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**File: ■ Astragalus (*Astragalus membranaceus*) Root
■ Chinese Salvia (*Salvia miltiorrhiza*) Root
■ Chronic Fatigue**

HC 060691-380

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RE: Astragalus and Chinese Salvia Aqueous Extract Formula Reduces Severity of Chronic Fatigue in Pilot Study

Cho JH, Cho CK, Shin JW, et al. Myelophil, an extract mix of Astragali Radix and Salviae Radix, ameliorates chronic fatigue: a randomised, double-blind, controlled pilot study. *Complement Ther Med.* Jun 2009;17(3):141-146.

Myelophil (Samik Pharmaceutical Company Ltd.; Seoul, Korea) is composed of the aqueous extracts of the roots of astragalus (*Astragalus membranaceus*) and Chinese salvia (*Salvia miltiorrhiza*). Astragalus is a tonic herb believed to enhance chi with immunomodulatory and antitumor effects. Chinese salvia is traditionally used to treat blood disorders, and it has haematopoietic, antioxidant, antihypertensive, and anti-inflammatory properties. Myelophil is prescribed to treat fatigue and the adverse effects of chemotherapy and radiation therapy. The purpose of this pilot clinical trial, conducted at Daejeon University Hospital in Daejeon, South Korea, is to assess the effect of Myelophil on chronic fatigue.

The authors recruited subjects (n=36, 13 men and 23 women, aged 21-61 years) with chronic fatigue lasting 6 months or longer. Chronic fatigue syndrome was not formally diagnosed, but medical causes of fatigue were ruled out with radiological and hematological testing and physician examinations. Myelophil was made from a freeze-dried aqueous extract of equal amounts of Chinese salvia and astragalus. The final product was granulated and contained 66% pure extract. Formula composition was verified with high-performance thin-layer chromatography based on rosmarinic acid and formononetin markers. The traditional digestive medicine Hyangsapyunweesan was used as the placebo. The Hyangsapyunweesan granules were made from extracts of the following: *Attractylodes japonica* roots, *Citrus unshiu* fruit cortex, cyperus (nut grass; *Cyperus rotundus*) roots, ginger (*Zingiber officinale*) rhizome, hardy orange (*Poncirus trifoliata*) seed, patchouli (*Pogostemon cablin*) herb, magnolia (*Magnolia officinalis*)

bark, *Amomum xanthioides* seed, costus (*Saussurea costus* syn. *S. lappa*) root, and Chinese licorice (*Glycyrrhiza uralensis*) root prepared by a process similar to Myelophil.

The subjects were randomized to 3 groups: the low dose (1.5 g) Myelophil (n=13), high dose (3.0 g) Myelophil (n=11), and the control group (1.5 g Hyangsapyunweesan, n=12). The subjects took their allocated treatment twice daily for 4 weeks. They rated their feelings of fatigue with a numerical rating scale (NRS) based on the Chalder fatigue severity scale at baseline and after 2 and 4 weeks. It included 7 items about physical health and 4 about mental health. The subjects scored each item on a scale of 0 (no symptoms) to 10 (severe). The researchers used an antibody array to measure cytokine expression before and after treatment. The patients also rated their general fatigue on a visual analogue scale (VAS) at the same times as the NRS.

At baseline, the NRS scores were similar between the groups (low dose: 52.5 ± 17.2 , high dose: 41.9 ± 15.8 , and control: 46.3 ± 17.8). The total NRS and physical symptom NRS scores significantly decreased in all 3 groups after treatment ($P=0.048$ and $P=0.027$, respectively), indicating symptom improvement. The mental health NRS scores did not change significantly. The total NRS scores decreased to 33.9 ± 14.4 , 28.5 ± 10.4 , and 39.4 ± 18.5 for the low dose, high dose, and control groups, respectively. The low dose Myelophil group had a significantly better improvement in the total NRS score compared to the control group ($P=0.034$). There was not a significant difference between the high dose and control groups. The change in the physical NRS scores was significantly greater in the low dose, but not the high dose, Myelophil group compared to the control group ($P=0.027$). The VAS scores for general fatigue significantly decreased in all 3 groups ($P=0.022$). The low dose Myelophil group demonstrated a significantly greater decrease compared to the control group ($P=0.012$). The antibody array revealed no significant changes in the expression of 42 cytokines for any of the groups after 4 weeks of treatment. This is an interesting result because prior studies have suggested a connection between chronic fatigue and immune system abnormalities like cytokine production.

The improvements observed in the control group may be due to the constituents of Hyangsapyunweesan, which was not an inert placebo. The authors conclude that low dose Myelophil is more effective than the high dose in the treatment of chronic fatigue symptoms. Based on the results of this study and others, the authors write, "we suggest that Myelophil exerts pharmacological effects against chronic fatigue, especially with respect to the physical manifestations of fatigue." More research is needed to confirm these results and to determine the mechanism of action. This study was conducted on patients with chronic fatigue; however, chronic fatigue syndrome is a separate ailment. Therefore, research is needed to determine Myelophil's effect on patients with chronic fatigue syndrome.

—*Marissa Oppel, MS*

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