P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

HerbClip™

FILE: ▪ Liv-52®
▪ Hepatoprotection
▪Ayurveda

HC 090251-290

Date: October 14, 2005

RE: Liv-52® Combination of Traditional Ayurvedic Herbs Shows Benefit for Liver Cirrhosis in Small Trial

Huseini H, Alavian SM, Heshmat R, Heydari MR, Abolmaali H. The efficacy of Liv-52 on liver cirrhotic patients: a randomized, double-blind, placebo-controlled first approach. *Phytomed.* 2005;12:619–624.

Hepatic cirrhosis (liver fibrosis) is most frequently caused by alcoholism, viral hepatitis, drugs, and hereditary conditions. The liver is one of the most important organs in the body and is involved in more than 300 processes. It is necessary for proper blood clotting, absorption of fats, blood pressure regulation, and metabolism of endogenous (from inside the body) and exogenous (outside the body) substances. It is also one of the largest immune system organs in the body. Hepatic cirrhosis is one of the most serious hepatic diseases. The liver gradually loses its many functions, contracts in size, and becomes hard and leathery. This small clinical trial evaluated Liv-52® (Himalaya Herbal Healthcare, Bangalore, India), a traditional Indian herbal formula, for the treatment of hepatic cirrhosis. Liv-52 is sold in the United States as LiverCare®.

Thirty-six subjects, 32 men and 4 women, ages 21 to 76 years (approximate average age 49 years) were enrolled in this 6-month, randomized, double-blind, placebo-controlled clinical trial. All volunteers had liver cirrhosis confirmed by liver biopsy, biochemical, pathological and abdominal examinations. Subjects were registered patients at the Tehran Hepatic Center in Tehran, Iran had no history of alcohol addiction, and did not have variceal bleeding (bleeding from the networks of veins).

Subjects were randomized to receive either 3 tablets of Liv-52 tablets, each of which contain 65 mg caper bush (*Capparis spinosa*) root, 65 mg chicory (*Cinchorium intybus*) seed, 32 mg black nightshade (*Solanum nigrum*) (whole plant), 32 mg arjuna (*Terminalia arjuna*) bark, 16 mg yarrow (*Achillea millefolium*) aerial parts, 16 mg tamarisk (*Tamarix gallica*) (whole plant) and 33 mg Mandur bhasma (Ferric Oxide Calx.), or 3 placebo tablets 3 times daily. The total amount of Liv-52 prescribed was 2,331 mg per day.

Outcome measures included serum alanine aminotransferase (ALT, a liver enzyme, the increased levels of which is an indicator of liver cell damage), serum aspartate aminotransferase (AST, another liver enzyme whose increased level is an indicator of liver cell damage), total bilirubin, prothrombin time, platelet, and white blood cells. Bilirubin and prothrombin are produced by the liver as are the enzymes ALT and AST. Abnormalities in these measurements can indicate severe liver pathology. Platelets and white blood cells are manufactured in bone marrow. Decreased levels of platelets or white blood cells could indicate immune suppression. Additional outcomes were the child-pugh score and ascites (accumulation of fluid in the abdomen). The child-pugh score determines the degree of hepatic disease by measuring 5 parameters: degree of ascites, encephalopathy, serum levels of albumin and bilirubin, and blood prothrombin time. Each parameter scored on a 3-point scale, from 1 to 3. Scores for all parameters were added together to create a total child-pugh score—5–6 = A, 7–9 = B, and > 9 = C. The lower scores were considered better. Ascites was ranked as none, mild, moderate and severe based on the amount of fluid accumulation. Outcomes were determined at baseline, and after 3 and 6 months of supplementation.

Ascites severity significantly decreased in the Liv-52 group from baseline to 6 months of treatment ($P < 0.032$). Child-pugh scores significantly improved in the treatment group during the study period compared to baseline ($P < 0.001$). Out of 18 subjects in the treatment group, 4 had no ascites at baseline vs. 6 after treatment, 6 had mild ascites at baseline vs. 10 after treatment, 5 had moderate ascites at baseline vs. 2 after treatment, and 3 had severe ascites at baseline vs. non with severe ascites after treatment. Average serum ALT and AST significantly decreased in the Liv-52 group (89.0 ± 24.56 at baseline vs. 38.5 ± 3.79 after treatment for ALT, $P < 0.044$, and 89.2 ± 14.24 at baseline vs. 57.2 ± 5.60 after treatment for AST, $P < 0.029$). None of the outcome measures significantly changed in the placebo group during the trial.

This study showed that three tablets of Liv-52 three times daily improved measures of ascites and liver damage. Since significant improvements were seen in the active, but not the placebo group, it can be concluded that Liv-52 is superior to placebo.

—John Neustadt, ND

Enclosure: Referenced article reprinted with permission from Elsevier, GmbH.