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BRIEF REPORT

Efficacy of six therapies for chronic hepatitis B

Hong-Tian Zhang, Ping-Qing Zhang, De-Long Huang

Hong-Tian Zhang, Associate Chief Physician, has published 23 papers.

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Telephone: +86-532-3833866

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INTRODUCTION

There are many therapies for chronic hepatitis B at present. However, the efficacy of most of them has not been confirmed. In order to select several effective therapies from them, we treated 302 chronic hepatitis B patients with six different therapies, observed their efficacy and side effects, and then followed the patients for 9 mo.

MATERIALS AND METHODS

Patients

A total of 302 patients (282 males and 20 females) with chronic hepatitis B were treated from 1992 to 1994. Their age ranged from 20 to 60 years. The diagnoses were established according to the standard developed at the "6th China Symposium on Virus Hepatitis". There were 92 cases of chronic persistent hepatitis and 210 cases of chronic active hepatitis. The course of diseases was within five years. Patients in this group had no family history of hepatitis. Before treatment, HBsAg, HBeAg, anti-HBC and HBV-DNA were all positive, and ALT was abnormal in all patients. During the 6 mo before treatment, no patient had been treated with antiviral drugs or immune drugs. The 302 patients were divided into six groups with comparable age, sex, hepatitis type, ALT and HBV-marker.

Methods

In group Ⅰ (n = 45), Zhuling Duotang was given at a dose of 40 mg (i.m.) per day for 60 days (the drug was used for 20 days and then discontinued for 10 days, and the course was repeated three times). In group Ⅱ (n = 63), Zhuling Duotang was given at the same dosage as in group Ⅰ, and hepatitis B vaccine was given at a dose of 30 μg (i.m.) every two weeks for a total of six times. All patients of groups Ⅲ, Ⅳ and Ⅴ had been treated with arabinofuranosy adenine monophosphate (ARA-AMP) for 28 days. From the first to the fifth day, the dosage of ARA-AMP was 10 mg/kg (i.m.) per day; and from the sixth to the 28th day, it was 5 mg/kg (i.m.) per day. Patients in group Ⅲ (n = 42) were treated with ARA-AMP alone. Group Ⅳ (n = 42) was given thymosin 10 mg (i.m.) daily for 3 mo besides ARA-AMP. Group Ⅴ (n = 58) received hepatitis B vaccine 30 μg (i.m.) every 2 weeks for a total of six times besides ARA-AMP. Group Ⅵ (control group, n = 42) was given diisopropylamine ascorbatis 180 mg (i.m.) daily for 3 mo.

Table 1 HBsAg negative cases and anti-HBs positive cases after treatment

Group	(n)	End of treatment		3 mo after treatment		9 mo after treatment	
		HBsAg(-)	Anti-HBs(+)	HBsAg(-)	Anti-HBs(+)	HBsAg(-)	Anti-HBs(+)
Ⅰ	45	1	0	2	1	2	1
Ⅱ	63	2	0	2	1	2	2
Ⅲ	52	1	0	2	1	1	1
Ⅳ	42	3	2	3	3	2	3
Ⅴ	58	3	0	3	2	2	2
Ⅵ	42	0	0	0	0	0	0

Table 2 HBeAg negative rate (%), anti-HBe positive rate (%) and HBV-DNA negative rate (%) after treatment

Group	(n)	End of treatment			3 mo after treatment			9 mo after treatment		
		HBsAg (-)	Anti-HBs(+)	DNA (-)	HBsAg (-)	Anti-HBs(+)	DNA (-)	HBsAg (-)	Anti-HBs(+)	DNA (-)
Ⅰ	45	44.4	33.3	46.7	46.7	40.0	48.8	42.2	35.6	40.0
Ⅱ	63	53.9	36.7	55.6	53.9	37.9	57.1	44.4	38.1	40.6
Ⅲ	52	51.9	25.0	55.6	50.0	28.8	52.8	30.8	28.8	32.7
Ⅳ	42	61.9	54.8[b]	71.4	64.9	56.8[b]	75.7	62.1[d]	62.1[b]	72.4
Ⅴ	58	55.2	37.9	70.7	56.9	41.1	74.1	57.7[a]	41.4	48.3
Ⅵ	42	14.3	11.9	14.3	19.0	16.3	19.0	16.7	16.7	16.7

[b]P < 0.01, group Ⅳ *vs* other groups; [d]P < 0.01, group Ⅳ *vs* group Ⅲ; and [a]P < 0.05, group Ⅴ *vs* group Ⅲ.

Observation methods

Before and after treatment, HBV markers, liver function, HBV-DNA and BUN were detected, and then the patients were followed for 9 mo. HBV markers were detected by ELISA, and HBV-DNA by dot hybridization. Before treatment, 154 cases were diagnosed both by liver biopsy and clinically.

RESULTS

After treatment, HBsAg and anti-HBs changed in only a few cases in each treatment group, but did not change in the control group (Table 1). At the end of treatment and during the follow-up, the negative seroconversion rate of HBeAg, positive seroconversion rate of anti-HBe and negative seroconversion rate HBV-DNA in each treatment group were higher than those in the control group (P < 0.01). The results of group Ⅳ were the best among all groups (Table 2). In the treatment groups, ALT recovery rates were from 97.6% to 84.5% at the end of treatment, while in the control group, it was 64.2% (P > 0.05). At 3 mo of follow-up, ALT recovery rates were from 77.6% to 91.9% in the treatment groups, but was 69.0% in the control group (P < 0.05). There was no severe side effects in all groups.

DISCUSSION

The present study showed that the five therapies were effective against HBV and in reducing ALT, and produced no severe side effects. Zhuling Duotang alone or in combination with hepatitis B vaccine was both effective in treating hepatitis B, and there was no significant difference between them (P > 0.05). Good efficacy and no severe side effects were observed in the treatment of chronic hepatitis B with ARA-AMP alone or in combination with other drugs. ARA-AMP combined with thymosin had the best therapeutic effect. ARA-AMP was used only intramuscularly in this study. The results showed that the clinical effects were even better and there were no severe side effects, thus the patients are able to be treated at the outpatient department. Nine months of follow-up revealed that the long-term efficacy of ARA-AMP combined with thymosin was the best, therefore this therapy is effective and safe in treating chronic hepatitis B.

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