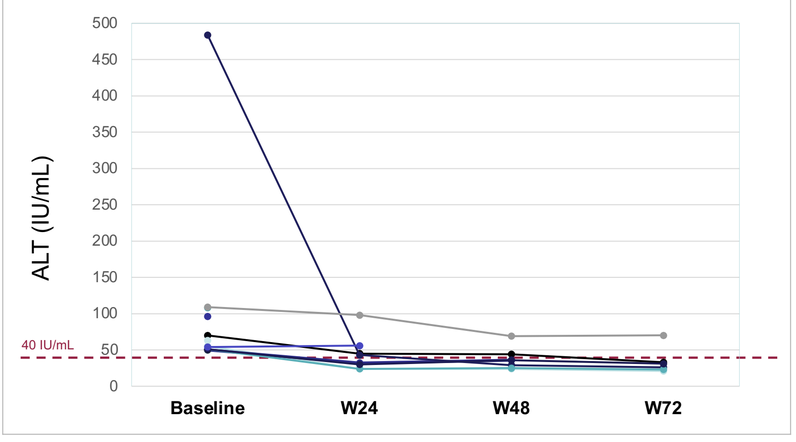
- Treatment with BLV was discontinued in **4 patients**, due to:
  - macopapular rash: n=1
  - nausea and malaise: n=1
  - loss of follow-up: n=1
  - non-compliance: n=1

Results of 3

RESPONSE TO TREATMENT

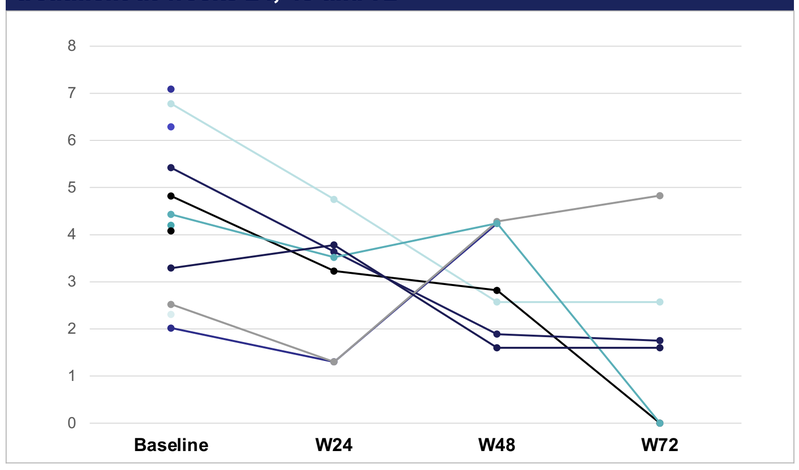
- Biochemical responses to BLV are shown in **Fig. 3.**
- Virological and complete responses are shown in **Fig 4.**

Figure 3 **Biochemical response to bulevirtide treatment at weeks 24, 48 and 72**



	Week 24	Week 48	Week 72
Biochemical response	50.0% (4/8)	71.4% (5/7)	83.3% (5/6)

Figure 4 **Virological and complete responses to bulevirtide treatment at weeks 24, 48 and 72**



	Week 24	Week 48	Week 72
Virological response	42.9% (3/7)	42.9% (3/7)	66.7% (4/6)
Complete response	28.6% (2/7)	28.6% (2/7)	66.7% (4/6)

FOLLOW-UP

- The patient with previous ascites developed recurring septic arthritis and recurrent ascites, resulting in death from sepsis at week 69.
- The patient with HCC started atezolizumab-bevacizumab due to tumour progression and eventually died at week 72 from a ruptured gastric varix.

Conclusion

- In this real-life experience with BLV in Portugal, both biochemical and virological responses increased over time, with virological response lagging behind biochemical response.
- Heterogenous HDV RNA assays, lacking standardization in some centers, may have hindered this assessment.
- Adherence to treatment is an issue that needs to be addressed in the future.

Reference

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