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**File: ■ Chinese Herbal Medicine
■ Hypertriglyceridemia
■ Triglycerides**

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RE: Three Clinical Studies Found Traditional Chinese Herbal Medicines May Benefit People with Hypertriglyceridemia

Liu ZL, Li GQ, Bensoussan A, Kiat H, Chan K, Liu JP. Chinese herbal medicines for hypertriglyceridaemia. *Cochrane Database Syst Rev.* June 6, 2013;6:CD009560. doi: 10.1002/14651858.CD009560.pub2.

Elevated blood triglyceride (TG) levels, known as hypertriglyceridaemia (HTG), is a risk factor associated with many diseases, including arteriosclerosis, diabetes, and hypertension. This clinical review evaluated the effects of traditional Chinese herbal medicines (single herbs, proprietary medicines, and herb combinations) in the treatment of HTG.

This review targeted randomized controlled trials (RCTs) on adults with HTG (>200 mg/dL TG concentration). The included trials compared Chinese herbal medicines with no treatment, placebo, pharmacological, or non-pharmacological treatments. Primary outcomes were cardiovascular and cerebrovascular events, death, and serum TG levels. Secondary outcomes were health-related quality of life, cholesterol concentrations, weight, body mass index (BMI), waist-to-hip ratio (WHR), adverse effects, and costs.

Databases searched included The Cochrane Library (2012), MEDLINE, EMBASE, Chinese Biomedical Database, China National Knowledge Infrastructure, Chinese VIP Information, Chinese Academic Conference Papers Database, and Chinese Dissertation Database up to May 2012. Studies that did not define their randomization process, had the control group also use traditional Chinese medicine, or included participants that had hypercholesterolemia or secondary HTG were excluded. The Cochrane Collaboration's tool was used to assess risk of bias on the following criteria: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and additional bias.

Three studies met the inclusion and exclusion criteria, and were evaluated.¹⁻³ The studies were all two-arm, parallel-design, comparative RCTs conducted in China and published in Chinese. A cumulative total of 170 Chinese subjects were included in the three studies; 90 were randomly assigned to receive the herbal treatment, and 80

received the comparator drug. Treatments ranged from 4 to 6 weeks. There were no data on cardiovascular or cerebrovascular events, deaths, health-related quality of life, or costs in any of the trial reports. The studies were not funded by companies.

The risk of bias assessment identified the following common deficits: methods and design were not well detailed, none were multi-center RCTs, none reported sample size calculations, and none stated that an intention-to-treat analysis was performed. All 3 trials were deemed to have a low risk of bias in random sequence allocation and "incomplete outcome data were adequately addressed." Two trials^{1,3} also had a low risk of bias in selective reporting. All 3 studies had unclear risk of bias in the domains of allocation concealment, blinding of subjects and personnel (performance bias), and blinding of outcome assessment (detection bias). Additionally, 2 trials^{1,2} had unclear risk in the domain "free of other bias". Only 1 trial was judged to have a high risk of bias in selective reporting.²

Traditional Chinese herbal medicines were compared (1) with fenofibrate (a TG-lowering drug), along with a "lifestyle intervention" in both groups, (2) in combination with gemfibrozil (a TG-lowering drug) versus gemfibrozil alone, or (3) with benzbromarone (promotes excretion of uric acid). All studies detailed both serum TG concentrations and adverse effects. Two studies reported uric acid^{1,3} concentrations, and one study detailed symptoms.³

The formulations used were decoctions known as Zhusuan Huoxue, Huoxue Huayu Tongluo, and Chushi Huayu, all containing astragalus (*Astragalus membranaceus*). (1) Zhusuan Huoxue specifically contained astragalus, poria (*Wolfiporia cocos* syn. *Poria cocos*), water plantain (*Alisma plantago-aquatica*), Asian plantain (*Plantago asiatica*), Chinese rhubarb (*Rheum palmatum*), eucommia (*Eucommia ulmoides*), codonopsis (*Codonopsis pilosula*), Tienchi ginseng (*Panax pseudoginseng* var. *notoginseng*), safflower (*Carthamus tinctorius*), Chinese salvia (*Salvia miltiorrhiza*), and imperata (*Imperata cylindrica*). (2) The basic Huoxue Huayu Tongluo decoction contained Chinese salvia, safflower, dong quai (Chinese angelica; *Angelica sinensis*), Sichuan lovage (*Ligusticum sinense* 'Chuanxiong'), Chinese peony (*Paeonia lactiflora*), rehmannia (*Rehmannia glutinosa*), and astragalus. (3) Chushi Huayu consisted of Chinese smilax (*Smilax glabra*), tokoro yam (*Dioscorea hypoglauca*), Job's tears (*Coix lacryma-jobi* var. *ma-yuen*), Chinese motherwort (*Leonurus japonicus* syn. *L. heterophyllus*), lysimachia (*Lysimachia christinae*), Asian plantain, Chinese salvia, astragalus, Chinese rhubarb, and Chinese licorice (*Glycyrrhiza uralensis*). None of the trials reported quality standards of the herbal preparations or analytical testing.

Zhusuan Huoxue together with a lifestyle intervention resulted in elevated TG concentrations as compared to the fenofibrate and lifestyle intervention group (mean difference [MD], 0.51 mmol/L, 95% confidence intervals [CI], 0.31, 0.71). The Huoxue Huayu Tongluo decoction in combination with gemfibrozil was not more effective than gemfibrozil alone in lowering TG; however, this combination had a positive effect in decreasing the number of subjects with TG \geq 2.2 mmol/L (risk ratio [RR], 0.20, 95% CI, 0.05, 0.84). Chushi Huayu was found to decrease TG in comparison to those using benzbromarone (MD, -1.14 mmol/L, 95% CI, -1.40, -0.88). Quality of life, serum cholesterol, weight, BMI, and WHR data were not reported in any of the studies.

No serious adverse events were noted; the reported adverse effects were as follows: increased alanine aminotransferase concentrations,¹ abdominal discomfort,² and gastrointestinal adverse reactions, renal colic, and acute arthritis.³

The authors conclude that Chinese herbal medicines used alone or in combination with lipid-lowering drugs or lifestyle changes may have positive effects on reducing TG levels. However, no definite conclusions can be made based on the current evidence because of the unclear risk of bias in the included studies and lack of reporting on long-term outcomes. The relatively small sample sizes and trial heterogeneity also limit extrapolation.

In spite of due diligence in searching out relevant studies, the authors recognize that there may be trials with negative results that have not been published. For future research, it is recommended that characterizations of herbal treatments and study endpoints be meticulous and that standardized monitoring and reporting be conducted with an emphasis on patient important long-term outcomes.

—Amy C. Keller, PhD

References

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