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ORIGINAL ARTICLE

Efficacy and safety of boceprevir-based triple therapy in HCV cirrhotic patients awaiting liver transplantation (ANRS HC29 BOCEPRETRANSPLANT)

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Abbreviations: HCV, hepatitis C virus; CHC, chronic hepatitis C; HCC, hepatocellular carcinoma; LT, liver transplantation; PEG-IFN, pegylated interferon; RBV, ribavirin; SVR, sustained virological response; ANRS, France REcherche Nord & sud Sida-HIV Hépatites-FRENSH; VL, viral load; EOT, end of treatment; ITT, intention-to-treat; SAE, serious adverse event; HRQL, health-related quality of life; IQR, interquartile range; MCS, mental component summary score; PCS, physical component summary score; RP, role limitations due to physical health.

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Summary
Background and aims: In this French multicentre, open-label study, we analyzed the efficacy, safety and patient-reported outcomes of a boceprevir-based triple therapy in HCV genotype 1 cirrhotic patients awaiting liver transplantation (LT).
Methods: Patients received PEG-IFN/ribavirin (RBV) for 48 weeks (W) and boceprevir from W4 to W48 or until LT.
Results: Fifty-one patients (80% males, median age: 56 years) were included. Fifty-seven percent had hepatocellular carcinoma and 43% end-stage liver disease. At enrolment, the median MELD score was 9 (range: 6—18); the Child-Pugh score was A in 65%, B in 35% and C in 2%. Therapy was discontinued because of severe adverse events (SAEs) in 39% of cases and virological inefficacy in 24%. 16% of patients had undetectable HCV RNA 24 weeks after the end of treatment (SVR24). LT was performed in 18 patients (35%). HCV RNA was undetectable in 16.6% at LT. Seven patients (14%) died and three deaths were attributed to treatment. SAEs ($n = 129$) were observed in 84% of patients. Twenty-four percent of patients developed severe infections. Albumin < 35 g/L was independently associated with severe infection. Compared with baseline values, a significant decrease ($P = 0.02$) of the physical dimension of health-related quality of life was observed between W4 and W24. The mean (95% CI) number of self-reported symptoms doubled during treatment (from 6.3 [4.8—7.7] to 11.8 [9.3—14.3]; $P < 0.001$).
Conclusions: The safety of the PEG-IFN/RBV/boceprevir combination is poor in patients awaiting LT, with a high risk of severe infection. Moreover, the limited efficacy confirms the indication for IFN-free combinations in these patients.