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TITLE: Efficacy and safety of eRVR patients treated with telaprevir, peginterferon alfa-2A and ribavirin: SVR Data from the German non-interventional PAN Study

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ABSTRACT BODY: Introduction: In pivotal trials shortening of triple treatment containing telaprevir (TVR) was possible in up to 58%*. Drawbacks are complex guidelines and a profound knowledge of treatment practices for different patient populations. Here we analyse whether this is feasible under real life conditions.

Methods: The PAN study is a non-interventional study conducted by the Association of German Gastroenterologists in Private Practice (bng) in collaboration with Roche. Selected patients got TVR plus peginterferon alfa-2a/ribavirin (Peg-IFN/RBV). We restricted the analysis to treatment naïve patients infected with genotype-1 who have started treatment until March 31st, 2012 and had documentations of at least 24 weeks completed.

Results: Overall 269 patients were included in the present analysis. Patients had a mean age of 46.6 years and a mean BMI of 25.6 kg/m2, 60.2% were male, 97.0% were Caucasian, 8.9% had one diagnostic measure consistent with cirrhosis, and the mean HCV RNA was 6.1 log10 IU/mL. 33.5% and 48.0% of the patients were infected with HCV G1a and G1b, respectively. (18.6% unknown subtype). Percentages of all virological responses as HCV-RNA undetectable or <10IU/ml are given in the table shown below. However, in real life a large number of HCV-RNA determinations were not assignable or not valid at the given time points. Of the 47 patients with a valid HCV RNA at w4 and w12 41 had had an extended RVR (eRVR) and of them 82.9% an SVR.
RBV or Peg-IFN dose modifications occurred in the first 10 weeks. Rates of haemoglobin <8.5 g/dL or ≥ 8.5 but <10 g/dL in the first 12 weeks and thereafter were similar with 13.1 or 34.0% and 9.0 and 26.2%, respectively. Rash and rash like symtoms were different in the first 12 weeks and thereafter with 42.0% and 4.5%, respectively.

Conclusion: Real world experiences with telaprevir plus peginterferon alfa-2a/ribavirin are generally consistent with the results of the published phase 3 trials, if treatment complies with SPC recommendations. Otherwise a lot of possible shorter treatments were not achieved due to inadequate therapy management.

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*Jacobsen et al., N Engl J Med 2011;364:2405-16

Table 1: Virological responses during different time points of treatment

	Visits completed	valid HCV-RNA (=100%)	Discontin-uations in total (%)	viral load undetectable and/or <10 IU/ml (%)	valid HCV-RNA at w4 and w12 (=100%)	viral load undetectable and/or <10 IU/ml (%)
week 4	269	210	2.9	68.1		
week 12	269	193	15.0	79.8	168	64.9
week 24	269	201	22.9	71.6	155	75.5
EoT week 24	121	92	15.2	80.4	67	86.6
follow up after 24w tx	87	78	12.8	82.1	47	83.0

(No Image Selected)

Co-Author Disclosure Status

The following authors have completed their AASLD 2013 disclosure:

Stefan Christensen: No Answer.
Klaus Boeker: No Answer.
Christoph Eisenbach: No Answer.
Marcus Schuchmann: No Answer.
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