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Bulevirtide effectiveness and safety in cirrhotic and non cirrhotic patients in Sardinia

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INTRODUCTION

HBV/HDV coinfection is considered to be the most severe chronic hepatitis.

In fact, HDV over infection is associated with major risk of hepatocellular carcinoma (HCC), decompensated cirrhosis, need for transplant and premature mortality.

In Italy, its prevalence is between 4,5 and 13% of all HBsAg+ (SEIEVA data, updated to 31/12/2023).

In 2020 a new drug against HDV chronic infection in compensated liver disease have been developed, called bulevirtide.

Since it became refundable by Italian sanitary system in 2023, a few studies have been conducted.

Our aim was to evaluate its safeness and preliminary effectiveness data among compensated-HDV carriers in Sardinia, Italy.

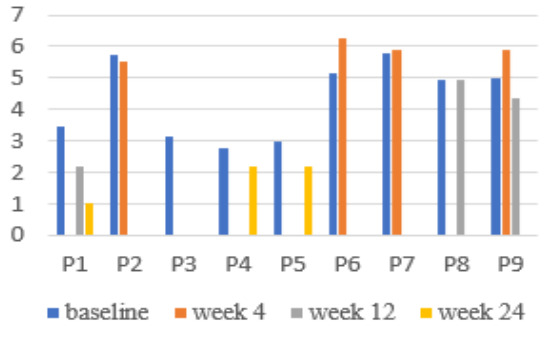
METHODS

We collected retrospectively data of consecutive HBV/HDV patients in treatment with bulevirtide 2 mg/day followed at four Sardinian hepatology ambulatories in Sassari and Cagliari from June 2023 to March 2024.

We evaluated the evolution of Alanine transaminase (ALT) and HDV-RNA levels in blood, at the baseline and at week 4,12 and 24.

Furthermore we analyzed bulevirtide safety collecting any adverse events (AE) occurred during the treatment.

Figure 1. Level HDV-RNA log_{10} copies/ml at baseline, week 4 - 12 and 24



RESULTS

We collected data of 9 HBV/HDV patients (88.9% Italians) treated with bulevirtide from June 2023 to March 2024.

Among the nine patients included, five were male (55.6%) and the mean age was 63±11 years old.

In the observed population, at baseline, no one was HIV coinfected; five patients were (55.6%) previously HCV infected.

Baseline

At baseline, five patients presented compensated cirrhosis (Child A), whereas the other four only not presented cirrhosis.

One patient (11.1%) had HCC treated–before bulevirtide start.

Before treatment, all patients presented HDV-RNA > 500 copies/mL, ALT were elevated (> 49 U/L) in 5 out of 9 patients (55.6%), and HBV-DNA detectable (2210 UI/ml) in one patient (11.1%).

The 77.8% of patients had bulevirtide therapy alone (7/9), while 22.2% had bulevirtide in combination with interferon (2/9).

Table 1. Demographic and clinical characteristics at baseline

Age	63±11
Male sex	M 55.6% (5/9)
Nationality	Italian 88.9% (8/9)
Chirrosis – Child A	55.6% (5/9)
HDV-RNA log_{10} copies/ml	4.3±1.2
ALT U/l	66.86±40.88
HIV infection	NO (0/9)
HCV infection	55,6% (5/9)
HCV-RNA undetected	100% (5/5)
HBV-DNA IU/ML	2210 (11.1% - 1/9)
BULEVIRTIDE 2mg	
Mono	77.8% (7/9)
BLV + IFN de novo combo	11.9% (1/9)
BLV add on a IFN	11.9% (1/9)
NA therapy	Entecavir (9/9)

All patients continued entecavir treatment for HBV during the study period (Tab. 1)

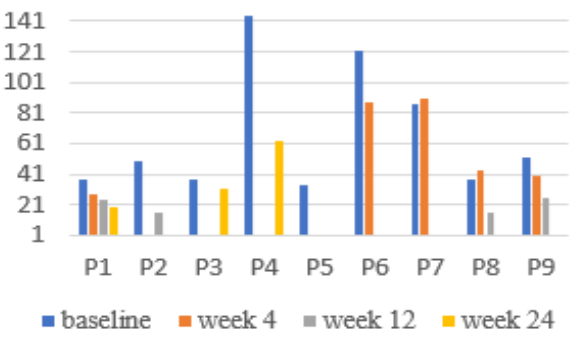
At week 12

Within week 12 eight patients out of nine (88.9%) had ALT normalization, and three had HDV-RNA reduction of one logarithm (3/9, 33.3%), including one viremia negativization (11.1%).

At week 24

All three patients who performed the 24-week follow-up within March 2024, had AST normalization and HDV-RNA was undetectable (Fig.1-2).

Figure 2. Level ALT U/l at baseline, week 4 - 12 and 24



The 88.9% of the cohort (8/9) showed good adherence and tolerability of the treatment, without any adverse event in both cirrhotic and non-cirrhotic patients.

One lost-to-follow up was recorded for reported daze at week 4.

CONCLUSION

In our experience, bulevirtide 2mg treatment demonstrated to be effective, well-tolerated and safe in both cirrhotic and non-cirrhotic patients, including those with mild hepatitis.

Moreover bulevirtide showed to be fast, reaching a clinical relevant HDV-RNA reduction and transaminases normalization already at week 12.

Reference

Heiner Wedemeyer, M.D.at All: A Phase 3, Randomized Trial of Bulevirtide in Chronic Hepatitis D. June 22, 2023 N Engl J Med 2023;389:22-32. DOI: 10.1056/NEJMoa2213429