Multicentre randomised controlled trial of recombinant interferon alfa-2b in patients with acute non-A, non-B/type C hepatitis after transfusion

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Abstract

To assess whether the risk of chronic disease in patients with acute non-A, non-B/type C (NANB/C) hepatitis after transfusion could be reduced by treatment with interferon, patients were randomised to receive 3 million units interferon (IFN) alfa-2b three times a week for three months or no therapy. At the end of treatment, IFN had significantly reduced the number of patients with abnormal alanine aminotransferase activities compared with untreated patients but this difference was not maintained during a 15 month follow up. Treatment with IFN alfa-2b was considered safe and was well tolerated.

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A multicentre, randomised controlled trial was undertaken to assess whether the risk of chronic disease in patients with acute non-A, non-B/type C (NANB/C) hepatitis as a result of transfusion could be reduced by treatment with interferon (IFN) alfa-2b, and also to assess the safety and tolerability of IFN alfa-2b in these patients.

Methods

Forty five patients with acute NANB/C hepatitis associated with transfusion were randomised to receive either 3 million units (MU) interferon alfa-2b intramuscularly three times a week for three months (n=26), or no treatment (n=19).

Results

Patient characteristics before treatment are shown in Table I. The two groups were similar in terms of age, incubation period, days from transfusion to randomisation, serum alanine aminotransferase (ALT) activities, or reasons for transfusion, although there was a higher male to female ratio in the treated patients.

At the end of the study, there was a significant difference between interferon

treated patients and controls in terms of the number with abnormal serum ALT activities (23% v 58%, respectively; $p < 0.05$) (Table II). At the end of the 15 month follow up period (month 18), more control than treated patients had abnormal ALT activities (61 v 38%) but this difference was no longer significant (Table II).

IFN was shown to be safe and well tolerated in these patients, as none of them developed severe IFN related side effects.

Conclusions

Early administration of IFN alfa-2b significantly improved the short term outcome of patients with hepatitis C. However, this favourable response faded during follow up as the disease relapsed after IFN withdrawal. Further studies are needed to assess whether long term cure of HCV infection can be achieved by a more aggressive treatment regimen.

TABLE I Patient characteristics

	Treated (n=26)	Untreated (n=19)
Age (y) (mean (SD))	49 (16)	44 (16)
Male/female	17/9	9/10
Incubation (days) (mean (SD))	52 (31)	60 (46)
Days from transfusion to randomisation mean (SD)	93 (56)	111 (56)
Peak ALT (IU/l) (mean (SD))	638 (556)	519 (401)
Baseline ALT (IU/l) (mean (SD))	357 (335)	397 (421)
No (%) anti-HCV+ve	20 (77)	16 (84)
Reasons for transfusion:		
Surgery	20	13
Medical	4	5
Delivery	2	1

ALT=alanine aminotransferase; HCV=hepatitis C virus.

TABLE II Number (%) of patients with abnormal serum alanine aminotransferase activities

Month	Treated (n=26) (%)	Untreated (n=19) (%)	p*
0	26 (100)	19 (100)	-
3	6 (23)	11 (58)	0.05
9	11 (42)	14 (74)	NS
12	10 (38)	13 (68)	NS
15	9/25 (36)	12/18 (67)	NS
18	9/24 (38)	11/18 (61)	NS

* χ^2 with Yates's correction.

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