Proof

CONTROL ID: 1729514

PRESENTATION TYPE: Oral or Poster

CURRENT CATEGORY: Viral Hepatitis C

CURRENT DESCRIPTORS: S02. HCV: Virology

TITLE: Baseline characteristics and treatment response of HCV genotype 1 patients with previous null response that are retreated with TVR or BOC triple therapy in real world setting

AUTHORS (FIRST NAME, LAST NAME): Wolf P. Hofmann[1], Stefan Mauss[2], Axel Baumgarten[3], Klaus H. Boeker[4], Ralph Link[5], Uwe Naumann[6], Peter R. Geyer[7], Dietrich Hueppe[8], Albrecht Stoehr[9], Hanns-Friedrich F. Loehr[10], Andreas Schober[11], Gero Moog[12], Stefanie Holm[13], Renate Heyne[14], Christoph Eisenbach[15], Thomas Lutz[16], Ulrich Alshuth[17], Marcus Schuchmann[18]

Institutional Author(s): bng study group

INSTITUTIONS (ALL): 1. Polikum Institut, Berlin, Germany.
2. Center for HIV and Hepatogastroenterology, Duesseldorf, Germany.
3. mib Dienstleistung GmbH, Berlin, Germany.
4. Center for Hepatology, Hannover, Germany.
5. MZV Offenburg, Offenburg, Germany.
6. Center for Addiction-Medicine, Hepatology and HIV, Praxiszentrum Kaiserdamm, Berlin, Germany.
7. Center of Gastroenterology, Fulda, Germany.
8. Center of Gastroenterology, Herne, Germany.
9. ifi-Institute for Interdisciplinary Medicine, Hamburg, Germany.
10. Center of Gastroenterology, Wiesbaden, Germany.
11. Center of Gastroenterology, Goettingen, Germany.
12. Center of Gastroenterology, Kassel, Germany.
13. Private Practice Dres. Kuhlmann/Holm/Heiken, Hannover, Germany.
14. Liver and study center Checkpoint, Berlin, Germany.
15. Dept. of Gastroenterology, University of Heidelberg, Heidelberg, Germany.
16. Infektiologikum, Frankfurt/M, Germany.
17. Virology, Roche Pharma AG, Grenzach-Wyhlen, Germany.
18. Dept Med 1, Gastroenterology and Hepatology, Johannes Gutenberg Univ Mainz, Mainz, Germany.

ABSTRACT BODY: Introduction:
In HCV genotype 1 null responder to a previous course of peginterferon alfa (PEG) and ribavirin (RBV), retreatment with telaprevir (TVR) or boceprevir (BOC) as part of a triple therapy is the only licensed therapeutic option today. However, recent phase III clinical trials indicate low antiviral response rates in these difficult-to-treat patients and physicians are challenged to give the best treatment recommendation.

Methods:
The PAN study is a non-interventional study conducted at multiple sites in Germany and includes treatment naive and treatment experienced patients with HCV genotype 1 infection who receive triple therapy with TVR or BOC at the physicians discretion. In the present analysis, all consecutive retreated patients with HCV genotype 1 infection and well defined previous non response to PEG and RBV were included. Baseline characteristics and treatment efficacy data were analysed.

Results:
There were 65 Patients with previous null response (63,1% male, mean age 50,5 years, BMI 26,1 kg/m2, 49,2% with HCV genotype 1b) and 121 Patients with previous partial response (59,5% male, mean age 50,0, BMI 26,7 kg/m2, 56,2% with HCV genotype 1b) who received retreatment with PEG and RBV plus TVR (n=155) or BOC (n=31). Liver cirrhosis (at least one result of ultrasound, transient elastography, histology or clinical signs) was present in 41,5% and 21,5% of patients with previous null response and partial response, respectively. High baseline viral load (> 400.000 IU/ml HCV RNA) was detected in 87,7% and 81,0% of the two groups, respectively. An extended rapid virologic response (eRVR, adjusted for TVR at weeks 4 and 12 and BOC at weeks 8 and 24 of therapy) was achieved in 29,5% of previous null responders and 56,8% of previous partial responders. Preliminary SVR rates (available for a total of 68 patients) were 11,8% (4/34) in previous null responders and 23,5% (8/34) in previous partial responders. Discontinuation rates due to virologic failure or adverse events were 55,0% and 24,8% for the two groups, respectively.

Conclusion:
The baseline characteristics of non responder patients in the PAN study demonstrate the high proportion of cirrhotic patients especially among previous null responders in Germany. In the real world setting, virologic response rates are poor and discontinuation rates are high and strongly confirm the medical need for new therapeutic options in this difficult-to-treat population.

(No Table Selected)
(No Image Selected)