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TITLE: Safety and efficacy of triple therapy containing boceprevir (BOC) or telaprevir (TVR) plus peginterferon alfa-2a / ribavirin in patients with advanced fibrosis or cirrhosis in real-life setting

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ABSTRACT BODY: BACKGROUND: Data from the French CUPIC study[1] and an Austrian cohort[2] showed that patients with F3 or F4 fibrosis status were associated with a modest outcome and a high rate of severe events, particularly in patients with platelet count <100,000/mm³ and serum albumin <35 g/L. Here, the impact of these baseline factors on the treatment efficacy was analysed in the noninterventonal "PAN" cohort, conducted by Association of German Gastroenterologists in Private Practice (bng) and Roche.

METHODS: Patients infected with HCV genotype 1, APRI Score > 1.5 and with BOC or TVR containing triple treatment start between October 2011 and March 2012 were included in this cross sectional analysis, if at least documentation of baseline factors was completed.

RESULTS: 204 patients were analysed, 45 with BOC and 159 with TVR triple therapy. 47.1% of patients had liver cirrhosis (at least one result of sonography, histology, elastography or clinical appearance). 56.4% male, mean age 53.6 years, BMI 27.1 kg/m². 65.2% of patients had ALT >3ULN, 33.3% platelets <100,000/ μ l and 17.1% albumin < 35 g/L. Genotype-subtypes distribution was 1a 29.9%, 1b 52.0%, unknown/other 18.1%; High viral load (HCV-RNA >400,000 IU/ml) 74.4%. 73.5% were pretreated with 61 relapsers, 86 nonresponders. Treatment discontinuation rate increased over time until week 48: 2.9% at w4, 12.7% at w8, 17.2% at w12, 30.9% at w24, and 33.3% before w48. 53.4% of patients have finished treatment before w48. Percentages of virological response are the following (undetectable or <10IU/ml): 43.5% at w4 (n=154), 59.0% at w8 (n=117), 67.1 at w12 (n=152), 53.7% at w24 (n=162), 83.9% at w48 (n=56). Preliminary data of 88 patients reveal 65.9 % treatment discontinuation and 25.0% SVR. Because of low hemoglobin level predominantly emerging in treatment w5, dose modifications were done for ribavirin in 39.2% of patients and for Peg-IFN in 20.1% of patients. 15.7% of patients had SAEs. This risk of SAE increased up to 28.6% with platelet count <100,000/mm³ and serum albumin <35 g/L. Of all SAEs anemia, infections and hepatic impairments were dominant with 3.4, 5.0 and 4.5%; one patient died because for unknown reasons.

CONCLUSION: In our cohort patients with advanced liver disease had a poor safety profile, in particular if they had platelet count <100,000/mm³ and serum albumin <35 g/L. Due to the high discontinuation rate the chance of achieving SVR is low. Treatment of such patients should be well monitored and a benefit-risk profile should be assessed.

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Co-Author Disclosure Status

The following authors have completed their AASLD 2013 disclosure:

Stefan Mauss: No Answer.

Andreas Schober: No Answer.

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Thomas Lutz: No Answer.

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