

Review Article

Hepatitis B

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Introduction

Hepatitis B is endemic in Southeast Asia, estimated to infect up to 20% of the population in some areas, such as the crowded subtropical city of Guangdong (Canton), China, with nearly as high infection rates in other major urban areas of China. In a 1983 survey by the Hong Kong Medical and Health Department, it was found that 10% of the local population is hepatitis B virus carriers. Statistics compiled at the Third Teaching Hospital of Zhongshan Medical College (Guangzhou), which specializes in the treatment of liver diseases, indicated about 15% of the local population in 1983 were hepatitis B carriers. Since techniques used at the time could not detect many cases, and because the epidemic has been spreading, figures of 20% infection rates are reasonable estimates of the situation in 1997. Hepatitis B is responsible for considerable morbidity and mortality, contributing to the incidence of liver cancer, the main cause of death in this area: 95% of liver cancer patients in Southeast China test positive for hepatitis B virus. Infection by hepatitis B is a reason for denial of exit visas from China. Further, the Chinese government has announced tentative plans to enforce strict birth prevention measures for those who test positive for viral hepatitis, as part of a larger program to reduce the number of births of children with various kinds of “defects.” Hepatitis B is also a major concern in other parts of the world, with its spread increasing to epidemic proportions during the past two decades. The vaccine that is used to prevent infection has not been well-accepted even by Western medical professionals who are at substantial risk of infection from their patients. Nonetheless, today it has become common practice in the U.S. to inoculate newborns against hepatitis B due to the high lifetime risk of infection. Historical records indicate that a disease corresponding to hepatitis B was known to Chinese doctors at least 1,800 years ago. At that time, the primary therapeutic measure was to prescribe a combination of Chinese herbs, usually in the form of a decoction.

The ingredients used in making such decoctions-which include some herbs well-known in the West, such as rhubarb,

licorice, and cinnamon have been a matter of record kept for all subsequent generations, so that today it is quite easy to study the traditional Chinese medical theory and specific treatments for infectious hepatitis. In ancient times, the appearance of jaundice was a primary indication of the disease, and relief of jaundice would indicate that the therapeutic measures were effective. Today, jaundice is most frequently associated with hepatitis A, an acute disease which, though often severe in symptoms, is usually self-limiting. Hepatitis B, especially in the chronic cases and in well-nourished individuals, rarely produces obvious jaundice. Beginning around 1950, scientific evaluation of herb materials used for treatment of viral hepatitis was undertaken in China and Japan, including isolation of active constituents, testing of crude herb extracts and purified components in laboratory animals, and clinical studies of complex formulas, individual herbs, isolated components, and synthetically-modified ingredients. Of the more than 6,000 species of plants and animals used as sources of Chinese medicine, about 150 crude materials have been identified as having measurable activity against viral hepatitis. The actions of anti-hepatitis herbs may be subdivided, for purposes of discussion, into two categories.

One category is “hepatoprotective,” including herbs and isolated compounds demonstrated to protect laboratory animals from the toxic effects of carbon tetrachloride, a liver poison that is frequently used to assay the ability of a substance to alleviate inflammation. Liver protection can reduce the impact of viral hepatitis without necessarily reducing the viral load or the immune response to the virus, though it appears that by using compounds with this property, the activity of the virus is often reduced. This might occur by making it more difficult for chemical and biochemical activators of the virus to affect cell surface receptors or to enter the infected liver cells; the ability of the virus to infect new cells may also be impeded by these compounds. Liver protection appears to be conferred by several processes including antioxidant activity, stimulating bile production and release, and by inhibiting inflammation and fibrinogenesis. The other category is “anti-

viral”, indicating the ability to inhibit viral activity by promoting the production of interferon or other immune responses to viruses (including both cell mediated and antibody responses to infected cells), or by blocking some step in viral replication, such as reverse transcriptase.

In clinical trials conducted in China during the past twenty years, reduction of serum liver enzyme levels (ALT, AP) and seroconversion from HBsAG+ or HBeAG+ to negative are usually used as modern standards of effectiveness, along with various measures of symptom reduction. Such tests have been used to demonstrate that a wide range of Chinese herbal compounds are highly effective in the treatment of viral hepatitis; specific results vary because of differing treatments and because of selection of differing populations for study. In some clinical trials, up to 2/3 of patients show seroconversion, and clinical improvement to “normal” may be attained for about 80% of the patients.

In Japan, medical doctors who prescribe Chinese herbs (up to 40% of all Western-trained medical doctors in that country) report that a diagnosis of hepatitis is one of the principal reasons for starting a patient on a course of Chinese herb therapy and that the Chinese herbs are more effective than Western medicine for treating this disease.

An objection that may be raised by Western researchers regarding the published Chinese studies is that the clinical reports may lack sufficient detail to reveal the true impact of the treatments. The number of tests available for analyzing the results of therapeutic interventions has grown in recent years, but not all such tests have been used in the Chinese research, perhaps because of budgetary limitations. The formula described in this article was administered in China to patients who were hospitalized for 12 weeks while taking the herb materials. Antigen tests for HBsAg and HBeAg, plus PCR evaluation of hepatitis viral DNA, were utilized to confirm the status of the hepatitis infection before and after treatment. Results comparable to previously-published Chinese trials were attained. This confirmation may help alleviate some of the concerns about results reported in other trials, making it possible to further utilize the vast experience of Chinese researchers in order to develop a satisfactory treatment for hepatitis B that is both economical and easily applied.

Principal Herbs/Active Components for Treating Hepatitis B

Licorice and Its Component Glycyrrhizin

One of the substances frequently mentioned in the Chinese literature regarding hepatitis B is glycyrrhizin, a component of licorice root (*Glycyrrhizauralensis* is the species used in China). Licorice was an ingredient in many of the prescriptions used in ancient times to treat hepatitis. The root is well-known for its anti-inflammatory activity; the root, its crude extract, certain active components, and synthetic derivatives of the active components

are used in modern pharmacies for the treatment of gastric ulcer. Glycyrrhizin zinc is useful topically as a treatment for skin inflammation and ulceration. In Japan, recent in vitro studies indicate that glycyrrhizin sulfate may be a useful compound for inhibiting HIV infection of cells, based on antiretroviral activity. Glycyrrhizin ammoniate is a common flavoring agent used in the U.S., so the recognition that glycyrrhizin is safe makes it attractive. Large doses of licorice or glycyrrhizin can, however, lead to increased aldosterone production (by the adrenals) and imbalance of serum sodium and potassium levels (both by affecting NaK-ATPase directly and via the action of aldosterone) in susceptible individuals. This response is not common when glycyrrhizin is used in standard therapeutic amounts for treatment of hepatitis; a typical dosage of glycyrrhizin corresponds to 15 grams per day of crude, dried licorice. Licorice and its active components can be used in the treatment of Addison’s disease (characterized by reduced production of aldosterone and other corticosteroids). Glycyrrhizin is an antioxidant and it promotes production of interleukin-2 (IL-2), two actions that help inhibit viral diseases. Glycyrrhizin sulfate appears more active than ammoniate or other forms. Crude licorice extract has the advantage of easy access, low cost, and a combination of several valuable active components, but isolated glycyrrhizin is more readily absorbed than the glycyrrhizin in the total herbal extract.

Schizandra and Its Component Schizandrin

Schizandrin, a lignan, is an active component of schizandra, the fruit from *Schizandrasinensis*. Studies conducted in the 1970’s in China revealed that schizandra and its component schizandrin could strongly lower ALT and AP in animal models of hepatitis and in human patients. However, it tends to have the problem that when administration of the compound ceased, there was a rebound in these enzyme levels. Screening of various analogues led to the production of a new drug for hepatitis known as DDB (dimethyl 1-4, 4’-dimethoxy-5, 6, 5, 6’dimethylene dioxybiphenyl 1-2, 2’-dicarboxylate). This compound is strongly hepatoprotective, lowering ALS and AP, reducing alpha-fetal protein levels and bilirubin, and reducing liver lesions, as indicated by biopsy.

DDB, as a new drug, has undergone numerous trials in China, but is not an accepted drug in the West. Schizandra extract has the advantage of being a safe food product of China that is also widely used in the U.S. as an energy tonic and immune enhancing agent. In China, it is used in the treatment of many ailments, including asthma, poor memory, severe fatigue, enteritis, and diabetes, as well as for viral hepatitis. It enhances adrenal cortical function. In clinical tests of anicteric infective hepatitis, just 3 grams per day of powdered schizandra fruit for one to three months led to a clinical cure in 65% of cases. Higher doses, up to 15 grams per day, have been used in the treatment of chronic hepatitis. It has been reported that schizandra, like its isolated lignans, has a quick action and high rate of effectiveness for reducing plasma liver enzyme levels, but that relapse occurs relatively easily. It has been suggested that

schizandra be used with other herbs to increase the therapeutic effect and prevent relapse.

Salvia and Its Components the Tanshinones

Salvia is perhaps the most frequently used herb in the modern practice of Chinese herbal medicine. Salvia has been known to Chinese doctors for centuries, but had been used in only a few applications, while today it is applied in the treatment of a wide range of diseases and symptoms. Salvia has a complex chemistry, and as a result, the crude herb extract is often used rather than an isolated component. The main active constituents are the tanshinones, a type of naphthaquinone. Salvia is used in China as a health food product; regular ingestion is thought to prevent cardiovascular diseases and other problems of aging. Salvia plays two major roles in the treatment of liver disease. First, it has been learned that in cases of severe or chronic liver disease, there are alterations in microcirculation (Capillary Bed Circulation) that appear to be part of the disease process. Patients treated with salvia who show clinical improvements also show normalization of the microcirculation. Second, salvia inhibits fibrinogen and aids in the resorption of fibrous plaques in the liver. It is thus widely used in the treatment of liver cirrhosis. Salvia is provided as a single herb or in complex formulas in the treatment of both acute and chronic hepatitis. As a single herb, it is given intravenously to quickly improve the condition of patients suffering from liver or kidney diseases. Usual oral dosages of salvia for treating severe diseases are 15-20 grams in decoction.

Hu-Chang and Its Anthraquinone Components

Hu-chang (*Polygonumcuspidatum*) refers to one of the many species of Polygonum used by Chinese doctors. It contains anthraquinones as main active components, as well as resveratrol, a stilbene. The herb, used alone, or in combination with other herbs, has been reported to cure both acute and chronic hepatitis, though it has been suggested to have greater impact on acute hepatitis. Hu-chang is one of the broad-spectrum antiviral agents under investigation in China and Japan. Hu-chang prevents lipid peroxidation, and thus prevents hepatic degeneration; it also promotes liver cell regeneration through RNA synthesis. The herb has been used in China to rescue patients with severe viral hepatitis who do not seem to recover when given standard Western therapies. In addition, Hu-chang influences microcirculation in a manner similar to salvia.

Curcuma and Its Essential Oil Components

Curcuma (*yujin*) refers to one of three major species of curcuma used in Chinese medicine; the other two are turmeric (*huangjiang*) and zedoaria (*ezhu*). It contains a complex essential oil that regulates blood lipids and treats infectious hepatitis. In a study of acute and chronic hepatitis involving 33 patients, all but one responded to the daily ingestion of a powder of curcuma (5 grams each time, three times daily), with 2/3 of the patients having subjective symp-

toms completely relieved. Curcuma stimulates bile secretion. Curcumin, a bright yellow complex ketone found in both turmeric and curcuma, is currently under investigation as an anti-HIV agent; it appears to block a Long Terminal Repeat (LTR) during reproduction of the virus. This action may apply to other viruses and to preventing activation of cancer genes. Curcumin is also a powerful anti-inflammatory agent.

Ligustrum and Its Component Oleanolic Acid

Ligustrum refers to the seed of *Ligustrum lucidum*. It is rich in Oleanolic acid, a compound that appears to be effective in treatment of liver diseases, acting mainly as a liver-protective agent. It is reported to be efficacious in treating both acute and chronic hepatitis, with a cure rate of 70% for acute hepatitis and it was markedly effective in treating 44% of cases of chronic hepatitis. Ligustrum has been identified as one of the herbs that strongly enhance immune responses, reversing leukopenia from cancer therapeutic agents. Ligustrum is used as a health food in the U.S. to enhance immune functions.

Silybum and Its Component Silymarin

Silymarin is a complex flavonoid from *Silybummarianum*, an herb that was initially introduced as a therapeutic agent by European researchers, but soon taken up by their counter-parts in China as a treatment for liver diseases. Its main action is to protect the liver from damage, and it is used, for example, in the early stage of liver destruction due to ingestion of poisonous mushrooms, to save the lives of victims. A concentrated extract of silybum, rich in silymarin, is sold as a health product in the U.S. and the isolate has been sold as a drug in Europe (“Legalon”) for the treatment of liver disease for the past 15 years. A dosage of 140 mg/day is reported to be liver protective and a dosage of 420 mg/day is reported to help repair liver damage. It is not clear that silymarin can cure viral hepatitis. Silybum extracts are widely sold as health foods in the United States.

A Protocol for Treatment

The following formula is recommended for treatment of hepatitis B and was the subject of a clinical trial conducted in China during 1994-1996, and later produced as a tablet for use in Western countries (Seven Forests Salvia/Ligustrum Tablets):

Salvia	(Danshen, root of <i>Salvia miltiorrhiza</i>)	21%
Licorice	(Gancao, root of <i>Glycyrrhiza uralensis</i>)	16%
Hu-chang	(Huzhang, rhizome of <i>Polygonum cuspidatum</i>)	16%
Curcuma	(Yujin, tuber of <i>Curcuma longa</i>)	11%
Schizandra	(Wuweizi, fruit of <i>Schizandra sinensis</i>)	10%

Ligustrum	(Nüzhenzi, fruit of Ligustrum lucidium)	16%
Atractylodes	(Baizhu, rhizome of Atractylodes macrocephala)	11%

[Total is 101% due to rounding]

Atractylodes is included in this formulation as a digestive aid, though its use can also be justified on the basis of laboratory studies showing that it protects mice from liver injury induced by carbon tetrachloride and promotes liver cell regeneration, it is also used as an ingredient in several complex formulas for treatment of viral hepatitis. The herb ingredients are made as a decoction, dried, and formed into tablets of 800 mg each (880 mg in the Chinese clinical trial). The dosage schedule for the herb materials is 9 tablets each time, three times daily, for a total dose of 27 tablets or about 23 grams of herb extracts. This corresponds, approximately, to 94 grams of crude herb materials used to prepare a decoction, after which the decoction is dried (the herb extract was manufactured by Sun Ten Laboratories, Irvine, California). The daily dosage of licorice, which is the marker compound for determining dosage of the mixture to administer, is 15 grams.

A vitamin tablet was used simultaneously, one tablet each time, three times daily in the Chinese trial. Each tablet contained:

- Silybum-extract (8:1):135mg
- Vitamin-C (as calcium ascorbate): 250 mg
- Beta-carotene:6mg (10,000IU)
- Vitamin E: 133IU
- Zinc (acetate):5mg
- Selenium (amino acid chelate): 40 mcg
- Quercetin: 100mg
- L-Cysteine: 40mg
- VitaminB1:5mg
- VitaminB2:3mg
- VitaminB3:10mg
- VitaminB5:10mg
- VitaminB6:12mg
- VitaminB12:50mcg
- Folic acid: 200 mcg

In the U.S., this tablet is replaced by two formulas (produced by ITM, White Tiger label): Quercenol, an antioxidant mixture that includes silybum, and Calmagnium, a mineral/vitamin mixture. In addition, some protocols include Alpha-Curcumone (a source of alpha-lipoic acid, an antioxidant used in the treatment of hepatitis). At standard recommended dosage, these supplements provide a larger amount and wider range of nutrients and antioxidants that were applied in the Chinese trial.

Duration of Treatment

Based on clinical experience in China, a 12-week treatment period is satisfactory as a standard course of treatment for chronic hepatitis B, which can be repeated once more if necessary. The basis for recommending this treatment period is a compromise between maximizing compliance and assuring measurable activity of the prescribed compounds. For the purpose of assuring maximum compliance, the treatment duration should be as short as possible. The minimum duration of treatment depends on the amount of time that is reasonable to obtain a satisfactory therapeutic effect, which is defined for the purpose of the Chinese study as the ability to attain 50% of patients experiencing both seroconversion (of HBsAg and/or HBeAg), and a decline of ALT and AP to within 1.5 times the maximal level of the normal range. For the other 50% (or fewer) of the patients, a second course of treatment is recommended. A certain number of non-responders is to be expected, even with two courses of treatment. A problem with long-term follow-up in the case of hepatitis B is that reinfection is always possible, especially since the disease can be sexually transmitted and the individual's partner may not have been treated at the same time. On the other hand, it is possible that the primed immune system of the successfully treated patient can prevent reinfection. According to Chinese reports, reversion to positive antigen test response occurs in only about 10% of patients successfully treated with Chinese herbs if followed-up during the first year after conclusion of herb therapy. This apparent conversion to positive hepatitis test is probably the result of activation of remaining latent virus in most cases.

Possible Adverse Reactions

There are some potential adverse reactions to any herb therapy, as follows:

- Gastro-intestinal reactions including nausea, bloating, flatulence, diarrhea, constipation, vomiting.
- Allergy type reaction, including hepatic reaction.

The above reactions are idiosyncratic, that is, they cannot be predicted in advance and do not represent inherent properties of the selected herbs. If such reactions occur, it may be necessary to have the individual experiencing the reaction discontinue the treatment. The gastro-intestinal reactions usually subside within three to five days and thus they should be tolerated for that long before discontinuing unless they are severe. Allergy-type reactions are not expected to resolve with longer use of the herbs. None of the herbs are inherently toxic in the dosage range recommended.

Traditional Chinese Medical Description of the Herb Therapy

Hepatitis begins as an acute disease with manifestations of heat, which is described in Chinese medical terminology as a toxic heat syndrome. As the disease develops, it is said to manifest symptoms of accumulated dampness and liver qi stagnation.

In the event that the disease becomes chronic, it is believed that the yin becomes deficient, there is blood stasis that mainly affects the liver, and the qi is weakened, weakness of qi may be the cause of the acute disease becoming a chronic disease.

Hu-chang is the herb that has been selected to treat the toxic heat syndrome. It is described as a cold, bitter, mildly pungent, and sour agent that clears up heat, detoxifies, invigorates blood, and disperses swelling. Antibacterial and antiviral effects have been demonstrated in pharmacology experiments with this herb.

Curcuma is the herb that has been selected to treat the stagnant qi that develops. The herb is said to have a cool property, with a bitter and pungent flavor. It is traditionally used to regulate the flow of qi, resolve qi stagnation, disperse stagnant blood, and control pain. It is applied to treatment of liver pain and jaundice. Modern research shows that it stimulates gastric secretion and bile secretion, to improve appetite and improve digestion.

Salvia is the herb that has been selected to treat blood stasis. It is described as having a mild cold property and bitter flavor. It is traditionally used to invigorate blood circulation, cool the blood, nourish the blood, and calm mental irritability. Modern research shows that it rectifies abnormal patterns of capillary bed circulation and successfully treats viral hepatitis when used in relatively large dosage.

Ligustrum is the herb that has been selected to treat yin deficiency. It is described as having a neutral property and bitter taste. It is traditionally used for yin deficiency, internal heat, weakness of the lower back and legs, and insomnia. Recent studies indicate that it enhances immune functions and protects liver cells from damage.

Licorice has been selected as the qi tonic herb. It is described as having a neutral property and sweet flavor. It is traditionally used to supplement the spleen, replenish qi, clear heat, remove toxin, and harmonize the stomach. It has been applied in the treatment of toxic swellings, diarrhea, thirst, cough, and palpitation. Recent studies show that it has anti-inflammatory action similar to that of the corticosteroids.

Atractylodes has been selected as the herb to remove dampness. It is also a qi tonic herb. It is described as having a warm property, sweet, mildly bitter and aromatic flavor. Traditionally, it is used to supplement the spleen, tonify qi, dry dampness, deliver water, and harmonize the stomach and spleen. It has been used for treatment of fatigue, loss of appetite, diarrhea, edema, spontaneous sweating, vomiting, and dizziness. Modern research shows that it promotes immune system functions, protects the liver from chemical injury, and has anticoagulant properties.

Schizandra has been selected as an aid to the qi tonic (licorice) and the yin nourishing herb (ligustrum). It is traditionally described as having a warm property and sour flavor. It is used

to nourish the kidneys, astringe the lungs, control diarrhea, and promote secretion of fluids (e.g., saliva). At higher dosage, it is said to reinforce the qi and nourish the yin. It has been applied to the treatment of fatigue, insomnia, amnesia, thirst, spontaneous sweating, cough, and thirst. Modern research shows that schizandra enhances adrenocortical function, promotes bile secretion, and reduces liver enzyme levels.

The complex formula has the properties of tonifying and regulating qi, of nourishing and astringing yin, of vitalizing blood, clearing heat and toxin, and drying dampness. Its quality is cooling; its taste is mainly sweet and bitter, with some sour and acrid (pungent) properties.

Herb Dosages

Chinese doctors recommend herbal dosages that have been recorded in the classical and modern Materia Medica publications. Modern clinical trials confirm the validity of these dosage suggestions. Generally speaking, when making a complex formula, the dosage of most ingredients is lower than would be utilized if the herb was selected as a sole ingredient, due to the expectation of synergistic action (attaining the same goal through complementary pathways). Because of the relatively short duration of treatment in this study, the dosage of each item has been selected at a relatively high level within the range that is usually recommended.

Hu-chang is recommended to be used in the dosage range 9-30 grams/day. A daily dosage of 15 grams has been selected for this treatment. In higher dosage, the herb can cause dry mouth, bitter after taste, nausea, vomiting, abdominal pain, and diarrhea. Curcuma is usually recommended in the dosage range 4.5-9 grams/day. However, in a published trial for treatment of hepatitis, it was used in a dosage (as powder) of 15 grams/day. A daily dosage of 10 grams per day has been selected for this treatment. In higher dosage, this herb may cause abdominal aching and diarrhea.

Salvia is recommended in the dosage of 6-15 grams for typical uses, but 15-30 grams to treat severe diseases, and up to 30-60 grams for severe blood stasis syndrome. The extract has been used intravenously in doses of 22.5 grams or higher (raw material equivalent) for treatment of hepatitis. A daily dosage of 20 grams has been selected for this treatment. Higher dosage may cause dry mouth, dizziness, lassitude, numb sensation of limbs, shortness of breath, nausea, vomiting, and gastrointestinal disturbance; these responses tend to subside of themselves without suspending treatment.

Ligustrum is recommended in dosages of 6-15 grams per day. Doses of up to 50 grams per day (made as fluid extract) have been used successfully to treat bronchitis. A daily dosage of 15 grams has been selected for this treatment. Higher dosage may cause bloating and diarrhea. Licorice is recommended to be used in doses of 3-6 grams per day. Doses up to 18 grams per day have

been used in treatment of tuberculosis. 7.5-15 grams per day have been used to treat gastric and duodenal ulcers. A daily dose of 15 grams has been selected for this treatment. Excessive dosage or long-term use of moderate dosage can cause an adverse reaction in up to 20% of patients, including possible symptoms of edema, weak limbs, spastic numbness, dizziness, headache, hypertension, hypokalemia.

Atractylodes is recommended in the dosage range of 3-12 grams. Doses up to 60 grams per day have been used for short-term applications. A daily dose of 10 grams has been selected for this treatment. Adverse reactions to large dosage have not been described, but gastro-intestinal responses might be expected.

Schizandra is recommended in the dosage range of 1.5-9 grams per day; with 6-9 grams per day recommended to reinforce qi and nourish yin. Up to 15 grams per day (powdered herb) have been used in the treatment of hepatitis. A daily dosage of 9 grams has been selected for this treatment. Higher dosage may cause heartburn, acid indigestion, stomach ache and anorexia.

The total dosage of the seven herbs is 94 grams. In a review of hepatitis formulas listed in modern Chinese books (at the ITM library), formulation characteristics were as follows: except for the one formula used temporarily at very high dosage, the formula size and dosage range is reasonably consistent at 9-12 herbs and 100-140 grams, typically 11-14 grams of each herb. In the formulation described in this article, the number of herbs is only 7, and the total dosage is just 94 grams (average, about 13 grams each). This reduction in number of ingredients-compared to that used in several recent trials with complex formulas-has been purposefully chosen to simplify the treatment protocol. A few clinical trials rely on one to three herbs. The relatively lower total dosage was deemed likely to be effective as the higher dosage treatments because of the careful selection of ingredients (focused formula design). It should be noted that there is an additional herb extract present in the "vitamin tablet," namely silybum, thus raising the total number of herbs to 8 (the substitute item, Quercenol, contains other herb extracts, including those from green tea, sophora, and grape seed); the dosage of herbs is therefore slightly increased by the inclusion of the vitamin tablet. The additional vitamins and minerals may provide an action in the current protocol that would otherwise have been obtained from herb ingredients. In allopathy Vitamins are used to provide nutrition to the bacteria present in the body which do not cause harm to body.

Results of One Chinese Clinical Trial

In a clinical trial carried out at three test sites in China, there were 94 patients treated and evaluated, utilizing three therapies (at each site). The main test therapy was the formula now called Salvia/Ligustrum Tablets, taken with the vitamin tablet. The primary control therapy was a tablet of the same size and same dosage made with Lentinus extract (shiitake mushroom, used in Japanese

treatment of hepatitis B), Atractylodes, and schizandra; the control patients also took the vitamin supplement. The third control group took a patent medicine made in China that was understood, by the Chinese researchers, to be the most effective one available.

As a result of 12 weeks treatment, in the Salvia/Ligustrum group and the Lentinus group there was marked improvement in symptoms and liver enzymes, more so than with the Chinese patent remedy. Antigen conversion from positive to negative occurred for HBsAg in 2/3 of patients treated by Salvia/Ligustrum or Lentinus Tablets, but in only 1/3 of those receiving the Chinese patent. HBsAg conversion occurred only in a few patients, 2 receiving Salvia/Ligustrum, 1 receiving Lentinus, and none receiving the Chinese patent. Nearly half (9/20) of those tested showed viral DNA conversion from positive to negative in those receiving Salvia/Ligustrum, and in one-third (7/21) of those receiving Lentinus, but only in about one-fourth (6/26) of those receiving the Chinese patent.

In sum, the Salvia/Ligustrum formula (used with a nutritional supplement) produced excellent results in treating hepatitis B patients. There were also obvious benefits, though less dramatic, for treatment with lentinus, schizandra, atractylodes, and the nutritional supplement. These treatments were superior to one that had been deemed the best available in China by the researchers. The study was conducted at the Hepo Medical Technical Research Institute in Beijing, the Haixia Hospital in Quanzhou (Fujian Province), and the Henan Medical Science Institute. Testing equipment and reagents were provided by the Tumor Virology Department of the Centers for Disease Control, Atlanta.

The original study design called for treatment of 200 patients. New government regulations in China require data on safety (such as laboratory animal tests) in order to carry out clinical trials, unless the herbs are in the form of decoction. This regulation halted (perhaps temporarily) continuation of the trial despite the fact that no significant adverse events were noted for any of the participants enrolled thus far.

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