Clinical and histological evaluation of interferon alfa-2b in the treatment of chronic hepatitis C

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Abstract

In a study of 37 patients with hepatitis C (proved histologically) positive chronic hepatitis, a correlation was seen between clinical efficacy and histological improvement after treatment with interferon alfa-2b (3 million units (MU) three times a week for six months plus six months' follow up). Alanine aminotransferase activities became normal in 18 (48%) patients during treatment; at the end of follow up eight (45%) had a continued response to the treatment. Paired liver biopsy specimens showed marked improvements in Knodell index score and portal inflammation in these patients.
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A study was undertaken to determine the correlation between treatment efficacy and histological improvement in patients treated with interferon alfa-2b for chronic hepatitis C virus (HCV)-induced liver disease.

Patients and methods

Patients aged between 16 and 60 who had histologically-proved, anti-HCV antibody positive chronic hepatitis, were included in the trial. They also had serum alanine aminotransferase activities greater than 1.5 times the normal upper limit for more than six months. Patients were excluded if they had a history of alcohol abuse or drug addiction, human immunodeficiency virus positivity, hepatitis B virus surface antigen (HBsAg) or HBV-DNA positivity, autoimmune diseases, hepatic enzyme disorders, decompensated cirrhosis or hepatocellular carcinoma.

All patients were given interferon alfa-2b (3 million units intramuscularly three times per week for six months) and were followed up for a further six months. Response to treatment was defined as follows: response (R): normal serum alanine aminotransferase during treatment and follow up; partial response (PR): decrease in alanine aminotransferase of more than 50% from baseline values; no response (NR): no change in alanine aminotransferase or a decrease of less than 50% from baseline.

Liver histology was examined before interferon treatment and 12 months after the start of treatment.

Results

Thirty seven patients were entered into the study (24 men and 13 women), with a mean age of 40 years (11, SD). Nine patients had cirrhosis, 13 had chronic active hepatitis (severe in seven cases), 11 had chronic persistent hepatitis, and four had chronic lobular hepatitis. Responses according to patient characteristics before treatment are shown in the Table. During and at the end of interferon treatment, serum alanine aminotransferase activity was normal in 18 (48%) of the patients ($p<0.0001$, Wilcoxon's rank sum test). During and at the end of follow up, eight patients (45%) continued responsive to treatment. A paired liver biopsy, evaluated according to the Knodell scoring system, was performed in 21 patients. At the end of follow up, statistically significant improvements in Knodell index score ($p<0.005$) and portal inflammation ($p<0.002$) were seen in the eight patients still responding at the end of follow up (Student's two-tailed t test) (Figure).

Conclusions

These results confirm a correlation between clinical efficacy and histological improvement in patients with chronic hepatitis C who respond to treatment with interferon alfa-2b.

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Figure Histological activity index according to response at the end of follow up.

TABLE Response according to patient characteristics before treatment

	Response	Partial response	No response
Patients	n=18	n=6	n=13
Age (years)*	48 (11)	50 (6)	49 (13)
Men/women	11/7	2/4	11/2
Cirrhosis (%)	11	66	23
Severe chronic active hepatitis (%)	5	16	38
Chronic active hepatitis (%)	27		7
Chronic persistent hepatitis (%)	38	18	23
Chronic lobular hepatitis (%)	16		7
Alanine aminotransferase (×upper normal values)*	4.8 (3.6)	4.4 (0.6)	3.9 (1.8)

*Mean (SD).