
Clinical study on wenmaitongguan decoction combined with Moxibustion in the treatment of lower extremity arteriosclerosis obliterans

GE Fuxu^{1#}; WANG Jingbao^{1*}; LIU Laijie¹; LI Wansheng¹; ZHAO Bin

¹Shouguang Hospital of traditional Chinese Medicine, Shouguang, shandong province, China

262700 [#]Gefuxu is first author ^{*}WANG Jingbao is the corresponding author,

Email: wangjingbao040@126.com; <https://orcid.org/0000-0001-8463-0656>

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Objective To explore the efficacy of wenmaitongguan decoction combined with Moxibustion in the treatment of lower extremity arteriosclerosis obliterans.

Methods From January 2020 to January 2021, 150 patients with lower extremity arteriosclerosis obliterans were randomly divided into treatment group (76 cases) and control group (74 cases). The treatment group was treated with wenmaitongguan decoction combined with moxibustion, and the control group was treated with alprostadiil. The clinical efficacy, the distance of intermittent claudication, brachial femoral index, no, endothelin-1 and inflammatory factor (TNF- α , CRP) were compared between the two groups before treatment, 7 days and 4 weeks after treatment.

Results 1. There was no difference in vascular endothelial function before treatment ($P > 0.05$); The level of ET-1 in the treatment group was significantly lower than that in the control group at 7 days and 4 weeks after treatment ($P < 0.05$), while the level of no in the treatment group was significantly higher than that in the control group ($P < 0.05$). 2. The level of ABI and intermittent claudication at 7 days and 4 weeks after treatment were significantly improved ($P < 0.05$), The difference was statistically significant ($P < 0.05$). 3. Tumor necrosis factor (TNF- α) in two groups. Comparison of C-reactive protein (CRP), before treatment, There was no difference in CRP, TNF- α ($P > 0.05$); The level of water in the treatment group was significantly lower than that in the control group 7 days and 4 weeks after treatment ($P < 0.05$). Conclusion: wenmaitongguan decoction combined with moxibustion can

alleviate clinical symptoms by reducing vascular endothelial injury, reducing vascular endothelial inflammatory reaction, restoring vascular tension, expanding peripheral blood vessels and improving peripheral microcirculation.

Keywords Wenmaitongguan Decoction; Arteriosclerosis obliterans of lower limbs; Blood tumor necrosis factor (TNF- α); C-reactive protein (CRP); Endothelin-1 (ET-1), nitric oxide (no); Brachial femoral index

Arteriosclerosis obliterans (ASO) of lower limbs is a common senile disease. It is mainly characterized by intermittent claudication, gradually progressing to resting pain, accompanied by weakening or disappearance of dorsalis pedis artery pulsation. In severe cases, gangrene of lower limbs may occur. If the treatment is not timely, amputation or death may occur^[1]. The main etiology is the pathophysiological changes such as intimal changes and inflammatory reaction of lower extremity arteries, which leads to chronic ischemic diseases with narrow or even occluded lower extremity arteries. With the development of aging society, the incidence rate is increasing year by year. The incidence rate of people over 70 is 15%-20%. There are many treatments for this disease, but there is no obvious effect in treatment.^[2], therefore, timely detection and early treatment can improve the quality of life and prevent the occurrence of adverse events. Traditional Chinese medicine believes that lower extremity arteriosclerosis obliterans cause qi stagnation and blood stasis and blood stasis due to the invasion of cold evil. Qi stagnation and blood stasis are the main contradiction of the disease. Therefore, in treatment, we should pay attention to regulating blood gas and dredging blood vessels. Therefore, from January 2020 to January 2021, we studied the effects of wenmaitongguan decoction combined with Moxibustion on intermittent claudication distance, brachial femoral index, no, endothelin-1 and inflammatory factors in patients with lower extremity arteriosclerosis obliterans.

1. Data and methods

1.1 general information

1.1.1 diagnostic criteria of Western medicine:

- (1) Age > 40 years old
- (2) There are manifestations of chronic limb arterial ischemia: numbness, fear of cold, intermittent claudication, congestion, changes in nutritional disorders, and even ulceration or gangrene. It often occurs in the limbs, especially in the lower limbs.
- (3) There was systolic vascular murmur near the heart of the affected limb
- (4) There were stenosis and occlusive changes of limb arteries, and lesions above popliteal and femoral arteries of lower limbs were common.

(5) with hypertension, coronary heart disease, hyperlipidemia, diabetes, cerebrovascular arteriosclerosis and other diseases.

(6) Thromboangiitis obliterans, Takayasu arteritis, Raynaud's disease, cold injury vascular disease and other limb ischemic diseases were excluded.

1.1.2

TCM diagnostic criteria:

(1) Intermittent claudication: This is the most prominent symptom. It alleviates and disappears at rest, forming intermittent claudication; In severe cases, it causes resting pain, especially at night

(2) Cold hair and abnormal sensation: the affected limb is cold and afraid of cold, especially at the toe. It also has a sense of acupuncture, numbness or burning

(3) Skin color change: the skin color is pale or purplish red

(4) Nutritional deficiency changes: dry skin, scaling, hair loss, nail deformation and slow growth; The peripheral diameter of lower leg shrinks, muscle relaxes and shrinks; Toe thinning.

(5) Gangrene and ulcer: blackened, shriveled, dry gangrene and ulcer formation at the toe end of the affected limb

1.1.4 inclusion criteria:

(1) It meets the diagnostic criteria of Western medicine for arteriosclerosis obliterans of lower limbs;

(2) Meet the criteria of TCM symptoms;

(3) Age ≥ 40 years;

(4) The patient had informed consent and was willing to cooperate with oral traditional Chinese medicine treatment.

1.1.5 exclusion criteria:

(1) Incomplete data affect the judgment of curative effect;

(2) Under 40 years old;

(3) Patients who need to take aspirin or glucocorticoid for a long time;

(4) Serious organic diseases such as heart, brain, kidney and liver;

1.1.6 removal and falling off standards:

(1) Cases found not to use drugs according to the provisions of the trial scheme after inclusion shall be excluded;

(2) The included cases with serious adverse events and complications, which are not suitable to continue the test, withdraw from the test on their own or fail to complete the whole course of treatment, which affect the efficacy or safety judgment, shall be regarded as falling

off.

1.1.7 test termination criteria:

(1) Those who have allergic reaction or serious adverse reaction before the end of the course of treatment should stop the test;

(2) In case of serious complications, the trial was suspended.

1.2 treatment

The treatment group was given wenmaitongguan Decoction (one-day dose): Angelica 20g, asarum 20g, Guizhi 20g, chuanmutong 12g, roasted licorice 12g, red peony 20g and jujube 50g, all of which came from the Chinese medicine pharmacy of the hospital, 100ml boiled water, one dose a day, twice a day, and moxibustion Guanyuan and Zusani points once a day.

Alprostadil (Kaishi) (1ml: 5ug, gyzz z20080033, Liaoning AODA Pharmaceutical Co., Ltd.), once a day, 1ml (alprostadil 5ug) + 10ml normal saline, slow intravenous injection.

1.3 outcome measures: clinical efficacy, brachial femoral index, intermittent claudication distance, nitric oxide, endothelin-1 and TNF before treatment, 7 days and 4 weeks after treatment- α , CRP and other indicators. Serum tumor necrosis factor- α (TNF- α) The level and relevant operations are carried out in strict accordance with the instructions of the corresponding kit (TNF- α ELISA Kit (purchased from Quanzhou Ruixin Biotechnology Co., Ltd.), CRP, no and ET-1 were detected by automatic biochemical analyzer in the outpatient laboratory of Shouguang traditional Chinese medicine hospital.,

Clinical efficacy criteria

(1) After clinical recovery, the patient had intermittent claudication, resting pain, skin color, tongue coating and pulse, and the TCM clinical symptoms and signs disappeared or basically disappeared;

(2) After effective treatment, the patient had intermittent claudication, resting pain, skin color, tongue coating and pulse, and the TCM clinical symptoms and signs were significantly improved;

(3) After effective treatment, the patient's intermittent claudication, resting pain, skin color, tongue coating and pulse were improved;

(4) After ineffective treatment, the patient had intermittent claudication, resting pain, skin color, tongue coating and pulse, and the TCM clinical symptoms and signs were not significantly improved or aggravated.

Effective rate (%) = (clinically cured + markedly effective + effective) / total number of cases * 100%

2. Statistical method

The statistical software is processed by spss19.0 (statistics package of social science for windows 19.0), the measurement data is expressed by mean \pm standard deviation (), and the counting data is expressed by rate. The t-test of paired data was compared before and after treatment. The t-test of group data was used for inter group comparison. When the data did not meet the normality, the rank sum test was used. Inspection level $\alpha = 0.05$.

3. Results

3.1 comparison of curative effects between the two groups

Comparison of curative effects between the two groups, comparison of total effective rates at 7 days and 4 weeks after treatment, the total effective rates at 7 days and 4 weeks after treatment in the treatment group were significantly higher than those in the control group ($P < 0.01$) (Table 1)

Table 1 effective rates of the two groups after treatment (%)

| Group | n | Day 7 after | The 4th week |
|-----------------|----|-------------|-----------------|
| | | treatment | after treatment |
| Treatment group | 74 | 44.37 | 85.45 |
| control group | 76 | 37.24 | 62.19 |

The effective rates of the two groups were compared, $\chi^2 = 11.89$, $P < 0.05$

3.2 ankle brachial index (ABI) and intermittent claudication distance before and after treatment in the two groups

There was no difference in ABI and intermittent claudication distance between the two groups before treatment ($P > 0.05$); The levels of ABI and intermittent claudication distance 7 days and 4 weeks after treatment were significantly improved in each group compared with those before treatment ($P < 0.05$) (Table 2 and 3)

Table 2 ABI before and after treatment (ng/L, $\bar{x} \pm s$)

| Group | n | Before | Day 7 after | The 4th week |
|-----------------|----|-----------------|------------------|-------------------|
| | | treatment | treatment | after treatment |
| Treatment group | 74 | 0.54 \pm 0.19 | 0.63 \pm 0.17* | 0.67 \pm 0.54** |
| control group | 76 | 0.54 \pm 0.17 | 0.69 \pm 0.18 | 0.77 \pm 0.54 |

Note: comparison between groups: $P < 0.05$, * *

Table 3 intermittent claudication distance before and after treatment (cm, $\bar{x} \pm s$)

| Group | n | Before | | Day 7 after | The 4th week |
|-----------------|----|-----------|-----------|-----------------|-----------------|
| | | treatment | treatment | after treatment | after treatment |
| Treatment group | 74 | 255.72 | ± | 665.72 ± 29.78 | 885.72 ± |
| | | 30.78 | | | 25.78** |
| control group | 76 | 253.72 | ± | 545.72 ± 24.78 | 655.72 ± 25.78 |
| | | 30.68 | | | |

Note: comparison between groups: P < 0.05, **

3.3 vascular endothelial function indexes of the two groups before and after treatment

There was no difference in endothelin-1 (ET-1) and nitric oxide (no) between the two groups before treatment ($P > 0.05$); The levels of ET-1 in the treatment group were significantly lower than those in the control group 7 days and 4 weeks after treatment ($P < 0.05$), while the levels of no in the treatment group were significantly higher than those in the control group ($P < 0.05$) and ($P < 0.01$) (tables 4 and 5)

Table 4 no levels before and after treatment in the two groups (umol/L, $\bar{x} \pm s$)

| Group | n | Before | | Day 7 after | The 4th week |
|-----------------|----|-------------|-----------|-----------------|-----------------|
| | | treatment | treatment | after treatment | after treatment |
| Treatment group | 74 | 38.81 ± 4.5 | | 49.32 ± 4.2* | 62.2 ± 3.9** |
| | | | | | |
| control group | 50 | 36.76 ± 3.2 | | 39.56 ± 4.3 | 46.2 ± 4.0 |
| | | | | | |

注：组间比较，*: P<0.05, **: P<0.01。

Table 5 ET-1 levels before and after treatment in the two groups (ng/L, $\bar{x} \pm s$)

| Group | n | Before | | Day 7 after | The 4th week |
|-----------------|----|-------------|-----------|-----------------|-----------------|
| | | treatment | treatment | after treatment | after treatment |
| Treatment group | 74 | 32.72 ± 3.4 | | 21.32 ± 3.1* | 12.2 ± 1.9** |
| | | | | | |
| control group | 76 | 32.76 ± 3.2 | | 29.56 ± 3.3 | 24.2 ± 3.0 |
| | | | | | |

Note: comparison between groups: P < 0.05, **

3.4 inflammatory transmitter indexes of the two groups before and after treatment

Two groups of tumor necrosis factor (TNF- α)、Comparison of C-reactive protein (CRP), TNF before treatment- α 、There was no difference in CRP ($P > 0.05$); The level of water in each group was significantly improved compared with that before treatment ($P < 0.05$) 7 days and 4 weeks after treatment. The average water level in the treatment group was significantly lower than that in the control group ($P < 0.05$) and ($P < 0.01$) 7 days and 4 weeks after treatment (table 5 and 6)

Table 5 tumor necrosis factor before and after treatment (TNF- α) (pg/L, $\bar{x} \pm s$)

| Group | n | Before | Day 7 after | The 4th week |
|-----------------|----|------------|-------------|-----------------|
| | | treatment | treatment | after treatment |
| Treatment group | 74 | 253.5±27.3 | 170.8±25.3* | 116.8±22.2** |
| control group | 76 | 255.7±26.5 | 218.7±27.4 | 195.2±25.9 |

Note: comparison between groups: $P < 0.05$, **

Table 7 C-reactive protein (CRP) before and after treatment in the two groups (mg/L, $\bar{x} \pm s$)

| Group | n | Before | Day 7 after | The 4th week |
|-----------------|----|-----------|-------------|-----------------|
| | | treatment | treatment | after treatment |
| Treatment group | 74 | 25.5±7.3 | 17.8±5.3* | 4.8±2.2** |
| control group | 76 | 25.7±6.5 | 18.7±7.4 | 15.2±5.9 |

Note: comparison between groups: $P < 0.05$, **

4. Discussion

Lower extremity arteriosclerosis obliterans (ASO) is a common chronic disease in the elderly. Its pathogenesis is unknown. It is mostly considered to be the theory of vascular endothelial loss, smooth muscle cell proliferation and inflammatory response. Its pathological mechanism is that the disease starts from the intima of lower extremity arteries and is caused by the formation of lower extremity atherosclerotic plaque Inflammatory reaction and other mechanisms lead to degeneration and calcification of vascular intima, thickening and hardening of arterial wall, and then loss of elasticity, lumen stenosis and even occlusion. The main manifestations are intermittent claudication, gradually progressing to resting pain, accompanied by weakening or disappearance of dorsalis pedis artery pulse, and gangrene of lower limbs in severe cases, Amputation or death may occur if the treatment is not timely [3].

The treatment methods are mostly surgical treatment and drug treatment. The treatment direction is mainly to reduce blood viscosity, improve intima, expand blood vessels, inhibit platelet aggregation and inhibit thrombosis, so as to increase blood supply to lower limbs, improve microcirculation and reduce symptoms, so as to treat the disease. The study found that, The effect of Western medicine is poor. Traditional Chinese medicine believes that lower extremity arteriosclerosis obliterans mainly belongs to the category of "pulse arthralgia", and its pathogenesis is mainly due to blood gas stagnation and pulse stagnation. Its treatment methods are mainly: we should pay attention to regulating blood gas, dredging blood vessels, supplemented by treatment such as dredging collaterals [4]. In recent years, traditional Chinese medicine has achieved good results in the treatment of ASO and has become the most important means of ASO treatment.

The pathogenesis of "pulse arthralgia" is Qi stagnation and blood stasis, resulting in blocked veins of lower limbs and pain. Its main manifestation is intermittent claudication, followed by limb pain and discomfort, which further develops into resting pain; The veins are blocked, the blood gas is blocked, the Yang Qi is insufficient, and the cold air enters the limbs. It can be seen that the limbs are cold, and the muscles, veins and skin are not nurtured, which is manifested as numbness, thick nail and hair loss. [5] According to the<INNER CANON>, "when evil forces gather together, their Qi will be empty", the blood Qi is not smooth, Qi deficiency and blood stasis, the diseased skin is out of nourishment, and the numbness is aggravated; Qi loses Yang, Yang Qi is deficient, warmth loses division, cold evil invades internally, limb coolness aggravates, deficiency due to excess, forming a vicious circle and persistent diseases [6]. Therefore, on the basis of previous studies, we continue to innovate. According to the theory of "same disease and different treatment" of traditional Chinese medicine, we independently develop wenmaitongguan decoction combined with moxibustion to treat this disease, mainly through warming the pulse, regulating blood gas, promoting blood circulation and removing blood stasis, so as to achieve the effect of dredging the blood vessels.

The clinical effects of Wenmai Tongguan Decoction mainly include warming pulse, promoting blood circulation and removing blood stasis, dredging collaterals and relieving pain. There are 20g Angelica sinensis, 20g asarum, 20g Cinnamon Twig, 12g chuanmutong, 12g roasted licorice, 20g red peony and 50g jujube. The prescription mainly uses drugs such as warming meridians and dispersing cold, activating blood circulation and dredging collaterals, removing blood stasis and relieving pain. Among them, Guizhi Xinwen has the effect of warming meridians and dispersing cold, warming and dredging blood vessels, which is a king's medicine. Asarum also has the effect of warming meridians and dispersing cold,

which can help Guizhi warm and dredge blood vessels. Chuanmutong can remove cold and heat in the spleen and stomach, dredge nine orifices and blood vessels, and can promote blood circulation and remove blood stasis. Angelica sinensis is sweet and warm, which can warm and abuse cold and heat. It can replenish blood, disperse stasis and relieve pain, activate collaterals and relax tendons. Red peony is the main evil Qi and abdominal pain. It can remove blood stasis, dredge meridians, activate blood circulation and remove blood stasis, break the cold and heat of deposition and relieve pain. It can be used with ginger to drive out the cold of the viscera, treat the cold of hands and feet, and have a fine pulse. The whole prescription is mainly composed of warming and dispersing cold, promoting blood circulation and removing blood stasis, dredging collaterals and relieving pain, taking into account the protection of stomach qi, dispersing the cold evil of Shangjiao, so as to significantly improve the blood stasis of limbs and veins. Guanyuan point is the intersection point of foot three yin meridians and Ren meridians [7]. Moxibustion can help healthy qi, warm and dredge meridians, and give play to the effect of dredging meridians, removing blood stasis and relieving pain. Zusanli is the Foot Yangming stomach meridian. Moxibustion can dredge lower limb impotence and arthralgia, and at the same time, it can replenish qi and benefit blood [8]. The two complement each other and have the effects of warming meridians, activating blood and dredging collaterals. Oral wenmaitongguan Decoction and moxibustion Guanyuan point The two acupoints of Zusanli can warm and dredge the blood vessels, remove "pulse obstruction", improve the blood circulation of the lower limbs, and have the effect of treating arteriosclerosis of the lower limbs.

No is a vasodilator synthesized in vascular endothelium, which can dilate blood vessels, inhibit platelet aggregation and thrombosis [9]. ET-1 is a vascular factor secreted by endothelial cells and has a strong vasoconstrictor effect. The two transmitters complement each other and jointly maintain vascular tension [10]. It is found that no synthesis is blocked in patients with lower extremity arteriosclerosis obliterans, The synthesis of ET-1 increased. This study found that there was no difference in vascular endothelial function before treatment ($P > 0.05$); The level of ET-1 in the treatment group was significantly lower than that in the control group at 7 days and 4 weeks after treatment ($P < 0.05$), while the level of no was significantly higher than that in the control group ($P < 0.05$) and ($P < 0.01$). The level of ABI at 7 days, 14 days and 4 weeks after treatment was significantly improved ($P < 0.05$), The level of ABI in the treatment group was significantly higher than that in the control group 7 days, 14 days and 4 weeks after treatment. Therefore, it can be considered that wenmaitongguan decoction combined with moxibustion can expand blood vessels, improve vascular endothelium, improve lower limb blood circulation, and have a good effect on the

treatment of lower limb arteriosclerosis.

CRP is an intravascular adhesion factor expressed by endothelial cells, which can induce leukocytes to adhere to vascular endothelium, thus inducing vascular endothelial inflammatory response. At the same time, CRP can inhibit vascular endothelial cells from secreting NO, reduce vascular tension, promote vasoconstriction, secondary intravascular coagulation, and further aggravate the clinical symptoms of patients with lower extremity arteriosclerosis obliterans [11]. Tumor necrosis factor α It is the main proinflammatory cytokine secreted by endothelial cells, which can directly damage or activate endothelial cells, cause endothelial injury, or affect leukocytes to release cytokines, cause intravascular dermatitis diseases, and reduce vascular tension [10, 12]. This study found that TNF before treatment- α . There was no difference in CRP ($P > 0.05$); The level of water in the treatment group was significantly lower than that in the control group 7 days and 4 weeks after treatment ($P < 0.05$) and ($P < 0.01$). Wenmaitongguan decoction combined with moxibustion can inhibit TNF- α . The production of CRP can inhibit inflammatory response, reduce vascular endothelial injury, increase vascular tension and reduce the clinical symptoms of ASO patients.

In conclusion, wenmaitongguan decoction combined with moxibustion can alleviate clinical symptoms and achieve the purpose of treating the disease by reducing vascular endothelial injury, reducing vascular endothelial inflammatory reaction, restoring vascular tension, expanding peripheral blood vessels, inhibiting thrombosis and improving peripheral microcirculation. This study found that the treatment group The total effective rate in 4 weeks was significantly higher than that in the control group ($P < 0.01$), so wenmaitongguan decoction combined with moxibustion was effective in the treatment of Aso, which was worthy of clinical application.

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