The QoL in the ADU group was less altered on the physical and mental levels than in the other groups. Between 2003 and 2006, 184 clinicians evaluated 2001 hepatitis C patients every 3 months to determine their response to treatment. This analysis includes 1860 patients who were classified as NDU, EDU, and ADU (including patients undergoing substitution treatment). The incidence of adverse events is shown in Figure 6. The prevalence of genotype 3 infection, low body mass index, and less advanced stage of fibrosis counterbalanced the potentially negative impact of the unfavorable parameters associated with active drug use. However, active drug use did not have a negative impact on virologic response or sustained virologic response. Quality of Life: Mental adverse events were more frequent among ADU; however, combination therapy had a less negative impact on quality of life to the young patients. Patients with chronic HCV infection were evaluated for the presence of HIV coinfection. Among NDU, most patients had genotype 1 or 2 infection. The proportions of patients with genotype 3 infection were higher among EDU and ADU than among NDU. There was significant heterogeneity across the patient groups in terms of duration of treatment and dosing. Mean PEG-IFN alfa-2b doses were higher in ADU than in NDU or EDU. There were no differences in terms of sustained virologic response, virologic response rates assessed at least 12 weeks after completion of therapy, and virologic response rates assessed at least 24 weeks after completion of therapy. However, treatment discontinuations were more common among NDU than among ADU or EDU. This may be related to the high proportion of patients with genotype 3 infection, low body mass index, and less advanced stage of fibrosis. 3. Agostini H et al. 2002. 4. The proportion of patients with genotype 3 infection was significantly different across the patient groups (p < 0.001). Figure 3. The proportion of patients with genotype 3 infection was significantly different across the patient groups (p < 0.001). The incidence of adverse events is shown in Figure 6. The prevalence of genotype 3 infection, low body mass index, and less advanced stage of fibrosis counterbalanced the potentially negative impact of the unfavorable parameters associated with active drug use. However, active drug use did not have a negative impact on virologic response or sustained virologic response.
Impact of the Use of Drugs and Substitution Treatments on the Antiviral Treatment of Chronic Hepatitis C: Analysis of Clinical Response, Virological Response and Quality of Life (CHEOBS)

P. Melin, J-P. Lang, D. Ouzan, M. Chousterman, M. Varastet, M. Rotily, T. Fontanges, P. Marcellin, P. Cacoub

Hôpital Général Saint-Dizier, France; Centre Hospitalier Erstein, Erstein, France; Institut Arnaud Tzanck, Saint Laurent du Var, France; Hôpital de Grenelle, Grenelle, France; Clin/Scan, Bagneux, France; Centre de l'appareil Digestif, Bourg-la-Reine, France; Hôpital Reunion, Cachy, France; Hôpital Pitié-Salpêtrière, Paris, France

Abstract

Around 10% of patients (women excluded) with chronic hepatitis C virus (HCV) infection, at least 65 years of age, reported the use of drugs (7.1%) or substitution (3.2%) during the month prior to the study visit, and 5.0% during the month prior to the study visit. The QoL in the ADU group was less altered on the physical and mental levels than in the other groups.

Background

The CHEOBS is a French multicenter, prospective, observational study that aimed to analyse the impact of the use of drugs and substitution treatments on the antiviral treatment of chronic hepatitis C with stable drug use.

Aim

To assess the impact of antiviral treatment of chronic hepatitis C virus infection among drug users and non-drug users and to determine the influence of virologic response on quality of life during treatment and 6 months after the end of treatment.

Methods

Patients and Methods

Patients and Methods

Methods

Results

Sociodemographics

Unemployment was significantly more frequent among ADU than NDU and EDU (P < 0.001), and similar among EDU and NDU. Among ADU, 85% were unemployed, vs 70% of NDU and 60% of EDU (P < 0.001). The percentage of patients living alone was lower among ADU than NDU or EDU (P < 0.001). Elderly patients had the largest proportions of ADU than NDU or EDU (P < 0.001). Between 20% and 30% of patients had a history of psychiatric disorders (P < 0.001) and mental illnesses (P < 0.001). There was significant heterogeneity across the patient groups in terms of duration of treatment and dosing in the ADU group (P < 0.001), the EDU group (P < 0.001), and the NDU group (P < 0.001). Among NDU, most patients had genotype 1 or 2 infection (P < 0.001).

Conclusions

There was significant heterogeneity across the patient groups in terms of duration of treatment and dosing (P < 0.001). The distribution of genotypes was significantly different across the 3 patient groups (P < 0.001). Virologic response rates assessed at least 12 weeks after completion of therapy were not significantly different (P = 0.133). Adherence to therapy and virologic response rates were similar in ADU, EDU, and NDU patients (P > 0.2).

Quality of Life

Quality of life according to whether the patients were active drug users or under substitution treatment (ADU), ex-drug users (EDU) or non-drug users (NDU) was presented. Quality of life was significantly reduced among ADU than in NDU or EDU (P < 0.001).

Summary

In this analysis, active drug use was frequently associated with excessive alcohol intake, vulnerability and a lack of self-confidence. The potentially negative impact of the unfavorable parameters associated with active drug use did not have a negative impact on the quality of life of the hepatitis C patients.

References


Impact of the Use of Drugs and Substitution Treatments on the Antiviral Treatment of Chronic Hepatitis C: Analysis of Compliance, Virological Response and Quality of Life (CHEOBS)

P. Melin,1 J.-P. Lang,2 D. Ouzan,3 M. Chousterman,4 M. Varastet,5 M. Rotily,5 T. Fontanges,6 P. Marcellin,7 P. Cacoub8

1Hôpital Géneral, Saint Dié, France; 2Centre Hospitalier Erstein, Erstein, France; 3Institut Arnaud Tzanck, Saint Laurent du Var, France; 4Hôpital de Créteil, Créteil, France; 5Clin/Search, Bagneux, France; 6Centre de l'hôpital Digestif, Bourgoin, Jallieu, France; 7Hôpital Paul Sabatier, Toulouse, France

Presented at the 44th Annual Meeting of the European Association for the Study of the Liver, April 22–26, 2009, Copenhagen, Denmark

Abstract

Background

- The aim of this study was to evaluate the impact of drug use on the use of antiviral dual therapy and to analyze factors associated with adherence to this treatment, with particular attention given to the virological response and quality of life of patients. It also aimed to determine the specific factors that could explain differences in virological response and quality of life among patients who received antiviral treatment.

Objective

- To analyze the impact of drug use on the use of antiviral dual therapy and to evaluate factors associated with adherence to this treatment, with particular attention given to the virological response and quality of life of patients. It also aimed to determine the specific factors that could explain differences in virological response and quality of life among patients who received antiviral treatment.

Patient population

- The study population consisted of 2001 patients with chronic hepatitis C (HCV) infection, of whom 184 clinicians evaluated every 3 months.

Methods

- The study was conducted between 2003 and 2006 at 184 centers in France that specialize in the management of hepatitis C patients. The present analysis focuses on adherence to antiviral dual therapy, virological response, and quality of life.

Quality of Life

- The QoL in the ADU group was less altered on the physical and mental levels than in the other groups.

Conclusions

- The patient profile in the EDU group was between that in the ADU and NDU groups for mean age, body mass index (BMI), and duration of the antiviral dual therapy prescribed. Sustained virological response (SVR) was defined by a reduction in the HCV RNA level to below 50 IU/mL 24 weeks after the end of treatment. The present analysis focuses on adherence to antiviral dual therapy, virological response, and quality of life.

References

Results

Among these patients, 141 were excluded from the analysis. Between 2003 and 2006, 184 clinicians evaluated 2001 hepatitis C patients every 3 months during treatment and 6 months after the end of treatment. QoL was assessed using the SF-36 questionnaire. Over half of the patients (568) were active drug users or substituted patients (ADU), 72 patients were receiving methadone therapy and 137 were receiving buprenorphine substitution treatment (BUP) at the beginning of the study. Ex-drug users (EDU) or non-drug users (NDU) were defined as patients who had stopped drug use for at least 6 months (EDU) or never used drugs at all (NDU). These two groups were compared to the ADU group. NDU = non-drug user.

Key findings from the Hepacom Study, a 12-month, multicenter, observational prospective study of treatment-naive chronic hepatitis C patients treated in the French health care system, were2: • The proportions of patients with genotype 3 infection were higher among EDU and ADU than among NDU (P ≤ 0.0001). • Mean PEG-IFN alfa-2b doses were higher in ADU than in NDU or EDU (P ≤ 0.001). • Ribavirin dose was higher in ADU than in NDU (P < 0.001). • Rate of premature discontinuation was lower in ADU than in NDU or EDU (P < 0.05). • Virologic response rates assessed at least 12 weeks after completion of therapy were not significantly different between the 3 groups. • Virologic response rates at 24 weeks and 48 weeks were lower in ADU than in NDU or EDU (P < 0.05).

Aim

The French Consensus Conference of February 2002 recommended treating patients infected with hepatitis C virus using pegylated interferon (PEG-IFN) alfa-2b (PegIntron®; Schering-Plough) + ribavirin (RBV) in 3 groups of patients based on risk factors: • Active drug users or substituted patients • Non-drug users • Ex-drug users

Virologic response rates at 12 weeks were significantly different between the 3 groups: • Among EDU, 52% of patients had at least a partial virologic response. • Among ADU, 48% of patients had at least a partial virologic response. • Among NDU, 41% of patients had at least a partial virologic response.

Conclusions

It is possible that a predominance of favorable characteristics, such as young age, recent HCV infection, high consumption of alcohol, psychiatric and psychiatric disability, and shorter duration of HCV infection, could explain the better virologic response rates in the NDU group. However, the potentially negative impact of the unfavorable parameters associated with active drug use may have outweighed the favorable characteristics associated with the use of substitution treatments. Combining treatment cut the negative impact on quality of life for these patients. ADU = active drug user or user undergoing substitution treatment; EDU = ex-drug user; NDU = non-drug user.

References


Figure 1. Virologic response rates at 12 weeks after completion of therapy. ADU = active drug user or user undergoing substitution treatment; EDU = ex-drug user; NDU = non-drug user. The distribution of genotypes was significantly different across the 3 groups (P < 0.001). Figure 2. Distribution of pretreatment HCV-RNA viral load across the 3 groups. NDU < ADU < EDU (P < 0.001). Figure 3. Adherence to PEG-IFN alfa-2b + ribavirin therapy. A < B < C (P < 0.001). Table 3. Investigator-Reported Dose and Duration of Peg-Interferon Alfa-2b and Ribavirin Therapy.
Impact of the Use of Drugs and Substitution Treatments on the Antiviral Treatment of Chronic Hepatitis C: Analysis of Cost-Effectiveness, Virological Response and Quality of Life (CHEOBS)


Hôpital Général, Saint Dizier, France; 2Centre Hospitalier Erstein, Erstein, France; 3Institut Arnaud Tzanck, Saint Laurent du Var, France; 4Hôpital de Gêtres, Gêtres, France; 5ClinSearch, Bagneux, France; 6Centre de l’Appareil Digestif, Bourgoin Jallieu, France; 7Hôpital Beaujon, Clichy, France; 8Hôpital Pitié-Salpêtrière, Paris, France

Abstract

The CHEOBS study was a prospective, multicenter, observational study conducted between 2003 and 2006 to evaluate the efficacy, tolerability, compliance, and cost-effectiveness of antiviral treatment in patients with chronic hepatitis C. The study included 2,001 patients, of whom 604 were non-drug users (NDU), 417 were ex-drug users (EDU), and 977 were active drug users or on substitution treatment (ADU). Treatment regimens included pegylated interferon alfa-2b (PEG-IFN alfa-2b) alone or in combination with ribavirin (RBV). The study had a follow-up of at least 6 months after treatment cessation. The primary endpoint was sustained virologic response, defined as undetectable HCV RNA levels 6 months after the end of treatment. The study used a cost-effectiveness framework, with costs expressed in euros (€) and quality-adjusted life years (QALYs) as outcome measure. The costs were calculated using a Markov model, which was calibrated with data from the CHEOBS study. The results showed that the PEG-IFN alfa-2b + RBV combination was more effective and less costly than PEG-IFN alfa-2b alone, with a higher sustained virologic response rate and lower treatment discontinuation rates. The study also found that the quality of life was significantly better in patients achieving sustained virologic response, with a higher health-related quality of life (HRQL) index.

Background

Patients with chronic hepatitis C virus (HCV) infection are at risk for complications such as cirrhosis, hepatocellular carcinoma, and liver-related mortality. Antiviral therapy with pegylated interferon alfa-2b (PEG-IFN alfa-2b) and ribavirin (RBV) is recommended for patients with HCV genotype 1 infection, but treatment options vary depending on the patient's risk factors. This study aimed to evaluate the efficacy, tolerability, compliance, and cost-effectiveness of antiviral treatment in patients with chronic hepatitis C, including those with comorbidities such as alcohol or drug abuse.

Aim

The aim of this study was to evaluate the efficacy, tolerability, compliance, and cost-effectiveness of antiviral treatment in patients with chronic hepatitis C, including those with comorbidities such as alcohol or drug abuse.

Patients and Methods

Patients were recruited from 30 centers in France and included non-drug users (NDU), ex-drug users (EDU), and active drug users or on substitution treatment (ADU). The study was a prospective, multicenter, observational study conducted between 2003 and 2006.

Study Design

The CHEOBS study is a prospective, multicenter, observational study conducted between 2003 and 2006. Patients were recruited from 30 centers in France and included non-drug users (NDU), ex-drug users (EDU), and active drug users or on substitution treatment (ADU). The study was a prospective, multicenter, observational study conducted between 2003 and 2006.

Abstract

The CHEOBS study was a prospective, multicenter, observational study conducted between 2003 and 2006. The study included 2,001 patients, of whom 604 were non-drug users (NDU), 417 were ex-drug users (EDU), and 977 were active drug users or on substitution treatment (ADU). Treatment regimens included pegylated interferon alfa-2b (PEG-IFN alfa-2b) alone or in combination with ribavirin (RBV). The study had a follow-up of at least 6 months after treatment cessation. The primary endpoint was sustained virologic response, defined as undetectable HCV RNA levels 6 months after the end of treatment. The study used a cost-effectiveness framework, with costs expressed in euros (€) and quality-adjusted life years (QALYs) as outcome measure. The costs were calculated using a Markov model, which was calibrated with data from the CHEOBS study. The results showed that the PEG-IFN alfa-2b + RBV combination was more effective and less costly than PEG-IFN alfa-2b alone, with a higher sustained virologic response rate and lower treatment discontinuation rates. The study also found that the quality of life was significantly better in patients achieving sustained virologic response, with a higher health-related quality of life (HRQL) index.

Background

Patients with chronic hepatitis C virus (HCV) infection are at risk for complications such as cirrhosis, hepatocellular carcinoma, and liver-related mortality. Antiviral therapy with pegylated interferon alfa-2b (PEG-IFN alfa-2b) and ribavirin (RBV) is recommended for patients with HCV genotype 1 infection, but treatment options vary depending on the patient's risk factors. This study aimed to evaluate the efficacy, tolerability, compliance, and cost-effectiveness of antiviral treatment in patients with chronic hepatitis C, including those with comorbidities such as alcohol or drug abuse.

Aim

The aim of this study was to evaluate the efficacy, tolerability, compliance, and cost-effectiveness of antiviral treatment in patients with chronic hepatitis C, including those with comorbidities such as alcohol or drug abuse.

Patients and Methods

Patients were recruited from 30 centers in France and included non-drug users (NDU), ex-drug users (EDU), and active drug users or on substitution treatment (ADU). The study was a prospective, multicenter, observational study conducted between 2003 and 2006. Patients were recruited from 30 centers in France and included non-drug users (NDU), ex-drug users (EDU), and active drug users or on substitution treatment (ADU). The study was a prospective, multicenter, observational study conducted between 2003 and 2006.

Study Design

The CHEOBS study is a prospective, multicenter, observational study conducted between 2003 and 2006. Patients were recruited from 30 centers in France and included non-drug users (NDU), ex-drug users (EDU), and active drug users or on substitution treatment (ADU). The study was a prospective, multicenter, observational study conducted between 2003 and 2006.
The rate of SVR was similar in the three groups. Excess consumption of alcohol, a precarious socio-
(p=0.1). The QoL in the ADU group was less altered on the physical and mental levels than in the other groups.

During treatment and 6 months after the end of treatment. Among these patients, 141 were excluded from the analysis.

Life (QoL) according to whether the patients were active drug users or under substitution treatment (ADU), ex-drug
users (EDU), or non-drug users (NDU).

Patients aged 18 and older who had chronic hepatitis C and initiated treatment with PEG-IFN alfa-2b (1.5 µg/kg/wk)
were enrolled from 184 centers in France that specialize in the management of hepatitis C.

The CHEOBS study was a prospective, multicenter, observational study conducted between 2003 and 2006
of pegylated interferon (PEG-IFN) alfa-2b (PegIntron®; Schering-Plough) + ribavirin (RBV) in 3 groups of patients
with chronic hepatitis C infection: Active drug users or users undergoing substitution treatment (ADU), ex-drug
users (EDU), or non-drug users (NDU).

The present analysis focuses on adherence to antiviral dual therapy, virological response, and quality of
life (QoL) among these patient populations.

Basic sociodemographic characteristics, and risk factors are shown in Table 1.

Table 1. Demographic Characteristics of Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ADU</th>
<th>EDU</th>
<th>NDU</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>53.5</td>
<td>50.6</td>
<td>52.5</td>
<td>= 0.51</td>
</tr>
<tr>
<td>Sex, female</td>
<td>47.1</td>
<td>49.7</td>
<td>48.6</td>
<td>= 0.66</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>High</td>
<td>42.1</td>
<td>46.4</td>
<td>35.3</td>
<td>= 0.13</td>
</tr>
<tr>
<td>Middle</td>
<td>50.3</td>
<td>50.0</td>
<td>55.5</td>
<td>= 0.70</td>
</tr>
<tr>
<td>Low</td>
<td>6.6</td>
<td>4.7</td>
<td>13.5</td>
<td>= 0.001</td>
</tr>
<tr>
<td>Income status</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>High</td>
<td>38.9</td>
<td>38.9</td>
<td>41.8</td>
<td>= 0.97</td>
</tr>
<tr>
<td>Middle</td>
<td>56.4</td>
<td>53.5</td>
<td>48.9</td>
<td>= 0.61</td>
</tr>
<tr>
<td>Low</td>
<td>4.7</td>
<td>7.6</td>
<td>13.3</td>
<td>= 0.04</td>
</tr>
<tr>
<td>Professional activity</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>Full-time</td>
<td>46.4</td>
<td>49.8</td>
<td>50.0</td>
<td>= 0.47</td>
</tr>
<tr>
<td>Part-time</td>
<td>49.3</td>
<td>44.5</td>
<td>43.4</td>
<td>= 0.27</td>
</tr>
<tr>
<td>Full-time or part-time</td>
<td></td>
<td></td>
<td></td>
<td>= 0.24</td>
</tr>
<tr>
<td>Occupational status</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>Active</td>
<td>45.9</td>
<td>46.3</td>
<td>50.0</td>
<td>= 0.51</td>
</tr>
<tr>
<td>Retired</td>
<td>46.6</td>
<td>43.3</td>
<td>39.3</td>
<td>= 0.39</td>
</tr>
<tr>
<td>Unemployed</td>
<td>4.5</td>
<td>10.4</td>
<td>0.7</td>
<td>= 0.001</td>
</tr>
<tr>
<td>Indebtedness</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>Difficult to manage</td>
<td>3.6</td>
<td>4.3</td>
<td>8.3</td>
<td>= 0.47</td>
</tr>
<tr>
<td>Professional status</td>
<td></td>
<td></td>
<td></td>
<td>= 0.001</td>
</tr>
<tr>
<td>Active</td>
<td>40.9</td>
<td>37.8</td>
<td>38.3</td>
<td>= 0.55</td>
</tr>
<tr>
<td>Retired</td>
<td>38.3</td>
<td>42.8</td>
<td>41.6</td>
<td>= 0.50</td>
</tr>
<tr>
<td>Unemployed</td>
<td>20.8</td>
<td>20.4</td>
<td>20.1</td>
<td>= 0.98</td>
</tr>
</tbody>
</table>

Questionnaires

- Add-on questionnaires and mental comorbidity are not reported here because of a lack of data.
- Among those patients who responded, the proportion of patients treated before the last treatment was higher in the ADU group than in the other groups. ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001

Adherence

- Adherence to the treatment protocol was higher in the ADU group than in the other groups. ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Adherence to the treatment protocol was lower in the ADU group than in the other groups. ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Adherence to the treatment protocol was lower in the ADU group than in the other groups. ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Adherence to the treatment protocol was lower in the ADU group than in the other groups. ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001

Virological Response

- In the ADU group, 75.8% of patients were treatment-naive; in the EDU group, 73.1% of patients were treatment-naive; and in the NDU group, 75.0% of patients were treatment-naive. ADU: p = 0.070, EDU: p = 0.070, NDU: p = 0.070
- In the ADU group, 57.8% of patients were treatment-naive; in the EDU group, 75.0% of patients were treatment-naive; and in the NDU group, 75.8% of patients were treatment-naive. ADU: p = 0.070, EDU: p = 0.070, NDU: p = 0.070
- In the ADU group, 57.8% of patients were treatment-naive; in the EDU group, 75.0% of patients were treatment-naive; and in the NDU group, 75.8% of patients were treatment-naive. ADU: p = 0.070, EDU: p = 0.070, NDU: p = 0.070
- In the ADU group, 57.8% of patients were treatment-naive; in the EDU group, 75.0% of patients were treatment-naive; and in the NDU group, 75.8% of patients were treatment-naive. ADU: p = 0.070, EDU: p = 0.070, NDU: p = 0.070

Quality of Life

- Access to treatment was more difficult among these patient populations: ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Access to treatment was more difficult among these patient populations: ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Access to treatment was more difficult among these patient populations: ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001
- Access to treatment was more difficult among these patient populations: ADU: p = 0.001, EDU: p = 0.001, NDU: p = 0.001

Table 2. Efficacy and Safety of the Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>SVR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEG-IFN alfa-2b + RBV</td>
<td>75.8</td>
<td>0.001</td>
</tr>
<tr>
<td>PEG-IFN alfa-2b + RBV</td>
<td>73.1</td>
<td>0.001</td>
</tr>
<tr>
<td>PEG-IFN alfa-2b + RBV</td>
<td>75.0</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Summary

- The results of this study show that patients with chronic hepatitis C who are active drug users or under substitution treatment have better virological response and quality of life than non-drug users. However, active drug use did not have a negative impact on the patients' adherence to antiviral treatment.
- The results of this study show that patients with chronic hepatitis C who are active drug users or under substitution treatment have better virological response and quality of life than non-drug users. However, active drug use did not have a negative impact on the patients' adherence to antiviral treatment.
- The results of this study show that patients with chronic hepatitis C who are active drug users or under substitution treatment have better virological response and quality of life than non-drug users. However, active drug use did not have a negative impact on the patients' adherence to antiviral treatment.
- The results of this study show that patients with chronic hepatitis C who are active drug users or under substitution treatment have better virological response and quality of life than non-drug users. However, active drug use did not have a negative impact on the patients' adherence to antiviral treatment.