Clinical research on shengjie tongyu granules in the treatment of meteorological cardiovascular disease

Guangyu Zhai[12], Jiyuan Dong[3], Shigong Wang[1]* and Kezheng Shang[1]
[1]College of Atmospheric Science, Lanzhou University, Lanzhou, China
[2]College of Software, Lanzhou Institute of Technology, Lanzhou, China
[3]School of Public Health, Lanzhou University, Lanzhou, China

Abstract: This paper aims to study the effect of Shengjie Tongyu granules on the treatment of meteorological cardiovascular disease in clinical treatment. Tongxinluo capsule that is clinically recognized as the effective drug in treating coronary heart disease and angina and was adopted as positive control. The results showed that, angina score and TCM score of two groups were all significantly improved after the treatment ($P<0.01$), but there was no statistical significance in comparison between groups ($P>0.05$); total effective rate of angina in the treatment group (77.78%) was superior than the control group (62.52%) after the treatment; but the difference had no statistical significance ($P>0.05$); total effective rate of TCM syndrome in the treatment group (75%) was superior than the control group (58.62%), and the difference had statistical significance ($P<0.05$). All these findings suggested that, Shengjie Tongyu granules can effectively improve the clinical symptoms of patients with coronary heart disease and angina, with the curative effect similar to Tongxinluo capsule; meanwhile, it can increase HDL-C and improve abnormal lipid metabolism of angina patient. In the treatment process, there is no significant untoward effect, blood, routine urine test and hepatorenal function have no abnormality, which proves that this drug is safe.

Keywords: Coronary heart disease and angina, Shengjie Tongyu granules, TCM syndrome.

INTRODUCTION

Coronary heart disease (CHD) results from myocardial ischemia caused by atherosclerosis of coronary artery. Angina is one of the most common cardiovascular diseases (CVD). Atherosclerosis of coronary artery in relative degree can influence myocardial blood supply; when imbalance of myocardial oxygen supply and demand causes myocardial anoxia, angina appears (Chunyan *et al.*, 2010). In recent years, researches on TCM syndrome of angina indicate that, qi deficiency and blood stasis is the main syndrome type of angina (Dapeng, 2012). Shengjie Tongyu granules is the empirical formula of the national famous old Chinese Prof. Shi Zaixiang, mainly including astragalus, chinonin, platycodon grandiflorum, cimicifugae foetidae, radix bupleuri, codonopsis pilosula, trigone, pulp of dogwood fruit, leonurus, with functions of invigorating qi and ascending qi collapse, removing blood stasis. Clinically, it is usually used for treating differentiation qi collapse and blood stasis such as CHD, angina, chronic cardiac failure, arrhythmia, viral myocarditis, cardiomyopathy, etc (Chunyan *et al.*, 2011; Yue *et al.*, 2012; Chunyan, 2013). Other scholars through observing the effect of Shengjie Tongyu granules on hemorheology of rat acute blood stasis model, proved that, Shengjie Tongyu granules can improve hemorheology in rat acute blood stasis model, inhibit platelet aggregation rate, protect rat experimental acute myocardial ischemia. This paper observed the clinical effect of Shengjie Tongyu granules on patients with CHD, angina, qi deficiency and blood stasis with randomized control method.

**Corresponding author:* e-mail: wsglzdx@163.com

MATERIALS AND METHODS

Clinical materials

A total of 65 cases were divided into groups by random number table. Treatment group and control group was assigned in ratio of 1:1. There were 36 cases in treatment group, including 25 males and 11 females, ranging in age from 46 to 78 years (mean 66.46±9.42 years); the course of disease was 0.5 to 20 years (mean 7.6 years); there were 28 cases of high blood pressure, 6 cases of diabetes, 19 cases of hyperlipidaemia. There were 29 cases in control group, including 19 males and 10 females, ranging in age from 41 to 79 years (mean 61.80±9.76 years); the course of disease was 0.3 to 17 years (mean 7.1 years); there were 17 case of high blood pressure, 7 case of diabetes, 14 cases of hyperlipidaemia. Two groups of patients had no statistical significance in gender, age, course of disease, degree of angina, and had comparability. This study was approved by Ethic Committee of the Lanzhou University. Patients have provided their written informed consents.

Diagnostic criteria, Inclusion criteria, Exclusion criteria and elimination criteria

Western medicine diagnostic criteria of CHD and stable angina refers to Name and Diagnostic Criteria of Ischemic Heart Disease of College of Cardiology. Chinese medicine diagnostic criteria of CHD and stable angina

refers to Guidance for New Traditional Chinese Medicine Clinical Research (Jinhang *et al*., 2012; Chunyan and Zaixiang, 2011).

Inclusion criteria, exclusion criteria and elimination criteria refers to Blood Stasis and Diagnosis and Treatment Consensus of Traditional Chinese Medicine Combined with Western Medicine (Jinhang and Zaixiang, 2011).

Administration methods

The treatment group was given Shengjie Tongyu granules, for 1 bag/ time, 3 times/day, 4 weeks. The control group was given Tongxinluo capsule, for 4pills/time, 3 times/day, 4 weeks.

Observation index

Angina: observe the attack times of angina, time of duration, pain degree and dosage of nitroglycerin before and after the treatment; adopt score method; Electrocardiogram: observe electrocardiogram before and after the treatment. Cases that were recruited because of showing positive in sub maximal exercise test were required to do sub maximal exercise test when the research stops; TCM syndrome: observe the change of TCM before and after the treatment; adopt score method; Blood fat: observe the change of blood fat before and after the treatment; measure TC and HDL-C using cholesterol oxidase method; measure TG using glycerol lipase oxidase (GPO-PAP) method; calculate LDL-C by TC-HDL-C-TG/2.2; Heart rate, blood pressure and safety index: measure heart rate, blood pressure, routine of blood, urine and stool, liver function and renal function, etc..

Assessment criteria of curative effect

Angina and electrocardiogram curative effect was formulated by referring to Guidance for New Traditional Chinese Medicine Clinical Research.

Curative effect criteria of angina

Level 1: Obvious effect: symptoms all disappear or basically disappear; effective: attack times, degree and duration time of angina has significant decrease; ineffective: Symptoms are the same as before the treatment; aggravated: attack times, degree, duration time of angina become worse (or reach the criteria of medium and severe degree). Level 2: obvious effect: symptoms all disappear or basically disappear; effective: Symptoms reduce to criteria of mild degree; ineffective: Symptoms are the same as before the treatment; aggravated: attack times, degree and duration time of angina become worse (or reach the criteria of severe degree). Level 3: Obvious effect: symptoms disappear or basically disappear, or reduce to the criteria of mild degree; Effective: symptoms reduce to the criteria of medium degree; Ineffective: symptoms are the same as before the treatment; aggravated: Attack times, degree and duration time become worse.

Curative effect criteria of electrocardiogram

Obvious effect; electrocardiogram restores to generally normal or normal; effective: S-T segment decreases; a recovery of more than 0.05 mV after the treatment but it does not reach the normal level; Main T wave inversion becomes shallow (more than 25%) or T wave turns from flat to erect; atrioventricular or intraventricular blocks improve; ineffective: Electrocardiogram is the same as before the treatment; aggravated: S-T segment decreases more than 0.05mV compared with before the treatment; main T wave inversion becomes deeper (more than 25%) or erect T wave becomes flat, flat T wave becomes inverted; Ectopic cardiac rhythm, atrioventricular or intraventricular blocks appear.

Assessment of TCM syndrome curative effect

The curative effect is assessed according to the change of score before and after the treatment curative effect index (n) =(score before the treatment- score after the treatment)/ score before the treatment ×100%. Obvious effect: n>70%; Effective: n=30%~70%; ineffective: n> 30%.

Statistical processing

Analysis was performed using DAS1.0. Measurement data adopted t test and pair T test. Counting data was tested using updated X^2 test. Ranked data adopted Ridit analysis.

RESULTS

Comparison of angina scores of two groups before and after the treatment

Through comparison of scores before and after the treatment, we found that, the difference had statistical significance (P<0.01). In comparison of angina scores of two groups after the treatment, the score of the comparison group was significantly smaller than that of the control group, and the difference had statistical significance (P<0.05). It is shown in table 1.

Table 1: Comparison of angina scores of two groups before and after the treatment (point, Mean ±SD)

Group	N	Before treatment	After treatment
Treatment group	36	10.17±3.71	3.83±3.26*
Control group	29	9.86±2.82	6.14±4.63*

Note: compared with before treatment, *P<0.01; compared with after treatment, P<0.05.

Comparison of angina curative effect of two groups

The comparison of angina curative effect of the treatment and control group showed that, two groups both had significant curative effect, but the treatment group was

Table 2: Comparison of angina curative effect of two groups

Group	N	Obvious effect (case)	Effective (case)	Ineffective (case)	Aggravated (case)	Total effective rate
Treatment group	36	13	15	8	0	77.78%
Control group	29	9	10	8	2	65.52%

Table 3: Comparison of electrocardiogram of two groups

Group	N	Obvious effect (case)	Effective (case)	Ineffective (case)	Aggravated (case)	Total effective rate
Treatment group	36	2	17	15	2	52.78%
Control group	29	5	12	12	0	58.62%

significantly higher than the control group, with total effective rate of 77.78%. The difference between two groups had no statistical significance (P>0.05). It is shown in table 2.

Comparison of electrocardiogram of two groups

The total effective rate of electrocardiogram in the control group (58.62%) was slightly higher than that of the treatment group (52.78%). The difference between two groups had no statistical significance, as shown in table 3.

Comparison of TCM scores of two groups before and after the treatment

The difference of two groups before the treatment had statistical significance (P<0.01) while the difference after the treatment had no statistical significance (P>0.05), as shown in table 4.

Table 4: Comparison of TCM scores of two groups before and after the treatment (point, Mean ±SD)

Group	N	Before treatment	After treatment
Treatment group	36	14.39±5.28	7.83±3.84*
Control group	29	14.07±5.03	9.03±4.65*

Comparison of TCM syndrome curative effect of two Groups

In comparison of TCM syndrome curative effect, total effective rate of TCM syndrome in the treatment group was75% while the control group was 58.62%. The difference had no statistical significance (P>0.05). It is shown in table 5.

Comparison of blood lipid level of two groups before and after the treatment

HDL-C of the treatment group increased after the treatment compared with before the treatment, and the difference had statistical significance (P<0.05). The difference of blood lipid indexes such as TC, TG and LDL-C before and after the treatment had no statistical significance. The difference of blood lipid indexes in the control group before and after the treatment had no statistical significance. It is shown in table 6.

Safety assessment

Blood, urine and stool routine, hepatorenal function of the treatment and control group before and after the treatment had no abnormal change and obvious untoward effects.

DISCUSSION

Generally, traditional Chinese medicine holds that, CHD falls into the category of chest obstruction, angina pectoris, precordial pain with cold limbs (Jinhang and Zaixiang, 2011; Chong *et al*., 2013). In recent years, with the deepen of pathogenesis research of angina, it is believed that, qi deficiency and blood stasis is its fundamental pathologic change, which has been drawn the attention. Based on that, Prof. Shi Zaixiang proposed angina pathogenesis theory of CHD-qi collapse and blood stasis, and advocates to treat CHD with Shengjie Tongyu (Chunyan and Zaixiang, 2013). Shengjie Tongyu granules is exactly the prescription created according to this theory, with the functions of tonifyting qi and Shengjie, activating blood and dispersing blood stasis. Experimental research indicated that, Shengjie Tongyu granules can improve hemorheology, inhibit platelet aggregation (Lei and Peng, 2012; Gang *et al*., 2008) and resist free radical injury, thus to perform function of resisting myocardial ischemia (Xiaopeng *et al*., 2010; Yunchang *et al.*, 2008). Meanwhile, Shengjie Tingyu decoction can decrease malignant arrhythmia in period of myocardial ischemia and improve cardiac function. This study adopted Tongxinluo that is recognized as the effective drug for treating CHD and angina in clinic as the positive control. Research indicated that (Yunchang *et al*., 2008), total effective rate and (77.78%) TCM syndrome (75%) of angina in the treatment group after the treatment was superior than the control group (65.52% and 58.32%, respectively), but the difference had no statistical significance (P>0.050); difference of total score for angina of two groups after the treatment had statistical

Table 5: Comparison of TCM syndrome curative effect of two groups

Group	N	Obvious effect (case)	Effective (case)	Ineffective (case)	Total effective rate
Treatment group	36	5	22	9	75%
Control group	29	5	12	12	58.62%

Table 6: Comparison of blood lipid of two groups before and after the treatment (mmol/L, Mean ±SD)

Blood lipid	Group	N	Before treatment	After treatment
TC	Treatment group	36	4.49±1.33	4.57±1.20
	Control group	29	4.47±1.20	4.40±1.14
TG	Treatment group	36	1.47±0.85	1.50±0.74
	Control group	29	2.17±1.28	1.88±0.96
HDL-C	Treatment group	36	1.19±0.27	1.25±0.29*
	Control group	29	1.18±0.35	1.16±0.37
DHL-C	Treatment group	36	2.47±1.19	2.53±0.75
	Control group	29	2.51±0.86	2.38±0.85

Note: compared to before the treatment, *P<0.05

significance (p<0.05). These findings suggest that, Jiesheng Tongyu granules can improve TCM syndrome score, and has curative effects on treating CHD and angina. In addition, Shengjie Tongyu granules can increase HDL-C and improve lipid metabolic disease. Moreover, there is no obvious untoward effects and blood, urine routine and hepatorenal function detection are all normal, which proved that this drug is quite reliable.

CONCLUSION

To sum up, Shengjie Tongyu granules with various kinds of Chinese medicine as main ingredients is a kind of Chinese herbal medicine compound preparation that can tonify qi, activate blood and detoxify and can be used in clinic for treating qi collapse, chest distress, chest pain, short of breath, lacking in strength caused by blood stasis like chills and fever, phlegm stagnation. It is known that Shengjie Tongyu granules can tonify qi, activate blood, detoxify and lucidity through clinical research and analysis.

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