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File: ■ Asian Ginseng (*Panax ginseng*, Araliaceae)
■ Non-alcoholic Fatty Liver Disease
■ Liver Function

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RE: Use of a Fermented Ginseng Powder Product May Benefit Liver Function

Jung SJ, Hwang JH, Park SH, et al. A 12-week, randomized, double-blind study to evaluate the efficacy and safety of liver function after using fermented ginseng powder (GBCK25). *Food Nutr Res*. April 6, 2020;64:10.29219/fnr.v64.3517. doi: 10.29219/fnr.v64.3517.

Non-alcoholic fatty liver disease (NAFLD) refers to a range of conditions characterized by excess fat in the liver, which causes inflammation and can lead to severe forms of NAFLD, including nonalcoholic steatohepatitis (NASH). Asian ginseng (*Panax ginseng*, Araliaceae) powder contains many bioactive compounds including saponin glycosides, which have demonstrated hepatoprotective and antifatigue effects. The purpose of this randomized, double-blind, placebo-controlled study was to evaluate the effects and safety of fermented Asian ginseng powder (GBCK25; GENERAL Bio Co. Ltd., Namwon, Jeollabuk-Do; Republic of Korea) on liver function and in the treatment of fatigue in patients with liver dysfunction.

The 12-week study was conducted between July 2016 and October 2017 at Chonbuk National University Hospital of South Korea. Participants were recruited from the Clinic Trial Center for Functional Foods at the hospital using advertisements, including brochures, posters, and the Chonbuk National University Hospital website. Participants aged 19 to 70 years with a serum alanine aminotransferase (ALT) level of 35-105 IU/L were eligible for inclusion. The exclusion criteria were as follows: use of liver function improvement medicines and/or functional health foods within the preceding four weeks; use of antipsychotic medications within two months of the screening test; use of Chinese medicine not considered reasonable by the tester within four weeks prior to the first dose date; suspected drug or alcohol misuse; significant history of hypersensitivity to drugs or functional health foods; past history of gastrointestinal disease or surgery; esophageal variceal bleeding, liver coma, or ascites within one year of the first dose; diagnosis of hepatitis B of C or carriers of the virus; signs of cirrhosis, liver cancer, or liver cancer syndrome; kidney disease; gallbladder conditions; pregnant or breastfeeding; women without reliable contraception; participation in other clinical trials within two months of the screening test; serum creatinine level >2.0 mg/dL; and any diagnostic result that was deemed inappropriate for study inclusion.

Ninety participants were randomized to receive a placebo (n = 30), 125 mg of GBCK25 (n = 30; low-dose), or 500 mg of GBCK25 (n = 30; high-dose). Participants were instructed to take two tablets of their assigned treatment once per day for 12 weeks; all study tablets appeared identical. Participants were instructed to continue their habitual physical activity levels and dietary patterns but avoid functional foods or dietary supplements throughout the study. Overall, 84 participants (28 in GBCK25 low-dose group, 30 in GBCK25 high-dose group, and 26 in placebo group) completed the study and were included in analysis. The majority were men (80%) with a mean age of 43.5 years. There were no statistically significant differences among the groups for sex, age, body mass index, liver function, or lipid profile at baseline.

Liver function was assessed at screening, baseline, and study completion. Primary outcomes were variations in ALT and gamma-glutamyl transferase (GGT) levels. Secondary outcomes were variations in the following markers: aspartate aminotransferase (AST), total bilirubin, triglycerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), high-sensitivity C-reactive protein (hs-CRP), total antioxidant capacity (TAC), and multidimensional fatigue scale (MFS) score. Participants' vital signs and complete blood count were also assessed, as was dietary intake using a self-reported food diary.

No significant difference in ALT was found among the groups. A significant decrease (P = 0.049) in GGT levels was found in the GBCK25 low-dose group, but the difference compared with placebo was insignificant. In men, however, the change in GGT in the GBCK25 low-dose group was significantly decreased compared with placebo (P = 0.036). Levels of hs-CRP decreased with GBCK25 low dose, but the difference was not significant compared with placebo (P = 0.052). In men alone, and after excluding men suspected of alcohol misuse (n = 2), subgroup analysis revealed a significant decrease in hs-CRP with GBCK25 low dose compared with placebo (P = 0.021). No significant difference in TAC was found among the groups nor were significant changes in AST, TC, TG, HDL-C, and LDL-C found among the groups. The MFS score decreased significantly with GBCK25 high dose compared with placebo and GBCK25 low dose (P = 0.024). When analyzed among men, CBCK25 high dose demonstrated a significant decrease in MFS score after 12 weeks (P = 0.023). No adverse reactions were reported.

The authors conclude that low dose use of GBCK25 for 12 weeks is safe and may improve liver function in patients with liver disease, while high dose GBCK 25 may be considered to aid their fatigue. However, because GBCK25 demonstrated a significant decrease in GGT and hs-CRP in men not suspected of alcohol misuse, it is unknown whether GBCK25 is beneficial for patients with acute or chronic liver damage secondary to alcohol. Additionally, abnormal liver function test results do not always indicate liver disease. That said, clinical trials in patients with confirmed liver disease using imaging procedures or liver biopsy rather than a single biochemical lab marker (ALT) are needed to confirm this. The authors report no conflicts of interest.

–Gavin Van De Walle, MS, RDN

Referenced article can be accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7217291/.