Comparison on Efficacy between Astragalus-Polygonum Anti-Fibrosis Decoction and Jinshuibao capsule in Treating Liver Fibrosis of Chronic Hepatitis B

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ABSTRACT

Objective: To observe the efficacy of Astragalus-Polygonum Anti-Fibrosis decoction (APAFD) and Jinshuibao capsule (JSBC) in treating liver fibrosis of chronic hepatitis B. Methods: Ninety-two cases of liver fibrosis of chronic hepatitis B were randomly divided into group A and group B. Patients in group A received APAFD for 48 weeks, and in group B, they received JSBC for 48 weeks. The effects on the level change of hyaluronic acid (HA), laminin (LN), pro-collagen III (PC III) and collagen IV (CIV) as well as liver functional tests and liver biochemical parameters before and after treatment were observed. Results: Level of serum HA, LN, PC III and CIV in group A declined more obviously than that of group B, the difference was significant (P < 0.01). The liver functional tests such as total bilirubin (TB), alanine aminotransferase (ALT), albumin/globulin (A/G) ratio, hepatitis related serum biochemical parameters such as cholylglycine (CG), serum ferritin (SF), prealbumin (PC) of group A were all improved more significantly than that of group B (P < 0.01). Conclusion: APAFD is more effective than JSBC in treating liver fibrosis of chronic hepatitis B and in the inhibition of hepatic inflammation, hence it is a good composite Chinese herbal preparation against liver fibrosis.

KEY WORDS chronic hepatitis B, liver fibrosis, Astragalus-Polygonum Anti-Fibrosis decoction, Jinshuibao capsule

Liver fibrosis will inevitably cause a histopathology change, in the course of which all kinds of chronic hepatitis develop into liver cirrhosis. Nowadays, it has been recognized that it is a reversible process\(^1\). In order to prolong, inhibit and even reverse such a process, Chinese medicine is of indispensable advantage. What’s more, composite Chinese herbal medicine is of more value than single herbal medicine\(^2\). Hence, in the year from June 1998 to June 1999, adopting a randomized method, we treated 47 of the 92 cases of liver fibrosis of chronic hepatitis B with Astragalus-Polygonum Anti-Fibrosis decoction (APAFD, group A) and the other 45 patients with Jinshuibao (金水宝) capsule, a clinically now widely used medicine (group B).

METHODS

Diagnosis Criteria

According to the revised criteria worked out at 1995 Chinese National Specific Conference for Infectious and Parasitic Diseases\(^3\), those patients were used as the object of observation whose two or over two parameters of hyaluronic acid (HA), laminin (LN), pro-collagen III (PC III) and collagen IV (CIV) exceed the normal levels. At the same time serum parameters related to liver function, such as TB, ALT, A/G, CG, SF and PA were selected as supplementary observation parameters. It was required that TB did not exceed double the normal parameter (< 50 μmol/L) and ALT did not exceed four times the normal parameter (< 200 IU/L) in order that liver inflammation disturbs less and influences the four serologic parameters (HA, LN, PC III, and CIV).

All the patients had serologic markers of hepatitis B: infected serum parameters (HB-VM), such as HBsAg, HBeAg, anti-HBe, HBcAg, anti-HBc, anti-HBcIgM, HBV-DNA, etc.

Clinical Data

A total of 100 cases were enrolled as observation subjects. Each group had 50 cases. For some reasons, 3 patients dropped out of group A and 5 patients out of group B, 47 cases in group A and 45 in group B were left. In

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group A, there were 35 male cases and 12 female cases. Their age was from 16 to 60 years and the average age was 38.67 years. Their course of disease was from 1 to 15 years. The average was 2.15 years. Twenty cases were of mild degree chronic hepatitis and 27 of medium degree. In group B, there were 45 cases, 34 males and 11 females, their age ranging from 16 - 60 and the average was 40.12 years. The course of disease was from 1 to 15 years and the average 2.67 years. Suffering from mild degree chronic hepatitis was 21 cases and medium degree 24 cases. There were no significant difference between group A and group B in age, sex, course of disease and patients' condition (P > 0.05). Twelve weeks before this observation and treatment, no patients received any anti-virus, anti-fibrosis or regulating immunity medicine.

Treatment Method

Group A received Astragalus-Polygonum Anti-Fibrosis decoction, which contains Astragalus membranaceus 30 g, Polygonum multiflorum 30 g, Ganoderma lucidum 30 g, Sedum sarmentosum 60 g, Salvia miltiorrhiza 15 g, Peonia rubra 15 g, Alismatis arientale 30 g, Coix lacyyma-job 30 g, Rosa rugosa 7 g, Flos Magnolia biloba 7 g, and Actinidia Chinensis 30 g. Then the mixture was made into 200 ml decoction. We let the patients of gorup A take 100 ml of the decoction in the morning and 100 ml in the afternoon. And let those of group B take Jinshuibao capsule (JSBC, product of China Nanchang Jinshuibao Pharmaceutical Co., Ltd.), 4 capsules a time, 3 times daily. The course of treatment for both groups was 48 weeks. Both groups were permitted to take any kind of vitamin, but not allowed to have any other Chinese and western medicine of anti-virus, anti-fibrosis or immunity modulator or any other preparations.

Testing Method

The test reagents of the 4 parameters (HA, LN, PC III and C IV) of liver fibrosis were provided by the Bio-Technology Center of Shanghai Institute of Naval Medicine. The test was made by the special personnel of the Central Laboratory of Ningbo Municipal Liver Disease Hospital. The testing method was radioimmunoassay (RIA). The normal data is HA<115 µg/L, LN<133 µg/L, PC III <169 µg/L, and C IV < 70 µg/L. The biochemical data (CG, SF and PA) of blood serum with hepatitis were tested by RIA. All the above tests met requirements of quality and monitoring.

Statistical Method

Adopting $\chi^2$ and t test.

RESULTS

Comparison of HA, LN, PC III, and C IV between the Two Groups before and after Treatment

See Table 1. Before treatment, the average of each of the data was insignificantly different (P >0.05). After treatment, however, there was significant difference in average of each parameter between the two groups (P <0.01). Among group A, HA, LN, PC III, and C IV lowered to normal range in 17 cases (36.17%), 36 cases (76.60%), 18 cases (38.30%) and 38 cases (80.85%) respectively, and in group B were 5 cases (11.11%), 21 cases (46.67%), 11 cases (24.44%) and 25 cases (55.56%) respectively. There was a significant difference between the two groups (P < 0.01). All these showed that the efficacy of APAFD was more obvious than that of JSBC.

Comparison of Liver Function and Biochemical Data of Blood Serum with Hepatitis

See Table 2. After treatment, group A reached normal parameter in TB and ALT (though not in A/G). Group B failed in all the three. As far as blood serum CG, SF and PA are concerned, group A lowered more obviously than group B in CG and SF. Yet group A went up greatly in PA. There was a remarkable difference in statistical analysis (P < 0.01). All this indicated that group A was better than group B in the recovery of hepatitis impairment, improvement of the micro-circulation disturbance, adjustment of protein metabolism, etc.