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TITLE: 24 week treatment of former relapse, HCV genotype 1 infected patients with telaprevir in combination with peginterferon alfa 2a/ribavirin – experiences under real life conditions

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ABSTRACT BODY: Introduction: Although in pivotal trials of telaprevir (TVR) a shorter treatment duration of 24 weeks was not explored, FDA and EMA approved reduction of treatment duration to 24 weeks, if former relapse patients achieve an extended RVR (eRVR) in triple treatment with TVR*. Are the physicians aware of this option and is a continuous monitoring of these patients doable under real life conditions?

Methods: Between October 2011 and April 2013 >1900 genotype 1 patients treated with TVR containing triple therapy were included in the non-interventional study PAN conducted by the Association of German Gastroenterologists in Private Practice (bng) and Roche. Data of 287 former relapse patients with simultaneous start of TVR and peginterferon alfa 2a/ribavirin before April 2012 and with complete data up to week 24 were analyzed. Precision of measuring HCV RNA at week 4 was set to +/- 5d and of weeek12 to +/- 10d.

Results: Demographic mean data were: age 51.5 yrs, male gender 65.5%, BMI 26.7 kg/m2, ALT 96.7 IU/l. 15.3% of patients had liver cirrhosis (at least one result of sonography, histology, elastography or clinical appearance). 66.6% of patients had high viral load (>400,000 IU/ml), distribution of GT-1 subtypes was 24.0% 1a, 50.9% 1b, 0.7% other and 24.4% unknown. Documented virological responses, treatment discontinuation and valid HCV RNA measurement rates are shown in the table below. 48 of 51 patients with a HCV RNA value at w4 and w12 had eRVR, of them 91.7% achieved SVR. Rates of anemia < 10 g/dl and < 8.5 g/dl were 27.5% and 6.7% during the first 12 weeks and 25.9% and 10.2% after week 12. Rash or Rash like symptoms were reported in 35.2% in the first 12 weeks of therapy and in 7.7% thereafter.

Conclusion: As revealed in a parallel study, ~25% of patients in weeks 4, 12 and 24 had no valid or assignable HCV RNA as recommended by SPC. Here is a clear potential to optimize monitoring and therapy regime resulting in an improved treatment outcome. Patients who achieve eRVR had low discontinuation rates in total and high chance to reach SVR. So continuous monitoring of treatment seems to be meaningful for shortening therapy in daily routine.

* J Liu et al, Hepatology 2013;57:897-902

Virological efficacy of week 4, 12, 24 , 24 as EoT and Follow-up after 24 weeks of treatment

	Visits	valid	Discontin-	viral load undetectable	valid HCV-RNA	viral load undetectable

	completed	HCV-RNA (=100%)	uations in total (%)	and/or <10 IU/ml (%)	at w4 and w12 (=100%)	and/or <10 IU/ml (%)
week 4	287	208	3.8	70.7		
week 12	287	214	8.9	86.0	181	70.2
week 24	287	214	14.5	84.6	181	75.1
EoT week 24	107	81	8.6	91.4	61	95.1
follow up after 24w tx	83	77	6.5	87.0	51	88.2

(No Image Selected)

Co-Author Disclosure Status

The following authors have completed their AASLD 2013 disclosure:

Klaus Boeker: No Answer.
Ralph Link: No Answer.
Axel Baumgarten: No Answer.
Albrecht Stoehr: No Answer.
Renate Heyne: No Answer.
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