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**File: ■ Birch (*Betula pubescens*) Bark  
■ Chronic Hepatitis C**

**HC 101134-439**

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**RE: Birch Bark Extract Produces Beneficial Effects in Patients with Hepatitis C**

Shikov AN, Djachuk GI, Sergeev DV, et al. Birch bark extract as therapy for chronic hepatitis C — A pilot study. *Phytomedicine*. 2011;18(10):807-810.

Infections of hepatitis B virus (HBV) and hepatitis C virus (HCV), which affect about 400 to 500 million persons worldwide, are associated with significant morbidity and mortality. Chronic infections may develop into cirrhosis and primary hepatocellular carcinoma. Treatment of HCV by pegylated interferon plus ribavirin eradicates the virus in 60% of patients; however, a significant number of patients do not respond to therapy, relapse following treatment, or have significant adverse side effects that necessitate the discontinuation of treatment. Many patients have turned to complementary and alternative medicines for treatment. Herbal preparations, including birch (*Betula pubescens*) bark, have long been used to treat various ailments. Noting that there are no clinical data on the hepatoprotective effect of birch bark extract (BBE), the authors report on their open, prospective pilot study to investigate its effect in patients with chronic HCV.

The outer bark of birch contains pentacyclic triterpenes, including betulin, betulinic acid, oleanolic acid, lupeol, and erythrodiol. These triterpenes have known antiallergic, antiviral, antimicrobial, hepatoprotective, and antitumor effects. In animal studies, BBE exhibited a preventive effect in HCV-infected mice,<sup>1</sup> and betulin exhibited a hepatoprotective effect on rats in models of paracetamol- and ethanol-induced hepatitis.<sup>2</sup>

This study included 42 patients aged 20 to 71 years with serologically confirmed chronic HCV. All had alanine aminotransferase (ALT) levels greater than 1.5-fold above the upper limit of normal for at least 4 months before the study. Of the patients included, 6 had been diagnosed with arterial hypertension, 4 with chronic gastritis and gastroduodenitis, 4 with chronic cholecystitis, 3 with chronic bronchitis, and 2 with thyroiditis. Twenty-eight patients had relapsed or were nonresponders to combination therapy with pegylated interferon and ribavirin, and 14 were not eligible for interferon treatment for various reasons.

BBE (SNS-Pharma; St. Petersburg, Russia) was given orally as hard gelatin capsules containing 20 mg of dry alcohol extract from birch bark per capsule. Standard solutions

of both betulin and betulinic acid were prepared in methanol to a final concentration of 1 mg/ml. The patients took 8 capsules daily (2 in the morning, 3 before lunch, and 3 in the evening) for 90 days.

The primary outcome measure was the rate of ALT levels (a marker for liver damage), quantitative HCV RNA levels (a measure of the viral load), subjective symptoms associated with chronic HCV (fatigue, abdominal discomfort, depression, and dyspepsia), safety, and compliance.

The authors report that after 4 weeks of treatment, none of the patients had normalized ALT levels. After 12 weeks, however, significant differences in mean ALT and HCV RNA levels were observed. ALT levels decreased in 54% of patients and returned to normal levels ( $P=0.046$ ). HCV RNA was reduced in 43.2% of patients ( $P=0.016$ ). At baseline, mean bilirubin was within normal limits and tended to decrease after 12 weeks of treatment.

At 12 weeks, the majority of patients reported the disappearance or alleviation of their chief clinical symptoms. Subjective complaints improved after 4 weeks of treatment. Reductions of 4-fold were reported for fatigue ( $P=0.049$ ), and of 2-fold for abdominal discomfort ( $P=0.012$ ), depression ( $P=0.045$ ), and dyspepsia ( $P=0.038$ ). At 12 weeks, fatigue was reduced 6-fold ( $P=0.028$ ), and abdominal discomfort was reduced 3-fold ( $P=0.05$ ). Dyspepsia was no longer reported ( $P=0.042$ ), which was significantly different from baseline.

Compliance was moderate: 60% of capsules were taken.

This study demonstrated beneficial effects of 12 weeks of BBE treatment in patients with chronic HCV infection. "However, because this study lacked a control group, clinical relevance of the data can only be estimated in the future by following controlled clinical trials," say the authors.

—*Shari Henson*

#### References

<sup>1</sup>Nosik NN, Deriabin PG, Isaeva EI, et al. [Interferon-inducing properties of dry birch bark extract and its effect on experimental infection caused by hepatitis C virus]. *Vopr Virusol.* 2005;50(5):29-32.

<sup>2</sup>Djachuk GI, Yurchenko IV, Vishnevetskaya TP, Karlina MV. Study of Hepatoprotective Properties of Betulin. *Vestnik Dermatologii i Venerologii.* St. Petersburg State Medicinal Academy; 2004;1:142-145.

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