

## CLINICAL STUDY

## Effect of Shoushen granule on arterial elasticity in patients with carotid atherosclerosis: a clinical randomized controlled trial

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### Abstract

**OBJECTIVE:** To investigate the effectiveness of Shoushen granule, Chinese herbal preparation, on carotid artery elasticity in patients with carotid atherosclerosis.

**METHODS:** The total of 156 carotid atherosclerosis patients were randomly divided into the interven-

tion group (83 cases, treated with Shoushen granule) and the control group (73 cases, treated with pravastatin). Brachial-ankle pulse wave velocity (baPWV) and Ankle-Brachial Pressure Index (ABI) were measured by automated arteriosclerosis detector. The changes of common carotid artery intima-media thickness (IMT) and parameters of the carotid artery elasticity in patients, including stiffness parameter ( $\beta$ ), pressure-strain elastic modulus (Ep), arterial compliance (Ac), augmentation index (AI), and pulse wave velocity  $\beta$  (PWV $\beta$ ) were detected by Echo-Tracking (ET) technique before and after 24 week treatment. In the meantime, levels of blood lipid, and liver and renal function were measured respectively.

**RESULTS:** After 24 weeks, baPWV, IMT and parameters of the carotid artery elasticity ( $\beta$ , Ep, AI and PWV $\beta$ ) were markedly decreased in intervention group compared with those of before treatment ( $P < 0.01$ ), but the level of Ac was increased significantly ( $P < 0.01$ ). And there were no significant differences compared with control group on the same period ( $P > 0.05$ ).

**CONCLUSION:** In this pilot study, it was demonstrated ET technology and automated arteriosclerosis detector could be used to evaluate carotid artery elasticity effectively, and the action of Shoushen granule on carotid atherosclerosis might be related to the regulation of carotid artery elasticity.

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**Key words:** Carotid artery diseases; Elasticity; Pulse wave analysis; Randomized controlled trial; Echo-tracking technique; Shoushen granule

## INTRODUCTION

Atherosclerosis is a condition characterized by vessel wall thickening that occurs over decades. Ultimately the process becomes clinically manifest as acute cardiovascular events in many individuals. Atherosclerosis underlies the vast majority of cardiovascular disease and cause death and disability. Arterial stiffness is a functional change of arteries, as opposed to arterial wall thickening, which is a morphological change.<sup>1</sup> Arterial stiffness is one aspect of atherosclerosis, and affects the morbidity and mortality associated with cardiovascular diseases.<sup>2</sup> Increased arterial stiffness is an independent risk marker of premature coronary artery disease, atherosclerosis, and cardiovascular mortality.<sup>3</sup> The measure of common carotid artery intima-media thickness (IMT) has been extensively used as an early marker of atherosclerosis in epidemiologic and clinical studies.<sup>4</sup> Longitudinal studies showed that increased IMT predicts carotid plaque occurrence<sup>5</sup> and stroke.<sup>6</sup> However, IMT only provides information about vessel anatomy, other important aspects of atherosclerosis related to vessel function, such as wall composition of stiffness, can also be studied in atherosclerosis with other noninvasive technique. In addition, carotid artery dilatation indicates compensatory vascular mechanism and is found in early stages of atherosclerosis.<sup>7</sup> PWV is a rather mature and classic method for measuring arterial stiffness. Measuring arterial PWV, which reflects the elasticity of the arterial wall between two points, is highly accurate and repeatable. Ultrasound Echo-Tracking (ET) technology has also become widely used for evaluating carotid stiffness in scientific research. Echo tracking systems, especially high resolution ones, may provide easy to measure local arterial stiffness parameters in the detection of early functional arterial changes that precede vascular structural remodeling. Echo tracking also provide reliable measurements of lumen size, distensibility, wall thickness, and the presence of atheroma in large arteries.<sup>8</sup>

Traditional Chinese Medicinal (TCM) usually is used to restore the balance of *Yin-Yang* of body energy so that the body's normal function and homeostasis is maintained. TCM has been widely used in the clinical practice for preventing atherosclerosis with less side-effect.<sup>9</sup> Method of reinforcing kidney, in terms of TCM theory, is therapeutical principle for the treatment of atherosclerosis.<sup>10</sup> Previous research indicated that Shoushen granule was effective for preventing atherosclerosis.<sup>11,12</sup> In this study, we aimed to investigate the possible mechanism underpinned the anti-atherosclerosis action of Shoushen granule.

## MATERIALS AND METHODS

### Subjects

All the participants were recruited from those attending the Shanghai Municipal Hospital of TCM, Depart-

ment of Gerontology specialist out-patient clinics of atherosclerosis, from June 2011 to June 2012. The study was approved by The Ethics Committee of Shanghai Municipal Hospital of Traditional Chinese Medicine and was performed in accordance with the principles outlined in the Declaration of Helsinki. The informed consent was obtained from all patients.

### Inclusion and exclusion criteria

The diagnosis of carotid atherosclerosis was based on clinical history and the guidelines.<sup>13</sup> To be included in the study, all patients had to have IMT  $\geq$  0.9 mm and brachial-ankle pulse wave velocity (baPWV)  $>$  1400 mm/s. Other inclusion criteria included an age of 45 to 65 years old. Patients were excluded if they had any of the following: (a) who did not fit the above diagnosis; (b) not signed the informed consent ; (c) with acute injury of liver and renal functions; (d) with acute myocardial infarction, major surgery to cerebral vessels, or severe accidental damage in the previous 12 months; (e) with peripheral arterial disease (PAD); (f) who were on medication for lipid management; (g) at pregnancy and lactation; (h) serious blood disease; (i) psychiatric disorder.

### Study design and intervention

The study was designed as an open, single-center randomized controlled trial including two parallel groups. After the eligible screening visit, participants entered a 2-week run-in phase: blood samples were obtained at baseline by our research nurse and checked by Shanghai Municipal Hospital of Traditional Chinese Medicine. Baseline data including blood lipid, liver and renal function tests, fasting blood sugar and creatine phosphokinase, were collected. After the run-in phase, block randomization method was applied, and patients were randomly divided by a random table into intervention group and control group with Version 9.0 (SAS Institute Inc., Cary, NC, USA). Groups were allocated randomly according to outpatient serial number paired with random number table. Intervention group, 31 males and 52 females, was treated with Shoushen granule, a recipe of TCM for reinforcing kidney in terms of TCM's theory. Patients were instructed to dissolve a sachet of granule (6.2 g) in 200 mL of hot water, they took this solution orally twice daily for 24 weeks. Control group, 25 males and 48 females, was treated with Pravastatin (a drug for lipid regulation and anti-atherosclerosis), for which each tablet consisted 10 mg Pravastatin Sodium. Patients were instructed to take 1 tablet once daily for 24 weeks. The baseline characteristics of the two groups of patients are shown in Table 2. In this pilot study, all patients were not treated by any other complementary and/or alternative treatment such as other traditional Chinese medicine including acupuncture, and excluded were those who had taken medicines for lipid management.

### Drugs and Shoushen granule

Pravastatin Sodium was manufactured by Sino Ameri-

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