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Essential hypertension treated by wuling powder and modified tianma gouteng decoction: A cohort study without controls

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KEYWORDS
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Summary
Objective: To evaluate the efficacy and safety of wuling powder and modified tianma gouteng decoction as an open add-on therapy for treating essential hypertension (EH).
Methods: 72 cases of EH patients took wuling powder and modified tianma gouteng decoction for 2 weeks to treat EH without changing their former medication. New York Heart Association (NYHA) heart function classification, heart rate, blood pressure and 6-min walking test were evaluated before and after treatment.
Results: Wuling powder and modified tianma gouteng decoction decreased the EH patients' heart rate, systolic pressure, diastolic pressure and increased the 6-min walking distance very significantly ($P < 0.01$). The total effective rate on blood pressure was 91.7%, and the total effective rate on NYHA heart function improvement was 95.1%. No serious side effect appeared.
Conclusion: From this study, treating EH with wuling powder and modified tianma gouteng decoction as an open add-on therapy seems to be effective and safe. Further randomized trials are needed to test the positive findings.

Introduction

Blood pressure above 140/90 mmHg is defined as hypertension. Essential hypertension, also known as primary hypertension, consists of 90—95% of hypertension patients. Genetic and environmental factors may interact to raise blood pressure.[1]

Hypertension has been affecting more and more people in the world and is the primary risk factor for mortality and morbidity since it may cause atherosclerosis, coronary heart disease, cerebrovascular diseases, as well as cardiac and renal failure etc.

Despite the antihypertensive medications such as thiazide-type diuretics, calcium channel blockers, beta blockers, direct renin inhibitors, angiotensin-converting

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enzyme inhibitors, and angiotensin II receptor blockers, about two thirds of patients receiving treatment still do not reach the modest goal of <140 mmHg/90 mmHg. EH is a chronic, lifetime disease needing to search for alternative and complementary treatment.[2]

Chinese herbal medicine has been used to treat hypertension-related symptoms for over 2000 years. Tianma gouteng decoction is widely used to treat EH. One study concludes that it can lower blood pressure, reduce total cholesterol, improve clinical symptoms and quality of life, and prevent the occurrence of stroke in hypertensive patients.[3] One experimental study in rats shows: Wuling powder also can lower blood pressure, induce diuresis, excrete liquids and eliminate edema, especially good for treating essential hypertension with chronic heart failure.[4]

In western medicine, it is common practice for patients who have already administered antihypertensive medications to increase numbers of antihypertensive drugs to control still elevated blood pressure. The add-on effect of the added drug is still considered to be effective if blood pressure finally attains normal range, no matter how many/what kinds of western medications have already been used before. And it is unethical to give placebo or no treatment to hypertensive patients, especially to those with elevated blood pressure and chronic heart failure. So we hypothesize that it is beneficial and convenient to use both wuling powder and tianma gouteng decoction as an open add-on therapy for treating EH and it can still demonstrate whether it is effective or not even without setting up control group.

To evaluate the efficacy and safety of wuling powder and tianma gouteng decoction as an open add-on therapy for treating EH, we collected 72 cases of EH patients to have taken wuling powder and modified tianma gouteng decoction for 2 weeks to treat EH without changing their former medication. Here is our report.

Materials and methods

Inclusion criteria

The patient according with all of the following list should be included: (1) In accord with the diagnostic criteria for essential hypertension[5] (2) Age ≥35 years (3) Have been administering antihypertensive medications for at least 3 months without changing (4) Systolic pressure (SP) ≥140 mmHg or/and diastolic pressure (DP) ≥90 mmHg (5) Willing to administer Chinese Medicine as an open add-on therapy.

Exclusion criteria

The patient according with any one of the following list should be excluded: (1) Secondary hypertension (2) Age <35 years (3) Gestational hypertension (4) Have been administering antihypertensive medications for less than 3 months or have changed medication within 3 months (5) SP<140 mmHg and DP<90 mmHg (6) Unwilling to administer Chinese Medicine as an open add-on therapy.

Subject of study

The patients were outpatients who came to consult Chinese medicine practitioner for better control. They had already administered antihypertensive drugs and were willing to administer Chinese Medicine as an open add-on therapy. So no one withdrew. 72 cases of EH patients with heart function ranging from NYHA classification I to IV were included. With 38 male and 34 female cases, the average age was 62.3 ± 13.1 years. 11 cases belonged to NYHA heart function classification I; 20, II; 23, III and 18, IV.

Treatment methods

All EH patients took wuling powder and modified tianma gouteng decoction for 2 weeks without changing their former medication. Formula: Poria 12 g, Polyporus 12 g, Rhizima Atractylodis Macrocephalae 12 g, Rhizoma Alismatis 12 g, Ramulus Cinnamomi 12 g, Rhizoma Gastrodiae 15 g, Gastradia Tuber 15 g, Loranthi Ramulus 15 g, Gardeniae Fructus 15 g, Haliotidis Concha 15 g, Caulis Polygoni Multiflori 15 g, Eucommiae Cortex 15 g, Herba Leonuri 15 g, Cyathulae Radix 30 g, Scutellariae Radix 12 g, Radix Astragali 15 g, Radix Puerariae 15 g, Radix Rehmanniae 15 g, Spica Prunellae 15 g, Herba Siegesbeckiae 15 g, Radix Stephaniae Tetrandrae 15 g.

One dose per day, decoct for about 35 min to produce 300—400 ml decoction, divide into two times daily oral administration.

Indexes measurement

NYHA heart function classification, 6-min walking test (6MWT), heart rate (HR), SP, DP were evaluated before and after treatment according to methods provided by the book and guidelines.[5–7] NYHA heart function classification, 6MWT were evaluated during 8:00—12:00 am; HR, SP, DP were measured by electronic measuring device two times a day (8:00—9:00 am and pm), taking the mean values.

Criterion of therapeutical effect on blood pressure

The criterion is exactly based on ''Guideline for clinical research on new drug of Chinese Medicine treating essential hypertension'' which forms one chapter of a book called ''Guidelines for clinical research on new drug of Chinese Medicine'' compiled by State Food and Drug Administration of China.[6] Markedly effective: one of the followings. (1) DP decreases ≥10 mmHg and returns to normal; (2) DP decreases ≥20 mmHg and does not return to normal. Effective: one of the followings. (1) DP decreases <10 mmHg and returns to normal; (2) DP decreases ≥10—19 mmHg and does not return to normal. (3) SP ≥30 mmHg. Ineffective: the above criteria had not been met. Total effective rate was the combination of markedly effective rate and effective rate.

Criterion of therapeutical effect on heart function

The criterion is exactly based on ''Guideline for clinical research on new drug of Chinese Medicine treating