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FILE: ▪Hochuekkito
▪Weakness in Elderly
▪Traditional Japanese Medicine

HC 090252-299

Date: February 28, 2006

RE: Study Evaluates Use of Japanese Herbal Formula in Elderly

Satoh N, Sakai S, Kogure T, et al. A randomized double blind placebo-controlled clinical trial of Hochuekkito, a traditional herbal medicine, in the treatment of elderly patients with weakness *N* of one and responder restricted design. *Phytomed.* 2005;12:549–554.

Decreased strength in elderly patients is a risk for injury due to falls. Frequently there is no frank pathology associated with weakness in the elderly, and the majority of treatments include dietary recommendations, exercise, and modification of the home environment to accommodate reduced function (e.g., adding tub shower bars so people can pull themselves up and out of a bathtub). The medical and financial consequences of aging are becoming more important as the mean age of the U.S. population increases. Between the years 2000 and 2030, it's estimated that the elderly population (> 65 years old) will increase from 35 million to 71.5 million persons. This clinical trial evaluated a traditional Japanese and Chinese herbal formula, Hochuekkito, in the treatment of elderly volunteers with weakness.

Fifteen elderly volunteers (mean age 78 years) enrolled in this trial, which took place at five hospitals—Tonami Sunshine Hospital, Hikarigaoka Hospital, Miwa Hospital, Hokusei Hospital, and Hagino Hospital. Included in the study were patients between 60 and 90 years old who complained of "general malaise or appetite loss due to chronic wasting disease." All volunteers had to be free of acute infections or vascular diseases for a minimum of 1 month prior to starting the study. Volunteers also had to be free of any malignancies.

The study was conducted in 3 phases. An initial 2-weeks run-in period identified responders from non-responders. Non-responders were eliminated from the trial, and responders were randomized into 3 groups: active–placebo group, placebo–active group, and active–active group. Each group underwent two 6-week periods in a crossover design, with a 2-week washout period in between.

Volunteers received 7.5 g of Hochuekkito (Kanebo Co. Ltd, Japan) or placebo per day, the active treatment contained 6.4 g total extract produced from 10 herbs in the ratio of 4 g eleuthero (*Eleutherococcus senticosus*) root, 4 g cang-zhu atractylodes (*Atractylodes lancea*) rhizome, 4 g astragalus (*Astragalus membranaceus*) root, 3 g dong quai (*Angelica sinensis*) root, 2 g jujube (*Ziziphus jujuba*) fruit, 2 g bupleurum (*Bupleurum falcatum*) root, 1.5 g licorice (*Glycyrrhiza glabra*) root, 0.5 g ginger (*Zingiber officinale*) root, and 2 g *Citrus unshiu* dried peel.

Outcome measures included quality of life (QOL) as determined by the SF-36: Short Form 36 Health Survey, Japanese edition. The SF-36 short-form was designed for use in clinical practice and research, health policy evaluations, and general population surveys. It assesses 8 health concepts on a 0–100 point scale (lower scores = relatively poorer health status, higher scores = relatively better health): physical functioning, role physical (limitations in role activities due to physical health problems), bodily pain, general health, vitality, social functioning, role emotional (limitations in usual role activities due to emotional problems), and mental health. Also assessed were mood, using POMS (Profile of Mood States); and immune system function as indicated by natural killer cytolytic activity (NK activity), IL-2 production by lymphocytes, lymphocyte proliferation, and lymphocyte cell-surface antigens. POMS is a systematic survey of 6 components: vigor (V), depression-dejection (D), anger-hostility (A-H), fatigue (F), tension-anxiety (T-A), and confusion (C).

Total SF-36 score did not change significantly in either the active or the placebo group; however, physical component summary (PCS) of the SF-36 significantly improved in the treatment group compared to baseline (36.2 ± 4.5 vs. 40.5 ± 5.4, P = 0.018). Four categories of POMS significantly improved in the Hochuekkito group from baseline to 12 weeks of treatment, including A-H (11.3 ± 1.3 vs. 8.5 ± 1.9, respectively; P = 0.013), F (15.1 ± 1.5 vs. 10.8 ± 1.6, respectively; P = 0.021), T-A (15.2 ± 1.5 vs. 13.4 ± 1.5, respectively; P = 0.003), and C (15.0 ± 1.1 vs. 13.3 ± 1.1, respectively; P = 0.013). Overall lymphocyte proliferation did not significantly increase; however, some of the percentages of lymphocyte subsets did significantly increase: CD3 and CD3CD4 lymphocytes significantly increased from baseline to 12 weeks of treatment (58.5 ± 2.4 vs. 60.4 ± 2.6, and 37.3 ± 2.2 vs. 38.2 ± 2.1, respectively; $P < 0.05$). These lymphocytes are important mediators of immune system function and may indicate improved immune status against bacterial and viral infections; however, the immune modulation demonstrated in this study was small and of unknown clinical significance. Two volunteers discontinued the study, but not due to reactions to the medication. Reasons for withdrawal were not elaborated. No adverse events were reported.

Data on the use of herbal therapies in the elderly are limited, and identification of botanical medicines that could improve the quality of life in this population would be helpful. This study showed that Hochuekkito was effective at improving some quality of life parameters in elderly patients suffering from weakness, including anger-hostility, fatigue, tension-anxiety, and confusion. It did not confer an improvement in vigor, nor did it produce an increase in strength. As previously noted, while some immune system parameters significantly increased, their clinical significance remains to be determined.

The authors of this study contend that limitations due to the small number of patients examined (17 active; 9 placebo) were somewhat offset by using an n of one study and twice randomizing.

—John Neustadt, ND

Enclosure: Referenced article reprinted with permission from Elsevier GmbH.