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File: ■ Korean Red Ginseng (*Panax ginseng*, Araliaceae)
■ Fibrosis
■ Chronic Hepatitis B

HC 031724-577

Date: September 29, 2017

RE: Korean Red Ginseng as a Complementary Therapy for Chronic Hepatitis B

Choi SH, Yang KJ, Lee DS. Effects of complementary combination therapy of Korean red ginseng and antiviral agents in chronic hepatitis B. *J Altern Complement Med*. December 2016;22(12):964-969.

Despite development of the hepatitis B virus (HBV) vaccine, people remain HBV carriers and often suffer from chronic hepatitis B (CHB). In past research, ginseng (*Panax ginseng*, Araliaceae) has been shown to have antiviral potential and may be able to play a therapeutic role. CHB activates hepatic stellate cells, which then induces hepatic fibrosis, and results in excess formation of type IV collagen, hyaluronic acid (HA), and transforming growth factor-beta (TGF-β). This study measured serum levels of these 3 biomarkers to determine the efficacy of Korean red ginseng (KRG) in combination with antiviral treatment in patients with CHB.

This 68-week, prospective, single-blinded, randomized, controlled trial was conducted at a single center, Daejeon St. Mary's Hospital, the Catholic University of Korea; Daejeon, Korea. Forty-two patients who were between 18 and 65 years of age, diagnosed with CHB within the past 6 months, HBV DNA(+) and HBeAg(+), and receiving antiviral treatment were enrolled between April 2012 and February 2014. Patients were randomly divided into 2 groups. The control group was given oral antiviral treatment (lamivudine, adefovir dipivoxil, entecavir, or tenofovir) and the experimental group was given oral antiviral treatment plus 3 g of KRG (Korea Ginseng Corporation; Seoul, Korea) daily (1-g dose, 3x/day, 500 mg/capsule). KRG was harvested "from the roots of a 6-year-old red ginseng, Panax ginseng Meyer" in the Republic of Korea. The fresh ginseng was steamed at 90-100°C for 3 hours followed by drying at 50-80°C, then ground into a powder. "The KRG extract was found to contain the major ginsenosides -Rb1 (4.26 mg/g), -Rb2 (1.62 mg/g), -Rc (1.80 mg/g), -Rd (0.29 mg/g), -Re (1.71 mg/g), -Rf (0.67 mg/g), -Rg1 (2.61 mg/g), -Rg2 (0.20 mg/g), -Rg3 (0.13 mg/g), and other minor ginsenosides." Type IV collagen, HA, and TGF-β were measured at 4 and 52 weeks after the initial assessment.

"[F]our patients were excluded because of various reasons, leaving 38 patients who were enrolled in the study." All 38 patients completed the study, with 19 patients in each

group. Ten males and 9 females were in the control group, and 17 males and 2 females were in the KRG group (P=0.293). No serious adverse events were reported in either group.

After treatment, there was no significant difference in type IV collagen levels between the control and KRG groups (P=0.174). Mean ± standard deviation (SD) HA levels changed from 65.61 ± 31.47 ng/mL (control) and 72.47 ± 37.91 ng/mL (KRG) at baseline to 5.27 ± 2.98 ng/mL (control) and 3.21 ± 2.71 ng/mL (KRG) after treatment, showing a statistically significant decrease in the KRG group compared to control (P=0.032). Mean ± SD TGF-β levels changed from 186.61 ± 64.63 pg/mL (control) and 219.81 ± 145.21 pg/mL (KRG) at baseline to 4.73 ± 5.72 pg/mL (control) and 1.38 ± 2.44 pg/mL (KRG) after treatment, showing a statistically significant decrease in the KRG group compared to control (P=0.008). There were no significant differences in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or HBV DNA levels between groups after treatment (P=0.517, P=0.176, and P=0.685, respectively).

While there was no significant change in type IV collagen levels between groups, significant differences were found in the levels of HA and TGF-β between the 2 groups. KRG could be a helpful adjunct to antiviral treatment, as it can help decrease some markers associated with hepatic fibrosis. However, further double-blind investigations are warranted to confirm this conclusion. "The work was supported by a grant from the Korean Society of Ginseng, funded by the Korea Ginseng Corporation."

—Alexis Collins, MA, MS

Peer Review Comments:
This report lacks sufficient evidence of potential anti-HBV effects as follows:

1. The test group (KRG administered) did not show any antiviral effects in comparison with that of the control group (the control group's numbers of HBV DNA copies were less than that of the test group when the primary endpoint was HBV DNA copies).
2. There were some statistically significant differences in measurements of HA and TGF-β, but it cannot be conclusively stated whether this was due to KRG treatment or individual different reactions.
3. Based on the above, further studies are needed. To show concrete outcomes, the clinical trials need more patients in test groups and/or there needs to be a re-design of the clinical trial.

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