The Burden of Hepatitis Delta in Italy: Potential Impacts of Bulevirtide through a Cost of Illness and Cost-Consequence Analyses

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INTRODUCTION

The manifestation of HDV infection can either be acute or result in prolonged, chronic illness. Its advancement can result in liver decompensation, hepatocellular cancer (HCC), and eventually necessitate liver transplantation [1]. Recently, new molecular targets for the treatment of HDV have been identified; among these, the inhibitory peptide bulevirtide (BLV).

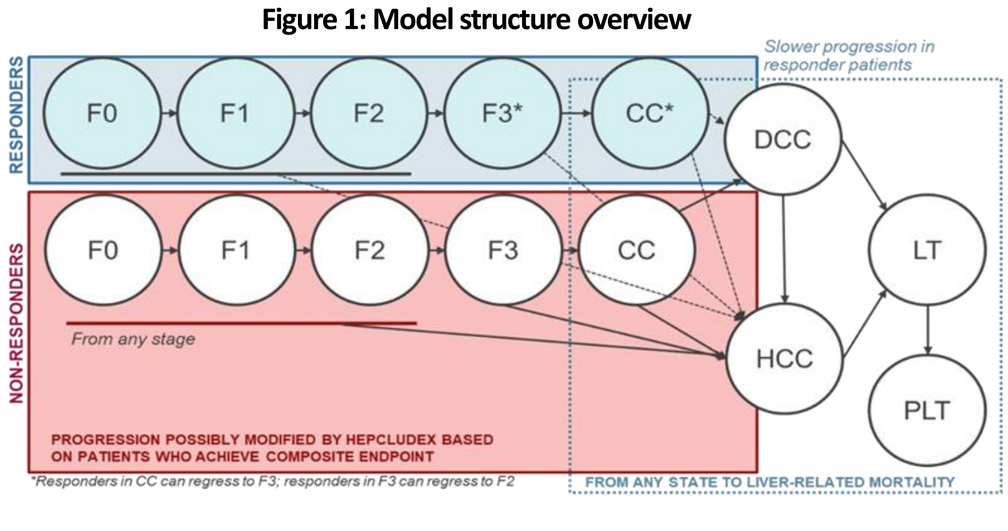
OBJECTIVES

The aim of this study was to assess the expenses borne by the National Health Service (NHS) and society due to HDV in Italy and to analyze the costs and impacts of bulevirtide in treating chronic hepatitis D infection among HDV-RNA positive adult patients with compensated liver disease.

METHODS

- The model was a decision tree followed by a Markov cohort model that follows patients through the lifetime of their disease, based on different state transitions and with a 24-week cycle length (**Figure 1**).

Figure 1: Model structure overview

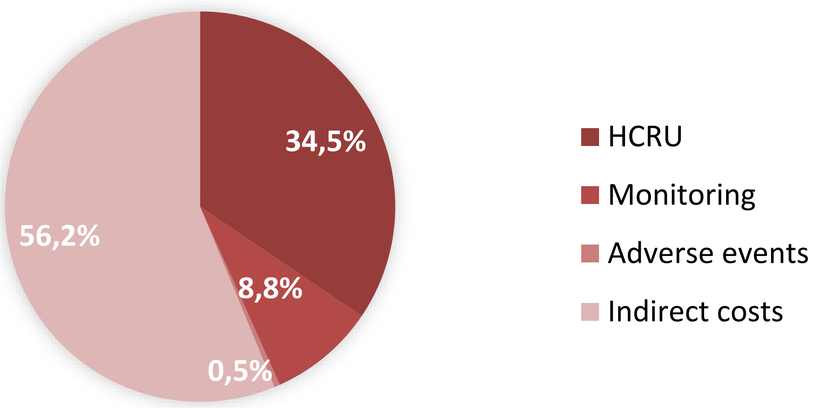


- A cost-of-illness analysis was developed to estimate the economic impact of HDV infection in Italy simulating a hypothetical cohort of 1,000 HDV-RNA positive adult patients with compensated liver disease and a mean age of 45.0 years, over a 10-year time horizon.
- A cost consequence analysis (CCA) was carried out with the aim of estimating the cost and consequences of using bulevirtide for the treatment of HDV. Two scenarios were considered: the first includes the treatment options available in the current clinical practice for HDV patients, while the second introduces the use of bulevirtide.
- The analyses were conducted from the NHS perspective and societal perspective, considering both direct and indirect costs.

RESULTS

The overall expenditure in the current scenario without bulevirtide was equal to € 34,939,429 (**Table 1**). Most of the total expenditure (current scenario) for HDV is allocated between indirect costs (56,2%) and health care resource use costs - HCRU (34,5%). The costs related to the management of adverse events are minimal (0,5%), while monitoring costs represent the remaining 8,8% of the total expenditure (**Figure 2**). HCRU costs relate to disease management, while the costs of monitoring and adverse events are linked to treatment.

Figure 2: Distribution of total HDV expenditure among 1,000 patients

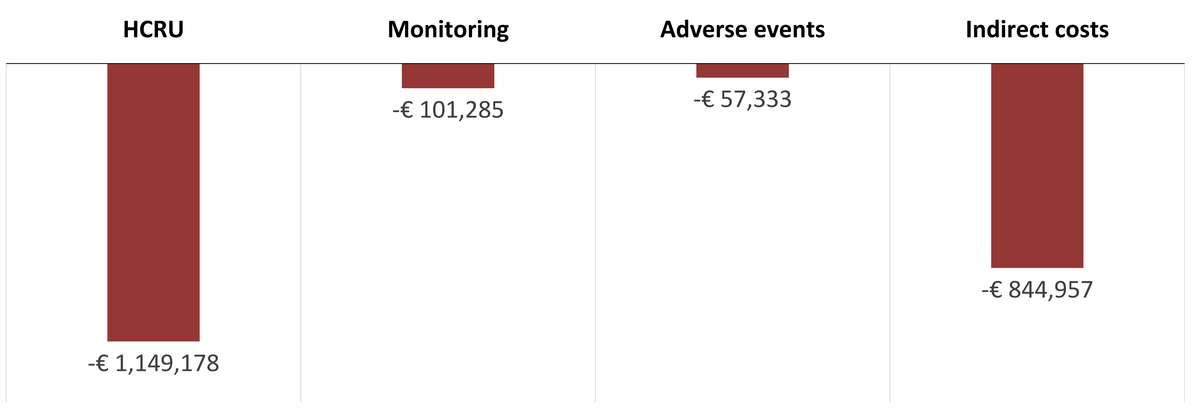


The introduction of bulevirtide resulted in a reduction of the total expenditure over 10 years from about 35 to 33 million euros compared to the actual scenario (**Table 1**). In general, all cost items were reduced with the introduction of bulevirtide (**Figure 3**)

Table 1: Cost of illness in current and new scenario among 1,000 patients

COSTS	Current costs	New scenario
Cost of Illness	€ 34,939,429	€ 32,786,677
HCRU	€ 12,039,860	€ 10,890,682
Monitoring	€ 3,086,689	€ 2,985,404
Adverse events	€ 167,457	€ 110,124
Indirect costs	€ 19,645,424	€ 18,800,466

Figure 3: Cost consequence of introducing bulevirtide over 10-year time horizon among 1,000 patients



The introduction of bulevirtide in the new scenario reflected an increase in QALYs from 4,434 to 4,800 and a decrease in the number of deaths from 595 to 521, as shown in **Table 2** below. Impacts are shown in **Figure 4.**

Table 2: Outcomes in the current scenario vs new scenario over 1,000 patients

OUTCOMES	Current scenario	New scenario
QALYs	4,434	4,800
Deaths	595	521

Figure 4: Impact on outcomes (current scenario vs new scenario) over 1,000 patients

CONCLUSIONS

This study provides an initial estimate of the total expenditure incurred by the NHS and society for the management of patients with HDV infection in Italy. The introduction of bulevirtide will significantly reduce the number of deaths, improve quality of life, and generate significant economic savings.

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FINANCIAL SUPPORT

This study was supported by Gilead Sciences.

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Poster # Presented at ISPOR Annual European Congress 2024, Barcelona, Spain