Is There a Real Difference in Viral Response of Chronic Hepatitis C between Men and Women?

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INTRODUCTION

Female sex has been reported to be a positive predictive factor for sustained viral response (SVR) of chronic hepatitis C treatment. In more detailed analyses the improvement in SVR was claimed to be restricted to premenopausal women. However these data are controversial.1-3 Since 2003 the Association of German Gastroenterologists in Private Practice (Niedergelassener Gastroenterologen Deutschlands e.V.) in cooperation with Roche, Germany, is conducting a real-world nationwide observational study including screening and treatment phases to determine the quality of treatment for chronic hepatitis C (CHC) in routine clinical practice.

OBJECTIVE

This interim analysis evaluates sex and age in patients with chronic hepatitis C receiving therapy with peginterferon alfa-2a 180 µg and ribavirin.

METHODS

This evaluation is part of a large ongoing German multicentre, open-label observational study including all anti-HCV-positive adults with detectable HCV RNA. The nature of this study allowed dosing and duration of both peginterferon alfa-2a (40KD) and ribavirin to be at the discretion of the physician.

The screening data include age, sex, weight, height, duration and source of infection, prior antiviral treatment, clinical symptoms, histology, genotype, viral load, concomitant diseases and social status.

This data set includes patients who completed treatment with peginterferon alfa-2a (40KD) plus ribavirin. The data collection was performed online via the internet.

The documented data should reflect the clinical routine as intended by the doctors in charge. Therefore, the statistical analysis remains descriptive.

RESULTS

Patients

From a total of 6081 patients treated with pegylated interferon alfa-2a and ribavirin 4186 patients were selected to create 2093 matched pairs. Every female patient was matched with a male patient according to age, HCV genotype and HCV RNA level.

The mean age of the patients was 43.5 years. Baseline epidemiological data for Western European women. SVR selected as presumed date of menopause based on current symptoms, histology, genotype, viral load, concomitant diseases and social status.

Virological Response

In the analysis of patients under the age of 50 years viral response was (see Figure 1):

- Rapid virologic response (RVR; HCV-RNA < 50 IU/ml 4 days after the start of antiviral therapy): male 51.1%, female 46.2%
- Early virologic response (EVR; HCV-RNA < 50 IU/ml 12 weeks after the start of antiviral therapy): male 80.2%, female 77.9%
- End of treatment response (EOT; HCV RNA < 50 IU/ml at the end of treatment): male 68.4%, female 68.9%
- Sustained virologic response (SVR; HCV RNA < 50 IU/ml 24 weeks after the end of antiviral therapy): male 54.2%, female 55.9%

In patients ≥50 years viral response was (see Figure 2):

- RVR: male 27.6%, female 22.2%
- EVR: male 69.7%, female 70.9%
- EOT: male 54.2%, female 58.1%
- SVR: male 34.7%, female 39.4%

The viral response for patients grouped according to decades is shown in Table 2, Figure 3 and Figure 4.

Discontinuation of Therapy

Treatment was discontinued in 30.6% of the patients (see Figure 5).

- The most frequent reason was missing virological response (3.8% of all patients), followed by lost to follow-up (5.9%) and patients’ request (5.1%, see Figure 6).

CONCLUSIONS

In the large matched pair analysis no advantage in viral response was observed for premenopausal women compared to men. In addition postmenopausal women did not seem to have an impaired viral response compared to men with chronic hepatitis C. Furthermore a worse response to antiviral therapy in women affected by chronic hepatitis C. Gastroenterology 2011;140:818–29.

References


Table 1: Baseline data

<table>
<thead>
<tr>
<th></th>
<th>male</th>
<th>female</th>
<th>male</th>
<th>female</th>
<th>male</th>
<th>female</th>
<th>Total</th>
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<tbody>
<tr>
<td>N</td>
<td>N=1,379</td>
<td>N=1,379</td>
<td>N=714</td>
<td>N=714</td>
<td>N=4,186</td>
<td>N=4,186</td>
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<tr>
<td>Age (mean ± SD in years)</td>
<td>36.8 ± 7.8</td>
<td>36.9 ± 8.4</td>
<td>55.9 ± 5.7</td>
<td>57.4 ± 6.4</td>
<td>43.5 ± 12.1</td>
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<tr>
<td>BMI</td>
<td>25.3 ± 4.0</td>
<td>24.6 ± 5.0</td>
<td>26.0 ± 3.9</td>
<td>26.5 ± 4.9</td>
<td>25.4 ± 4.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV genotype</td>
<td>1/4/5/6 2/3</td>
<td>60.7%</td>
<td>60.7%</td>
<td>78.4%</td>
<td>78.4%</td>
<td>66.7%</td>
<td></td>
</tr>
<tr>
<td>Duration of infection</td>
<td>9.6 ± 7.5</td>
<td>10.9 ± 8.1</td>
<td>16.6 ± 10.9</td>
<td>19.0 ± 10.8</td>
<td>12.7 ± 9.7</td>
<td></td>
<td></td>
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<tr>
<td>High viral load (&gt;400,000 IU/ml)</td>
<td>49.5%</td>
<td>49.5%</td>
<td>63.9%</td>
<td>63.9%</td>
<td>54.4%</td>
<td></td>
<td></td>
</tr>
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</table>

Table 2: Treatment outcome according to decades

<table>
<thead>
<tr>
<th></th>
<th>&lt;18 - &lt;30 yrs.</th>
<th>≥30 - &lt;40 yrs.</th>
<th>≥40 - &lt;50 yrs.</th>
<th>≥50 yrs.</th>
<th>≥60 - &lt;70 yrs.</th>
<th>≥70 yrs.</th>
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<tbody>
<tr>
<td>RVR</td>
<td>61.0% / 53.7%</td>
<td>55.4% / 49.5%</td>
<td>43.2% / 37.4%</td>
<td>28.6% / 26.0%</td>
<td>26.5% / 19.7%</td>
<td>18.2% / 7.3%</td>
</tr>
<tr>
<td>EVR</td>
<td>81.8% / 86.6%</td>
<td>81.6% / 77.7%</td>
<td>78.4% / 76.6%</td>
<td>66.6% / 72.2%</td>
<td>77.5% / 71.1%</td>
<td>60.0% / 52.5%</td>
</tr>
<tr>
<td>EOT</td>
<td>72.8% / 67.3%</td>
<td>67.4% / 72.0%</td>
<td>67.0% / 67.2%</td>
<td>55.9% / 61.9%</td>
<td>57.1% / 52.3%</td>
<td>32.1% / 36.2%</td>
</tr>
<tr>
<td>SVR</td>
<td>61.6% / 51.8%</td>
<td>56.7% / 61.1%</td>
<td>48.4% / 54.0%</td>
<td>35.4% / 42.8%</td>
<td>33.9% / 33.3%</td>
<td>25.0% / 21.3%</td>
</tr>
</tbody>
</table>

Fig. 1. Virological response in patients <50 years of age

Fig. 2. Virological response in patients ≥50 years of age

Fig. 3. RVR and EVR acc. to age categories

Fig. 4. EOT and SVR acc. to age categories

Fig. 5. Discontinuations of therapy

Fig. 6. Main reasons for discontinuation

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