INTRODUCTION

For patients and physicians the likelihood of a treatment success is one of the most relevant factors for a decision to start or defer therapy of chronic hepatitis C (CHC). For this reason, baseline variables are important.

The current evaluation is based on PRACTICE (Pegylated Interferon and Ribavirin: Analysis of CHC Treatment in Centres of Excellence), a nationwide retrospective observational study on routine clinical practice including centres with large expertise in the treatment of chronic hepatitis C (CHC).

OBJECTIVE

- Aim of this analysis is to identify predictive factors for the success of treatment of CHC-patients under real life conditions.

METHODS

This evaluation is a part of a large retrospective German multicentre, open-label observational study including anti-HCV-positive adults with detectable HCV RNA. According to the nature of this study, all treatment decisions concerning peginterferon and ribavirin (selection, dosing and treatment duration) were at the discretion of the physician.

The data set includes patients who completed treatment with peginterferon alfa-2a or alfa-2b plus ribavirin. The data collection was performed via an e-CRF online via the internet.

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

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RESULTS

Patients

- 3470 patients treated with pegylated interferon plus ribavirin under real life conditions were documented between 2000 and 2007 from 23 large outpatient clinics.

Matched data sets were available for 1204 pairs of patients (N=1204 Peg-IFN alfa-2a; N=1204 Peg-IFN alfa-2b).

- In order to evaluate only patients with chronic hepatitis C, patients with acute hepatitis C were excluded from the analysis.

The resulting CHC-data set included 1189 matched pairs (N=1189 Peg-IFN alfa-2a; N=1189 Peg-IFN alfa-2b).

The demographic data for the 2378 CHC-patients and the total group of 2408 patients are shown in Table 1.

The following analysis is based on matched pairs of 2378 CHC-patients.

Virological response

- Over all, a Sustained virological response (SVR) was achieved in 1377 of 2378 patients (57.4%).

Univariate analyses

- In univariate analyses SVR was significantly associated with genotype (p<0.001; see Figure 1), peginterferon treatment (p<0.05; see Figure 2), viral load (p<0.001; see Figure 3), BMI (p<0.001; see Figure 4) and platelets (p<0.001).

- No association was observed with gender, ALT and opioid maintenance.

Multivariate analysis

- Positive predictive factors being significantly associated with SVR in multivariate logistic regression (MLR) are (see Figure 5): - genotype 2 (p<0.001; OR=3.5; 95% CI: 2.7-4.6), - genotype 3 (p<0.001; OR=2.9; 95% CI: 2.2-3.9), - age <30 years (p<0.001; OR=0.3; 95% CI: 0.2-0.5), - BMI >28 (p<0.001; OR=1.2; 95% CI: 1.1-1.3), - peginterferon alfa-2b (p<0.001; OR=2.8; 95% CI: 2.3-3.3).

- Negative predictive factors being significantly associated with SVR in multivariate logistic regression (MLR) are (see Figure 6): - genotype 4 (p<0.001; OR=0.1; 95% CI: 0.04-0.2), - BMI >28 (p<0.001; OR=0.8; 95% CI: 0.7-0.9), - age >50 years (p<0.001; OR=0.5; 95% CI: 0.4-0.6), - peginterferon alfa-2b (p<0.001; OR=0.5; 95% CI: 0.4-0.7), - BMI >28 (p<0.001; OR=0.8; 95% CI: 0.7-0.9).

- The BMI was not significantly associated with SVR (data not shown).

Table 1: Baseline data

<table>
<thead>
<tr>
<th></th>
<th>Acute chronic hepatitis C</th>
<th>Only chronic hepatitis C</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (mean ± SD in kg/m2)</td>
<td>23.6 ± 3.6</td>
<td>24.7 ± 3.6</td>
</tr>
<tr>
<td>Age (mean ± SD in years)</td>
<td>42.2 ± 11.3</td>
<td>42.2 ± 11.4</td>
</tr>
<tr>
<td>Genotype 1</td>
<td>61.9</td>
<td>61.6</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>6.6</td>
<td>6.6</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>30.2</td>
<td>30.4</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>1.3</td>
<td>1.3</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- Genotype 2, genotype 3, low viral load and treatment with Peginterferon alfa-2a were identified as positive predictive factors for treatment success in this well controlled large cohort.

- Higher age (> 40 years), elevated GGT and platelets <150 000/µl were identified as negative predictors for treatment success.

Figure 1. Sustained virological response (SVR)

Figure 2. SVR and peginterferon treatment

Figure 3. SVR and age

Figure 4. SVR and GGT

Figure 5. Multivariate logistic regression (references were Peg-IFN alfa-2a, genotype 1, age <30 years, viral load (>400 000 IU/ml), GGT (m<66, f<39 UI/l), PLT <150 000/µl).