CLINICAL EXPERIENCE

Clinical Observation on the Treatment of Chronic Severe Hepatitis B by Retention Enema with Huchang Jiedu Decoction

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ABSTRACT  Objective: To observe the efficacy of retention enema with Huchang Jiedu Decoction (护肠解毒汤, HJD) in treating chronic severe hepatitis B (CSHB). Methods: Sixty patients of CSHB were equally randomized into the treated group and the control group. Both groups were treated with conventional integrative medicine, but to patients in the treated group, retention enema with HJD was given in addition, once every day for 3 weeks. The dominant symptoms, physical signs, and related biochemical indices, as well as the incidence of complications in patients before and after treatment, were observed. Results: Good therapeutic effects were shown in the treated group, with a total effective rate better than that in the control group (83.3% versus 60.0%, P<0.05), superior in terms of lowering alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBil), globulin (Glb), and endotoxin (ET) levels and increasing prothrombin activity (PTA), total cholesterol (TC), and calcium (Ca) levels, as well as eliminating ascites and preventing hepatic encephalopathy (P<0.05); especially in treating middle/early stage patients with Chinese medicine syndrome differentiated as water-toxin accumulation pattern. Conclusion: Retention enema with HJD is surely effective in treating CSHB, and its primary mechanism may be related to the mitigation of enterogenous endotoxemia.

KEYWORDS  Huchang Jiedu Decoction, severe hepatitis, type B, retention enema, endotoxemia

Severe hepatitis is the most serious and critical clinical type of viral hepatitis, with the mortality up to about 70%\(^{(1)}\). As China is a high epidemic region of hepatitis B, severe hepatitis is mostly caused by hepatitis B consequently. The self-prescribed Huchang Jiedu Decoction (护肠解毒汤, HJD) was used via retention enema by the authors in recent years for the treatment of chronic severe hepatitis B (CSHB), and favorable clinical efficacy was obtained. The study is reported as follows.

METHODS

General Materials and Grouping

All 60 CSHB patients enrolled were the inpatients hospitalized in the Department of Hepatopathy, the Affiliated Hospital of Shandong University of Traditional Chinese Medicine from March 2005 to December 2008, whose diagnosis and stage ascertaining were made fitting to the "Diagnostic Standard of Viral Hepatitis\(^{(2)}\)\) revised in the National Conference of Infectious and Parasitic Diseases (2000, Xi’an). Their syndrome patterns were differentiated referring to literature\(^{(3,4)}\) as water-toxin accumulation (WTA) type, heat-toxin flourishing (HTF) type, and Gan (肝)-Shen (心) yin-deficiency (GSYD) type.

Patients were randomized by a digital table into two groups. The 30 patients in the treated group were 21 males and 9 females, age 27–67 years, 47.03 ± 12.22 years on the average; their mean duration of disease was 14.10 ± 6.92 years. By the severe hepatitis classification, 21 were classified to early stage, 6 to middle stage, and 3 to late stage; the basic disease was chronic hepatitis B for 16 patients, and hepatitis B caused liver cirrhosis for the other 14 patients. By Child-Pugh grading\(^{(5)}\), 1 belonged to grade A, 6 to B, and 7 to C. The 30 patients in the control group were 20 males and 10 females, age 25–64 years, 45.50 ± 11.02 years on the average; their mean duration of disease was 14.80 ± 7.99 years. By the severe hepatitis classification, 23 were classified to early stage, 5 to middle stage, and 2 to late stage; the basic disease was chronic hepatitis B for 17 patients, and hepatitis B caused liver cirrhosis for the other 13 patients. By Child-Pugh grading, 2 belonged to grade A, 5 to B, and...
The two groups were not significantly different in sex, age, condition, stage and grade of illness, and Chinese medicine syndrome pattern ($P>0.05$).

**Treatment**

Conventional integrative medical therapy was applied to both groups, including absolute bed rest, intravenous dripping of hepatocyte growth-promoting factor, prostaglandin E$_1$, glutathione, blood plasma, albumin, electrolyte, and acid-base balance maintaining and orally taking Chinese medicine decoction prescribed according to their syndrome. Upon these treatments, HJD was given additionally to patients in the treated group. It was a recipe consisting of Rhizoma Rhei 6 g, Radix Paeoniae rubra 24 g, Poria 30 g, Rhizoma Bletillae 15 g, and Radix Glycyrrhizae 3 g, etc. The Chinese herbs were decocted with water, and the decoction was concentrated to 100 mL, administered by retention enema once every day for 3 weeks. Retention enema was also given to patients in the control group but with 30 mL of lactulose plus 70 mL normal saline instead of HJD.

**Items and Methods of Observation**

**General Conditions**

General conditions, including dominant symptoms as lassitude, abdominal distension, poor appetite, nausea, vomiting, oliguria, mental change, hemorrhagic tendency, loose stool, constipation, etc., as well as the physical signs as jaundice, ascites, bleeding, etc., were observed before and after treatment.

**Blood Biochemical Indices**

Blood biochemical indexes, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin (TBil), albumin (Alb), globulin (Glb), prothrombin activity (PTA), total cholesterol (TC), and contents of calcium (Ca) and endotoxin (ET), were measured.

**Main Complications**

Main complications as hepatic encephalopathy, hemorrhage, infection, liver-kidney syndrome, etc. were observed.

**State of Ascites**

State of ascites was compared before and after treatment by measuring the maximal depth of ascites under horizontal position by a appointed staff using type ESAOTE Caris Plus colored Doppler’s ultrasonography (USA).

**Criteria for Effectiveness Assessment**

Clinical effectiveness was assessed by comparing the scores of symptoms before and after treatment, with the scoring method and criteria formed according to the “Standard for Diagnosis and Efficacy Evaluation of Traditional Chinese Medicine Diseases and Syndromes” and “Guiding Principle of Clinical Research on New Drugs of Traditional Chinese Medicine” promulgated by the State Administration of Traditional Chinese Medicine. It was graded into three grades: markedly effective, which denoted apparent alleviation or disappearance of symptoms after treatment and normalized various indices; effective, which denoted alleviated symptoms with various indices improved by 50% (compared to those before treatment); and ineffective, which denoted the improvement unreached to the above mentioned criteria or for cases that died.

**Statistical Analysis**

SPSS 12.0 software was used for statistical analysis. Data were expressed by mean ± standard deviation ($\bar{x} \pm s$); t-test was used for the measurement of data analyzing; $\chi^2$ test was used for rate comparing; and Ridit test was used for ranked data analyzing.

**RESULTS**

All patients showed good compliance, and no one dropped out in this study.

**Comparison of Clinical Comprehensive Therapeutic Effectiveness**

In the treated group, the efficacy was judged as markedly effective in eight patients, effective in 14, and ineffective in 5, with the total effective rate of 83.3%; while in the control group, the corresponding digitals were 4, 14, 12, and 60.0%. The therapeutic effectiveness in the treated group was significantly better than that in the control group ($P<0.05$).

Therapeutic effectiveness in patients of the treated group at different stages and with different syndromes was analyzed separately. The outcomes were listed in detail in Tables 1 and 2, which showed that the therapeutic effectiveness in the early stage