Recombinant interferon alfa-2b treatment in chronic non-A, non-B/type C hepatitis

V De Conca, S Mesiti, E Vallarino, A Mornese, M Dodero

Abstract

In a study of 60 patients with non-A, non-B/type C (NANB/C) chronic hepatitis alanine aminotransferase (ALT) activities returned to normal after treatment with interferon alfa-2b (3 million units for six months) in 70.7% and 29.3% did not respond. The response was maintained during four to six months, follow up in 41.4% of patients. Liver biopsy specimen showed histological improvement in all patients surveyed. Treatment was well tolerated with only mild side effects.

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In this paper, we present the results of a study of recombinant interferon alfa-2b treatment in 60 patients with chronic non-A, non-B/type C (NANB/C) hepatitis, 57 of whom were positive for antibodies to hepatitis C virus (anti-HCV).

Patients and methods

Sixty patients (38 men and 22 women), aged between 18 and 65 years, were included in the study. All were required to have a histopathological pattern of chronic hepatitis and serum alanine aminotransferase (ALT) activities greater than twice the upper limit of normal for at least 12 months.

Patients were excluded from the study if they had hepatitis from other causes (autoimmunity, alcohol, hepatitis B virus, or metabolic effects), cirrhosis of the liver, drug addiction, or alcoholism. Positivity for antibodies to HIV was an additional exclusion criterion, as was pregnancy.

All patients were treated with recombinant interferon alfa-2b (INTRON A, Schering-Plough), 3 million units (MU) given subcutaneously three times a week for six months. Liver biopsy was performed in all patients before treatment and in 11 after treatment. Response was defined as a complete return to normal of serum ALT activities during the six months of treatment.

Results

Patient characteristics before treatment are shown in the Table. Fifty eight of the 60

patients completed the full six months of interferon treatment. Among these, 41 (70.7%) achieved a return to normal of serum ALT activity and 17 (29.3%) did not respond. The nonresponders were investigated for serological markers of autoimmunity but all proved negative.

Seventeen of the 41 patients who responded (41.4%) maintained a normal ALT activity during the follow up period, which ranged from four to six months. In addition, 11 of the 17 patients with a continued response after six months underwent a second liver biopsy, which showed histological improvement in all cases. There were no differences in improvement between patients with different histological subtypes at baseline. The remaining 24 patients who responded relapsed on stopping treatment. None of those who responded to treatment lost anti-HCV antibodies.

Two patients did not complete the study: one because of an appreciable increase in serum ALT activities at week eight, and the other because of non-compliance after four weeks of therapy. Overall, treatment was well tolerated with only mild side effects (for example asthenia, myalgias, fever).

Conclusions

Recombinant IFN alfa-2b, at a dose of 3 MU three times weekly for six months, induced a biochemical and histological improvement in 71% of patients with chronic NANB/C hepatitis. Normal ALT activities were maintained after the end of treatment in 41% of these patients, or about one third of all patients.

TABLE Patient characteristics

Male/female	38/22
Mean (SD) age (y) (range)	45.4 (18.3) (20-65)
Histological pattern (no (%)):	
Chronic lobular hepatitis	11 (18.3)
Chronic persistent hepatitis	9 (15)
Chronic active hepatitis	40 (66.7)
Anti hepatitis C virus+ve (no (%))	57 (95)
Previous acute hepatitis (no (%))	5 (8.3)
Source of infection (no (%)):	
Transfusion	10 (16.7%)
Surgery	5 (8.3%)
Drug addiction	5 (8.3%)
Unknown (community acquired)	40 (66.7%)

EO Ospedali Galliera,
Genova, Italy
V De Conca
S Mesiti
E Vallarino
A Mornese
M Dodero

Correspondence to:
Dr V De Conca,
EO Ospedali Galliera,
Divisione di
Gastroenterologia, Mura
delle Cappuccine 14, 16128
Genova, Italy.