Treatment of chronic hepatitis C with recombinant interferon alfa-2b

M Piazza, R Orlando, G Tosone, D Tiseo, M C D Conte, F Minervini, G Santoro, F Scordino, D Vitale

Abstract

In a study of 87 patients with chronic hepatitis C, 12 months' treatment with interferon alfa-2b at a dose of 6 million units (MU) three times per week seemed to be more effective than treatment with 3 MU three times a week for two months plus 1.5 MU three times a week for 10 months in increasing the percentage of long-term responders. The percentage of patients in whom alanine aminotransferase activities returned to normal was highest in the 6 MU group, as was the percentage of responders who sustained this normal activity after treatment. Side effects were moderate and self-limited in most patients.

(Gut 1993; supplement: S128-S129)

The efficacy of three different treatment schedules of recombinant interferon (IFN) alfa-2b (INTRON A, Schering-Plough) was evaluated in patients with chronic hepatitis C virus (HCV) infection.

Patients and methods

For inclusion in the trial, patients had to be aged between 18 and 65 years, with a white blood cell (WBC) count >3×10^9/l, platelets >1×10^11/l, and serum alanine aminotransferase (ALT) activities twice the upper limit of normal for nine months. They were also required to have a histologically proved diagnosis of chronic persistent hepatitis, chronic active hepatitis, chronic lobular hepatitis or compensated cirrhosis, and to be positive for antibodies to hepatitis C virus (anti-HCV) on second generation ELISA (ELISA II, Ortho).

Patients were excluded if they had a history of drug or alcohol abuse; cardiac, renal, or respiratory failure; or positivity for antibodies to HIV or autoimmune antibodies (antinuclear, antimitochondrial, or anti-liver-kidney microsomal-1).

All patients received recombinant interferon alfa-2b for 12 months, according to the following schedule:
- Group A: 6 million units (MU) intramuscularly three times weekly for 12 months.
- Group B: 3 MU three times weekly subcutaneously for 12 months.
- Group C: 3 MU three times weekly subcutaneously for two months followed by 1.5 MU ITW for 10 months.

Clinical and laboratory parameters were evaluated every 15 days for the first two months, and then at monthly intervals. A return of alanine aminotransferase (ALT) activities to normal during IFN treatment was considered a complete response.

Patient characteristics before beginning treatment are shown in the Table. No significant differences were observed between the three study groups in respect of age, sex, or biochemical and histological features.

STATISTICAL ANALYSIS

Data were evaluated using the χ² test and Student's t test.

Results

After 12 months, the percentage of patients with normal ALT activities (responders) was highest in group A (70%) and lowest in group C (48%) (Fig 1). Furthermore, the percentage of responders with ALT rebound after treatment was stopped was highest in group C (56-2%) and lowest in group A (19%), a statistically significant difference (p<0.05) (Fig 2). The percentage of responders whose
None of the responders lost anti-HCV antibodies.

The side effects were moderate and self limited in most patients (asthenia occurred in 40 patients, flu like syndrome in 28, alopecia in 16, granulocytopenia in 21, thrombocytopenia in 16 and arthromyalgias in 10). Doses were reduced for a short period in five patients (two in group A, two in group B, and one in group C) as a result of granulocytopenia and thrombocytopenia.

Conclusions

Twelve months' treatment with recombinant interferon alfa-2b at a dosage of 6 MU three times weekly seemed to be more effective than treatment with 3 MU three times weekly for two months plus 1.5 MU three times weekly for 10 months in increasing the percentage of long term responders. This regimen was well tolerated with no appreciable toxicity.
Treatment of chronic hepatitis C with recombinant interferon alfa-2b.

M Piazza, R Orlando, G Tosone, D Tiseo, M C Conte, F Minervini, G Santoro, F Scordino and D Vitale

Gut 1993 34: S128-S129
doi: 10.1136/gut.34.2_Suppl.S128

Updated information and services can be found at:
http://gut.bmj.com/content/34/2_Suppl/S128

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Topic Collections
Articles on similar topics can be found in the following collections
Hepatitis C (160)

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/