INTRODUCTION

Although treatment with pegylated interferon and ribavirin has increased the Sustained Virological Response (SVR) substantially, there is still a relapse rate after End of Treatment Response (EOT) about 20-30%. It is unknown whether there are defined parameters at baseline or in the course of treatment, which are deciding for relapse.

The Association of German Independent Gastroenterologists (bng) (Berufsverband Niedergelassener Gastroenterologen Deutschland e.V) in cooperation with Roche, Germany, is conducting a nationwide observational study including screening and treatment phases to determine the quality of treatment for chronic hepatitis C in routine clinical practice.

OBJECTIVE

The main aim of this evaluation of the ongoing study on the treatment of HCV patients is to find out parameters characterising patients with relapse after EOT.

METHODS

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

RESULTS

Anamnesis

The mean duration of HCV infection was 14.5 years for the patients with relapse (REL) and 11.0 years for the patients with SVR. The rate of Adverse Events (AE) was 57.5% in relapsers (REL) and 51.3% in patients with SVR. The difference between relapsers and patients with SVR was smaller: 91.6% (REL) vs. 96.6% (SVR) (see Figure 4).

- 167 patients (24.4%) had a relapse (group REL).
- 517 patients (75.6%) with EOT achieved an SVR (group SVR).

Adverse events

The rate of Adverse Events (AE) was 57.5% in relapsers (REL) and 51.3% in patients with SVR.

CONCLUSIONS

- Concomitant diseases were found in 56.3% of the relapsers (REL) and in 59.9% of the patients with SVR. The profile of concomitant diseases was not substantially different between both groups.
- Viral load: At baseline, 39.9% of the relapsers (REL) had low viral load (cut-off of 400,000 IU/ml) in contrast to 55.2% of the patients with SVR (see Figure 3).


table 1: baseline data

<table>
<thead>
<tr>
<th>REL</th>
<th>SVR</th>
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<tbody>
<tr>
<td>patients N</td>
<td>167</td>
</tr>
<tr>
<td>gender male</td>
<td>57.5%</td>
</tr>
<tr>
<td>age* years</td>
<td>46.8±12.5</td>
</tr>
<tr>
<td>body mass index* kg/m²</td>
<td>25.8±4.4</td>
</tr>
<tr>
<td>duration of infection* years</td>
<td>14.5±11.0</td>
</tr>
<tr>
<td>* mean of SD</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Study patients

Figure 2. Source of infection

Figure 3. Virological response

Figure 4. Viral load at baseline

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