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Treatment of HDV infection in Solid Organ Transplant with Bulevirtide: a case report

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Background

HDV infection poses a significant challenge in solid organ transplant recipients due to its aggressive nature and limited therapeutic options. Bulevirtide, a novel antiviral agent, approved by the European Medicines.
Agency in 2020 for the treatment of HDV infection, has limited data on its use in solid organ transplant recipients. In this report, we present what is to our knowledge the first case of a kidney transplant patient with HBV-HDV co-infection receiving treatment with entecavir and bulevirtide over a six-month management and observation period.

Case presentation

A 42-year-old male kidney transplant patient with HBV-HDV co-infection underwent a kidney transplant in September 2023. He was in treatment with entecavir 1 mg/day, due to prior lamivudine experience, and he had never been treated for HDV.
In January 2024, the patient began therapy with bulevirtide 2 mg/day administered via subcutaneous injection.
The clinical-laboratory controls consisted of a thorough clinical examination and comprehensive blood tests, evaluating the following parameters: hematological indices, coagulation profile, liver function and cytolysis tests, metabolic markers and serum levels of immunosuppressants (Tacrolemia and Everolemia) (see **Table 1**). We underline the rapid virological and biochemical response observed in our patient just two months after initiating bulevirtide therapy.
Achieving both negative serum HDV-RNA levels and normalization of transaminases within such a short timeframe reveals a profound antiviral effect of bulevirtide in our patient. (see **Table 1**)
With respect to tolerability, it is noteworthy that the stabilization of bile acid levels over the six-month treatment period, without causing itching, aligns with existing literature on the effects of bulevirtide therapy.
Moreover, the preservation of renal function despite bulevirtide therapy is also a significant finding, especially considering the patient's status as a kidney transplant recipient with baseline mild altered renal function.
Six months after the start of antiviral therapy with bulevirtide, the patient did not present any particular adverse reactions, but reported increased tenderness at the injection site over time. Additionally, starting from the fourth month of therapy, he experienced mild but tolerable asthenia, which did not deter him from continuing the treatment. This mild symptomatology was not associated with laboratory changes. The patient reported no other symptoms or adverse reactions during the six months of antiviral therapy. As of now, the patient is still continuing his current therapy with bulevirtide.

Conclusions

This case underscores the importance of individualized treatment approaches and highlights the potential efficacy of bulevirtide in solid organ transplant recipients with HDV infection. Further research is warranted to better understand management factors in this patient population.

Table 1. Blood chemistry and instrumental characteristics at baseline and during the six months of treatment with bulevirtide

	TOE	***T1***	***T2***	***T3***	***T4***	***T5***	***T6***	***T7***	***T8***
PLT (cell/µL)	*143,000*	*170,000*	*151,000*	*157,000*	*137,000*	*151,000*	*192,000*	*158,000*	*152,000*
INR	*1.1*	*1.1*	*1*	*1.02*	*1.02*	*0.99*	*1.03*	*1*	*1.01*
eGFR (ml/min)	*63*	*61*	*62*	*54*	*60*	*58*	*61*	*58*	*57*
Total bilirubinemia (mg/dl)	*0.24*	*0.3*	*0.26*	*0.3*	*0.34*	*0.23*	*0.17*	*0.26*	*0.27*
Bile acids (µmol/l)	*8*	*23*	*55*	*22*	*26*	*22*	*32*	*24*	*25*
AST (U/l)	*68*	*66*	*57*	*58*	*33*	*24*	*22*	*22*	*24*
ALT (U/l)	*137*	*134*	*121*	*110*	*42*	*22*	*21*	*19*	*20*
Tacrolimus blood level (ng/ml)	*3.8*	*6.3*	*4.5*	*4.8*	*6.7*	*4.5*	*4.8*	*4.3*	*4.2*
Everolimus blood level (ng/ml)	*3.3*	*2.3*	*1.5*	*0.82*	*1.9*	*3.4*	*5.9*	*3.5*	*3.4*
Quantitative HBsAg (UI/ml)	*2,120*			*1,540*	*1,170*				*1,130*
Serum HBV-DNA (IU/ml)	*<10*			*<10*	*<10*				*<10*
Serum HDV-RNA (IU/ml)	*22,360*			*5,220*	*<100*				*<100*
Hepatic stiffness (kPa)	*5.7*				*5.5*				*5.4*

TOE: time of enrolment pre-bulevirtide, T1: time of 7 days post-bulevirtide, T2: time of 14 days post-bulevirtide, T3: time of 1 month post-bulevirtide, T4: time of 2 months post-bulevirtide, T5: time of 3 months post-bulevirtide, T6: time of 4 months post-bulevirtide, T7: time of 5 months post-bulevirtide, T8: time of 6 months post-bulevirtide. PLT: Platelets, eGFR: Estimated Glomerular Filtration Rate, AST: Aspartate Aminotransferase, ALT: Alanine Transaminase, kPa: kilopascal.