

Real life experience of HBV/HDV-related compensated cirrhosis treatment in an Italian prison. A case report.

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Background and aim

- HDV infection affects approximately 12 million to 72 million people worldwide and is associated with more rapid progression to cirrhosis and liver failure and higher rates of hepatocellular carcinoma than infection with HBV alone.
- Bulevirtide is the first entry inhibitor with specific antiviral activity in subjects infected with both hepatitis B virus (HBV) and HDV.
- The objective of this study was to analyse the efficacy of Bulevertide and its safety in a difficult-to-treat condition such as a prison regime.

Case report

- We presented a case of a 59-year-old Caucasian male restricted in an Italian prison in Terni, Umbria, HBV infected under TDF 245 mg/die therapy with HBV-DNA consistently undetectable (<10 IU/mL).
- At the end of 2022 during blood test routine test we found an impaired liver function: ALT 64 UI/l and AST 62 UI/l. Autoimmune test was negative. Virus Delta positive. HDV RNA 4 log IU/ml.
- In may 2023 2mg subcutaneous bulevirtide once per day with TDF was approved by EMA for HBV/HDV-related compensated cirrhosis.

CLINICAL EVALUATION		
LABORATORY		IMAGING
MONTH 1, 2, 3, 4, 5, 6	BASELINE MONTH 4 AND 6	BASELINE AND MONTH 6
Liver function	HBV DNA	Fibroscan®
Alphafetoprotein	HDV RNA	MRI with contrast enhancement
Bile acid levels	HBsAg	EGDS
INR		

- A combined response was defined as undetectable HDV RNA or ≥ 2 log IU/mL decline at week 24 versus baseline and ALT normalization.

Results

MONTH 6		
LABORATORY	IMAGING	THERAPY
HDV-RNA 2log IU/ml decline	No HCC	No missing doses were recorded
HBV-DNA remained undetectable	No portal hypertension	No reported systemic itching
AST and ALT normalized	No esophageal varices	No reaction at the injection site
Bile acid levels increased (was indirect confirmation of treatment adherence)	Liver stiffness unchanged	No liver decompensation or major complications
INR decline		No drug-related serious adverse events
Alphafetoprotein negative		No changes in Child-Pugh or MELD-Na

Conclusion

- Our data show the efficacy of subcutaneous bulevirtide monotherapy 2mg/day in reducing HDV RNA and no changes in Child-Pugh class and MELD score.
- Adherence and treatment retention are important issues in long-term pharmacotherapy. Prison regime seems to be a place to insure adherence to bulevirtide 2mg/day monotherapy administration because there is no self-administration but due to nurse staff.
- This treatment is safe in a prison regime and effective even for difficult-to treat patients with HBV/HDV-related compensated cirrhosis.

Reference

1. E. Degaspero et al. Bulevirtide monotherapy for 48 weeks in patients with HDV-related compensated cirrhosis and clinically significant portal hypertension. J Hepatol. 2022 Dec;77(6):1525-1531.
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3. E. Degaspero et al. Bulevirtide for patients with compensated chronic hepatitis delta: A review. Liver Int. 2023 Aug;43 Suppl 1:80-86.