

Summary of 6 Cases of Hepatic Cirrhosis Treatment Using Vitalliver Suppository

I. Cases Background

There were six patients (three males and three females) of aged from 44 to 72 (average age was 59.67). All of them were diagnosed to have Hepatic Cirrhosis, five of them were diagnosed with the decompensated type with ascites complicated by hypoalbuminemia (ALB<35g/L), splenomegaly, hyperactivity of spleen, prolonged prothrombin time, etc. The patients had different degrees of such symptoms of bowel swelling, fatigue, poor appetite and yellow urination. Those with ascites were on long-term diuretic therapies like spironolactone.

Etiology: Four patients had Cirrhosis secondary to Hepatitis B. Before treatment Hepatitis B viral indicators were: HBsAg(+), Anti-HBe(+) and Anti-HBc(+). In terms of HBV DNA, three cases were positive, with virus level 1.1×10^6 copies/mL and 2.1×10^4 copies/mL and 3.2×10^3 copies/mL respectively. The causes of Cirrhosis in the other two patients were unknown, with laboratory results of HBsAg(-), Anti-HCV(-) and, in one case, Anti-HBs(+).

II. Treatments

All the patients were administered with Chinese medicine Vitalliver suppositories. The dosage was two suppositories daily (one in the morning and one at night). During this period, other therapies including liver-supporting, anti-viral and immunomodulating therapies were stopped, except for diuretics (with suitable oral electrolyte supplements) for those with ascites. The patients were hospitalized in the first two months of the treatment for rest and nutrition. The patients used the medication of Vitalliver suppository for 9 months and they keep using the suppositories continuously.

III. Investigation Parameters

The following tests were performed in every two months, like blood biochemistry, normal blood tests, Hepatitis B virus antigen-antibody indicators, HBV DNA quantification and ultrasound B scanning on the bowel. The ultrasound test was carried out at the Chinese Hospital of Gaoyao, Guangdong Province. The other tests were performed at the Guangzhou Medical Affiliated Hospital.

IV. Treatment Results

(i) General Conditions:

The symptoms of all patients showed different extents of improvements.

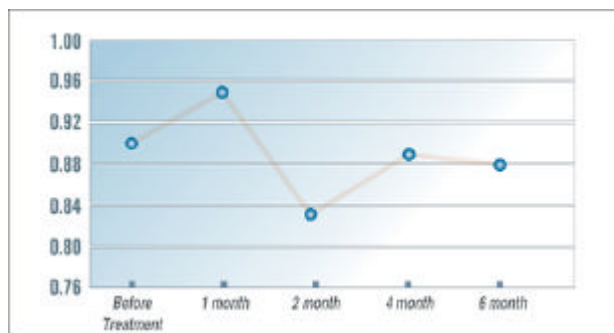
For fatigue (n=6), four cases disappeared and two cases reduced. For poor appetite (n=6): four cases disappeared, one case improved and one case unchanged. For bowel swelling (n=6): three cases disappeared, one case improved, one cases unchanged. For bitter tongue (n=5): four cases disappeared, one case reduced. For swelling in the lower limbs (n=5): four cases disappeared, one case reduced; For body weights: all cases increased, from 1kg to 5.5 kg, average increase was 2.3 kg. For ascites, before treatment five patients had moderate to severe ascites, after treatment three cases had ascites disappeared completely. One patient had ascites disappeared and stopped diuretics after two months of treatment. In the fourth month some minor ascites re-appeared but diuretics were not needed. There are still some ascites in that patient at this moment. For the last patient with ascites before treatment, ascites disappeared after two months of treatment. However, due to lack of rest after discharge from hospital, ascites re-appeared. In the ninth month of treatment, ascites were quite severe and diuretics were used intermittently.

(ii) Test on virus level:

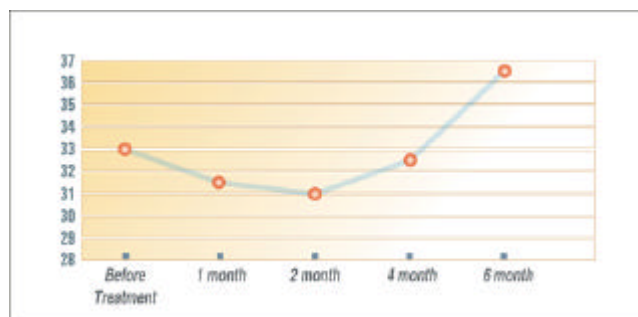
After treatment, four patients with Cirrhosis secondary to Hepatitis B had their Hepatitis B virus antigen-antibody system changed to HBeAg(+) and the other two cases had no change. For HBV DNA quantification, in one case the virus count turned to negative, one from negative to positive, another two unchanged

(iii) Biochemistry (liver functions) tests:

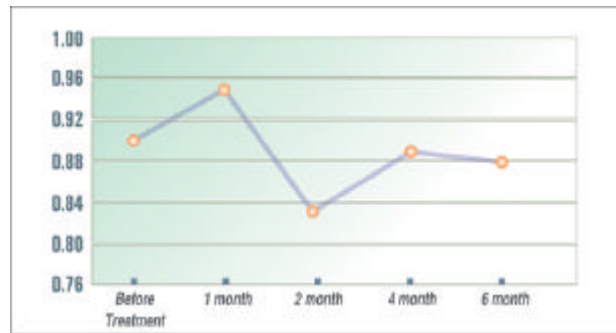
(1) ALT & AST: Rise followed by fall after treatment.



(2) ALB: A gradual increase after treatment ALB.



- (3) A/G: A significant increase after one month of treatment, followed by a decrease in the second month and then increase again.



- (4) Platelets: An increase in three patients and a decrease in the three after treatment, but the average count was increasing. Prothrombin Time (PT): an average prolongation of two seconds after treatment.

- (iv) Adverse effects:

The suppositories were well tolerated, with no observable or complained adverse effects.

V. Discussions

1. Vitalliver is a Chinese medicine and its dosage form is suppository, which is uncommon among Chinese medicines. Medications released from the suppositories were absorbed directly from the circulation around the rectum and then reached the liver via portal vein. Therefore this formulation may have special values in treating liver diseases.
2. Vitalliver, as Chinese medicine, showed significant efficacy in improving patients' symptoms. This study found that cirrhosis patients, after administering the suppositories, had significant changes in such symptoms as reduced fatigue, poor appetite, bowel swelling, increased urine output and gradual fall in ascites. The efficacy was especially prominent during the first two months of treatment: diuretic doses were reduced due to disappearance or decrease in ascites. Body weights in most patients increased due to improved appetite. Although in some patients the body weight was not increased much, the actual increase might have been masked by the subsiding ascites, which led to gross body weight decrease. Because of rapid improvements in symptoms, patients showed better mental conditions and quality of life, and some of them were even able to do some simple farming or housework.
3. Vitalliver suppository is made from natural Chinese herbs. Basic pharmacological studies showed it has good immunomodulating functions, and it can increase the activities of T-cells, B-cells and NK cells. Therefore it is useful in treating immuno-compromised patients. In this study, among the five patients with Cirrhosis secondary to Hepatitis B, two patients had their HBV DNA changed to negative after treatment. This may have been related to the immunomodulating functions of Vitalliver suppository.

4. The efficacy of Vitalliver suppository on improving LFTs was still not satisfactory. ALT and AST showed a short rise during the initial period of treatment and then decreased gradually. This trend follows the usual pattern of immunomodulating therapies in Hepatitis B. However, after six months of treatment, ALT and AST rose again with unknown reason. Albumin level increased slightly after treatment, but the globulin level decreased by an insignificant extent and even increased after six months. It is uncertain whether these observations could be related to Vitalliver suppository's immuno-boosting effects. Other indicators like bilirubin level were not improved significantly, and were even rose slightly in the eighth and ninth month.
5. Vitalliver suppository did not show any significant adverse effects. In this study, all the patients, including elderly patients (aged around 80) and final-stage Cirrhotic patients with severe ascites, tolerated the suppositories well. The patients found no difficulties in using suppositories, so compliance rate was good.
6. Limited by the small number of subjects in this study, the therapeutic effects of Vitalliver suppository on Cirrhotic patients are still not confirmed. But the data on hand showed a good trend, especially in the improvement of symptoms. The clinical uses of this Chinese medicine, with a special dosage form and formula, worth further studies. Since there have no effective therapies (including Chinese and Western medicines) against decompensated Cirrhosis, Vitalliver suppository could be a good try for this group of patients.



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