1. INTRODUCTION

Shortening of treatment duration with peginterferon and ribavirin to 24 weeks in patients with chronic hepatitis C virus (HCV) genotype 1 infection and low baseline viral load (<6–8 × 10^5 IU/ml) in addition to a rapid virologic response (RVR) is approved in Europe. Currently, it is unknown whether patients with high baseline viral load and RVR really need 48 weeks of therapy. Furthermore, it is conceivable that also in patients with undetectable HCV-RNA at week 6 shortening of treatment duration is possible.

2. METHODS

398 treatment-naïve HCV genotype-1 patients were enrolled in a multicenter, randomized trial for individualization of duration of treatment with peginterferon alfa-2b and ribavirin. (Figure 1)

Here we report an interim analysis of patients with shortened treatment to 24, 30 or 36 weeks based on low-viral load (LVL) or high-viral load (HVL) (cut-off 800,000 IU/ml bDNA3.0) and undetectable HCV-RNA at week 4 (RVR) or 6 by a highly sensitive assay (Versant HCV Quantitative bDNA 3.0) and undetectable HCV-RNA at week 6 and a HVL (cut-off >8 × 10^5 IU/ml).

Sustained virologic response (SVR) rates were compared to a historical control group of 224 patients treated for 48 weeks (INDIV-1-study) based on identical HCV-RNA assays (bDNA3.0 and TMA).

3. RESULTS

Thirty-eight patients with RVR and LVL were treated for 24 weeks. One discontinued therapy and one was lost to follow-up. Six patients with RVR and a HVL were treated for 30 weeks. One discontinued treatment at week 13 followed by a relapse. Twenty patients with undetectable HCV-RNA at week 6 and LVL were treated for 30 weeks. One patient experienced a relapse. Eleven patients with undetectable HCV-RNA at week 6 and a HVL received 36 weeks of therapy. One of these patients had a relapse. SVR rates for individualized treated patients in comparison with the control group are given in Table 1. The remaining patients are currently still under therapy.

4. CONCLUSION

Based on differentiation between low and high baseline viral load together with virologic response to treatment at week 4 and 6 further individualization of treatment duration to 24, 30 and 36 weeks seems possible.

Table 1

<table>
<thead>
<tr>
<th>INDIV-1</th>
<th>INDIV-2</th>
<th>INDIV-3</th>
<th>INDIV-2*</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 weeks</td>
<td>30 weeks</td>
<td>36 weeks</td>
<td>24 weeks</td>
</tr>
<tr>
<td>91%</td>
<td>95%</td>
<td>100%</td>
<td>91%</td>
</tr>
<tr>
<td>77%</td>
<td>91%</td>
<td>100%</td>
<td>91%</td>
</tr>
</tbody>
</table>

* includes patients with HCV-RNA undetectable for the first time at week 5, 6 or 7

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