



A randomized placebo controlled trial of an innovative herbal formula in the prevention of atherosclerosis in postmenopausal women with borderline hypercholesterolemia



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Summary

Background: Danshen (*Salvia miltiorrhiza*) and Gegen (*Radix puerariae*) (D&G) are two herbs frequently used for the treatment of angina and other cardiac symptoms in Chinese *materia medica*. Recent studies have demonstrated their cardio-protective and anti-atherosclerosis effects. Earlier we have conducted two clinical trials in 2004 and 2007 which demonstrated such effects in extremely high risk patients.

Study objective: The aim of the study was to demonstrate the safety and effectiveness of D&G in the prevention of atherosclerosis in postmenopausal women with early hypercholesterolemia.

Design: The study was designed as a randomized, double-blinded, placebo-controlled trial with a 12-month treatment period.

Subject: A population based sample of 165 postmenopausal women aged 47–65 were included in the trial. Only women who experienced menopause for more than 12 months were recruited.

Interventions: The eligible subjects were randomized to take the D&G preparation (two capsules), or image-identical placebo capsules (two capsules) daily, in a double-blind and parallel fashion for 12 month.

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Measurements: The postmenopausal women with mild hypercholesterolemia (mean age 56.5 ± 4.1 of treatment group and 56.0 ± 3.8 years of placebo group) were randomized to the D&G group or placebo group for trial treatment. Carotid intima-media thickness (IMT) was used as the surrogate marker and was measured using high resolution ultrasound. Lipid profile was also tested.

Results: Baseline characteristics were comparable between the two groups. After 12 months, there were no significant changes in the blood pressures and general biochemical profiles in both groups, however, there was a remarkable decrease in serum low density lipoprotein (LDL) cholesterol (-6.92%) and total cholesterol (TC) (-5.85%) in the D&G group compared with the placebo group (-3.21% and -3.42%) when compared with the baseline. The carotid intima-media thickness (IMT) decreased 1.52% from baseline in the D&G group ($p < 0.004$) but the decrease was only 1.13% in the placebo treatment group ($p = 0.009$) after 12 months treatment. Twelve adverse events were reported (six in placebo group and six in D&G group) but none of them was directly relevant to the study herbal preparation.

Conclusions: Postmenopausal women with early hypercholesterolemia tolerated D&G well. D&G improved the carotid intima thickness, lowered LDL and total cholesterol. D&G therefore can be recommended for the prevention of atherosclerosis in postmenopausal women with hypercholesterolemia.

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Introduction

Salvia miltiorrhiza and *Puerariae lobata* (D&G) are two medicinal herbs (Traditional Chinese Medicine, TCM) used for the control of angina and some other cardiac symptoms in the Chinese *materia medica*. Completed pharmacological studies suggested that these herbs could control high blood pressure, lower serum lipids, and improve microcirculation.^{1,2} Two clinical trials on patients with ischaemic heart disease and hypertension had been completed in our institute using carotid intima thickness as surrogate markers.^{2,3,30} We hypothesized that this herbal mixture was effective in lowering serum LDL cholesterol, improving endothelial function and lowering carotid intima media thickness (IMT) in postmenopausal women with borderline hypercholesterolemia with or without hypertriglyceridemia.

Menopause is associated with a more rapid increase in serum LDL and triglyceride, and a decline in HDL, which put them at risk of atherosclerosis, ischaemic heart disease and cerebrovascular disease in later life.⁴ Prevention of this progressive process is important for postmenopausal women with hypercholesterolemia.

The causal link between serum LDL and atherosclerosis has been well accepted and evidenced based guidelines on the use of statin for hypercholesterolemia are plentiful.⁵ Statin was recommended for those with LDL > 4.9 mmol/L, but was optional for those between 3.5 mmol/L and 4.9 mmol/L. For this latter group, attention was advised to be focused on lifestyle modification, e.g. healthy diet and physical exercises, rather than taking medication.⁶ Besides, reported that the benefit of statins is indisputable, but they need to be taken with care and knowledge of their side effects e.g. the potential for muscle damage and the risk of diabetes should be noticed. A safe nutritional supplement which retards the process of atherosclerosis for those at risk could be welcome.

Current strategies recommended for the control of atherosclerotic risks include quitting smoking, perfect

control of hypertension, diabetes mellitus, and obesity, while other novel means to improve *folate*,⁷ *homocysteine*,⁸ and to control pro-inflammatory markers⁹ are emerging. Danshen (*S. miltiorrhiza*) and Gegen (*Radix puerariae*) have long been used for patients suffering from angina and other cardiac symptoms in the Chinese *materia medica* and related literatures.^{10–15}

The purpose of this study was to investigate the efficacy of D&G when used among menopausal women with regard to their cardiovascular health on a long-term consumption of 1 year.

Methods

This was a 12-month randomized, controlled study on postmenopausal women receiving either D&G or placebo capsules. The primary objective was to evaluate the efficacy of D&G capsules on the prevention of atherosclerosis in the selected postmenopausal women with early hypercholesterolemia from baseline to the end of treatment as compared with placebo. The secondary objectives included the lipid profile, and the quality of life. The eligible subjects were clinically assessed and invested with B-mode ultrasonography on their carotid arteries.

Clinical assessment included sitting blood pressure, resting electrocardiogram (ECG), and physical Activity Scale for the Elderly questionnaire.¹⁶ Fasting blood was taken for serum glucose, creatinine, LDL, HDL, triglyceride, liver and renal functions. Those with fasting serum LDL ≥ 3.5 mmol/L and < 4.9 mmol/L were included. Those with persistent hypertension ($> 140/90$), significant ischaemic ECG changes, fasting serum glucose > 7.0 mmol/L, creatinine > 100 μ mol/L, or triglyceride > 11.3 mmol/L were excluded.

The eligible subjects were randomized to take D&G or placebo capsules daily, in a double-blind and parallel fashion for 12 months. Clinical visits for progress and tolerability monitoring were arranged at 12 weekly intervals. Blood

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