

Clinical profile of patients with chronic HDV infection by the nationwide Italian PITER-cohort

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ABSTRACT

Background and Aims: We aimed to comprehensively characterize patients with chronic hepatitis D (CHD) and explore treatment eligibility and prioritization criteria.

Methods: In this multicenter, cross-sectional cohort study, hepatitis B surface antigen (HBsAg)-positive patients were enrolled from 59 centers across Italy from November 2019 to February 2023. Multivariate logistic regression models explored the association between the considered variables with hepatitis D virus (HDV)-ribonucleic acid (RNA) positivity or liver cirrhosis.

Results: Of 4,152 enrolled patients, 422 (10.16%) were anti-HDV positive. Patients with anti-HDV were younger, more frequently non-Italian native, with a history of injection drug use, elevated ALT, and the presence of cirrhosis or hepatocellular carcinoma (HCC). Non-Italians were younger (42% aged <42 vs. 2.1%; $p < 0.001$) and more frequently female (68.6% vs. 43.0%; $p < 0.001$). Cirrhosis and HCC were more frequent among Italian patients. HDV-RNA was detected in 63% of tested patients who were likelier to have elevated ALT or gamma GT values, cirrhosis, and HCC. Body mass index (BMI) >25 was more frequent among HDV-RNA-negative patients. In the multivariable Cox model, only ALT was associated with HDV-RNA presence (OR 12.9, CI 95%: 6.3-26.3). Comorbidities were diagnosed in 47% of anti-HDV-positive patients; comorbidities were independently associated with cirrhosis, together with age and male gender. Based on absolute or relative contraindications, 22% of patients were eligible for IFN-based therapies.

Conclusions: CHD affects young foreign-born patients and older Italians, of whom two-thirds had cirrhosis or HCC. Comorbidities were associated with cirrhosis, and their role in liver disease progression should be further explored.