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WJCC mainly publishes articles reporting research results and findings obtained in the field of clinical medicine and covering a wide range of topics, including case control studies, retrospective cohort studies, retrospective studies, clinical trials studies, observational studies, prospective studies, randomized controlled trials, randomized clinical trials, systematic reviews, meta-analysis, and case reports.

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ORIGINAL ARTICLE

Randomized Controlled Trial

Application of buried auricular point combined with Wenjing Sanhan prescription in arteriosclerosis obliterans patients with resting pain

Ya-Ping Li, Tian Su, Xiao-Li Xue, Huan-Ren Shi, Zhi-Hui Su, Jun Li

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Abstract

BACKGROUND

Research on the combined use of ear acupoint embedding beans and warming meridians with cold-dispersing formulas for alleviating resting pain in patients with arteriosclerosis obliterans (ASO) remains limited.

AIM

To explore the therapeutic efficacy of auricular point embedding beans combined with Wenjing Sanhan prescription in alleviating resting pain in patients with lower-limb ASO.

METHODS

A total of 100 patients with ASO experiencing resting pain who were treated at our hospital from January 2022 to January 2023 were enrolled. They were randomly allocated into two groups using a double-blind approach. The control group was treated using a warming meridian with a cold-dispersing formula, while the study group received additional treatment with ear acupoint embedding beans. The clinical efficacy, ankle-brachial artery pressure ratio, hemorheological indicators, and traditional Chinese medicine symptom scores were compared between the two groups.

RESULTS

The clinical efficacy rate in the study group was significantly higher (94.00%) than that in the control group (72.00%, P < 0.05). Moreover, the ankle-brachial artery pressure ratio was significantly higher in the study group after treatment (*P* < 0.05). Hemorheological parameters, including whole blood viscosity, plasma viscosity (1.83 \pm 0.11) mPa/s, fibrinogen levels (3.30 \pm 0.21) g/L, platelet adhesion rate (49.87% \pm 10.51%), and erythrocyte aggregation index (1.79 \pm 0) were improved in the study group compared to the control group. In addition, the scores for decreased skin temperature (1.41 \pm 0.26), intermittent claudication (1.30 \pm 0.20), and resting pain (1.23 \pm 0.31) were significantly lower in the study group than those in the control group (all P < 0.05). The level of oxidative stress in the study group also exhibited significant improvement (P < 0.05), and the levels of inflammatory factors were considerably lower than those in the control group.

CONCLUSION

The combination of ear point embedding beans and Wenjing Sanhan prescription demonstrates promising clinical efficacy in alleviating resting pain associated with ASO.

Key Words: Embedding beans in ear acupoints; Prescription for warming channels and dispelling cold; Lower limb arteriosclerosis obliterans; Resting pain; Blood flow rheology; Curative effect

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Core Tip: The combination of ear point embedding beans and Wenjing Sanhan prescription demonstrates promising clinical efficacy in alleviating resting pain associated with arteriosclerosis obliterans. It substantially improves the ankle-brachial artery pressure ratio, reduces hemorheological abnormalities and traditional Chinese medicine symptom scores, and alleviates resting pain.

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INTRODUCTION

Lower limb atherosclerosis obliterans (ASO) represents a prevalent vascular condition characterized by the narrowing or occlusion of lower limb arteries due to the formation of atherosclerotic plaques. Prolonged ischemia ensues, leading to the development of ASO over time[1,2]. Timely identification and effective management of atherosclerosis risk factors can delay disease progression and reduce ASO incidence rates. Currently, endovascular intervention surgery is a common therapeutic approach for ASO, offering advantages such as minimal trauma and reproducibility, thereby gaining widespread clinical acceptance[3]. However, patients undergoing interventional surgery are susceptible to complications such as restenosis[4]. Clinical manifestations of ASO onset frequently include symptoms such as numbness, discomfort, chills, and resting pain [5]. If severe ischemia affects the lower limbs, ischemic ulcers may occur. Resting pain manifests as a persistent, non-pulsatile discomfort in the limbs, frequently accompanied by intermittent claudication[6]. Middle-aged and older individuals comprise the majority of patients with ASO, with a prevalence rate reaching up to 17%[7]. These patients often have multiple comorbidities, and as the disease progresses, they experience pronounced resting pain, especially when lying flat and resting at night. This condition significantly affects patients' physical and mental health, resulting in decreased quality of life and increased medical expenses[8]. In traditional Chinese medicine (TCM), ASO is associated with "degeneracy" and "de rheumatism," attributed mainly to insufficient qi and blood, impaired blood circulation, and blocked meridians, leading to inadequate nourishment of the extremities. TCM approaches involving syndrome differentiation and treatment have demonstrated efficacy and gained widespread patient acceptance[9]. The earliest written records in the "Yin-yang Eleven-pulse Moxibustion Classic" highlight the significance of the "ear pulse." Similarly, the "Huangdi Neijing" documents the ear acupoints and their connections with various organs in the body, laying the theoretical groundwork and treatment modalities for addressing ailments through auricular therapy. However, research on the combined use of ear acupoint embedding beans and warming meridians with cold-dispersing formulas for alleviating resting pain in patients with ASO remains limited. Therefore, this study selected 100 patients with ASO experiencing resting pain to investigate the therapeutic outcomes[10,11].

MATERIALS AND METHODS

General information

A total of 100 patients with ASO experiencing resting pain underwent treatment at our hospital between January 2022 and January 2023. Among them, 52 patients exhibited blood stasis and meridian syndrome, while 48 presented with qi and yin deficiency syndrome. Employing a double-blind method, they were randomly allocated into two groups. The control group comprised 26 men and 24 women, aged 40 years to 74 years, with an average age of 56.30 ± 9.46 years. The duration of illness varied from 3 years to 9 years, with an average duration of 5.69 ± 1.45 years. The patients in this group had comorbidities such as hypertension and diabetes. In the study group, there were 26 men and 24 women, aged 40 years to 76 years, with an average age of 56.61 ± 9.52 years. The duration of illness ranged from 2 years to 10 years, with an average duration of 5.58 ± 1.36 years. Similar comorbidities were present in this group, including hypertension and diabetes. Informed consent forms were signed by the patients and their family members, and the study received approval from the internal ethics committee (Figure 1).

Inclusion criteria: Patients were included in the study based on the following criteria: meeting the relevant diagnostic criteria for ASO[12]; presence of ischemic resting pain as the primary symptom; conformance to the applicable standards for blood stasis syndrome outlined in "Traditional Chinese Medicine Surgery" [13]; Doppler ultrasound examination indicating a stenosis degree of \geq 50%; normal mental state with the ability to communicate effectively.

Exclusion criteria: Patients who had recently undergone other relevant treatments; those with different malignant tumors; those with abnormalities in heart, liver, and kidney functions; those with coagulation disorders; and those with concurrent systemic diseases were excluded from the study.

Treatment methods

Both groups received conventional antihypertensive, hypoglycemic, and lipid-lowering treatments before the initiation of the study, supplemented by intracavitary intervention.

The control group underwent ear acupoint embedding bean treatment, as follows. One side was explored daily using an ear probe to locate acupoints, followed by disinfection with medical alcohol. A Wangbuliuxing seed was centered on medical tape and applied to specific acupoints, including Shenmen, sympathetic, subcortical of the cardiovascular system, hot acupoint, posterior sulcus of the lower limbs, and toe ear acupoint. Each acupoint received one seed, and pressure was applied using a method ranging from light to heavy, inducing sensations such as numbness, swelling, heat, and ear pain within the patient's tolerance range. This process was repeated 3-5 times daily, with 30-50 times presses each time, ensuring a time interval of at least 3 h. Seeds were replaced every other day, and bilateral auricles were treated.

The study group received the same ear acupoint embedding bean treatment as the control group, supplemented by the Wenjing Sanhan prescription, consisting of 5 g each of Wuyao, Xiaofenxiang, and Myrrh; 9 g each of Xiangfu, Yujin, Puhuang, and Wulingzhi; and 12 g each of Litchi seed, Safflower, Angelica sinensis, and Fuzi (prepared). This formula was administered in a water decoction of 300 mL divided into two doses (morning and evening), taken daily. The medicinal materials were soaked for 30 min before decoction. Both groups were treated continuously for 4 wk.

Evaluation criteria

TCM symptom score: Skin temperature reduction, intermittent claudication, and resting pain syndromes were scored according to the "Diagnosis and Treatment Criteria for Arteriosclerotic Occlusion" [10]. Scores were as follows: Skin temperature reduction in the lower limbs or feet: 0 points for no reduction, 1 point for mild reduction, and 2 points for significant reduction; Intermittent claudication: 0 points for none, 1 point for mild intermittent claudication, with the ability to walk a long distance (> 200 m) without experiencing claudication symptoms, 2 points for moderate intermittent claudication, appearing after walking a short distance (50-200 m), and 3 points for severe intermittent claudication: Appearing after walking a short distance (< 50 m); Resting pain: 0 points for none, 1 point for intermittent resting pain, without affecting sleep, 2 points for intermittent resting pain affecting sleep, and 3 points for persistent resting pain, with scores proportional to severity.

Hemorheology: Peripheral venous blood samples (5 mL) were collected from both patient groups 12 h before and after treatment. The samples were centrifuged at a rate of 3500 rpm with a radius of 0.2 mm for 10 min to separate the supernatant. Whole blood viscosity and plasma viscosity were measured using an automatic hemorheological analyzer (HT-100B; Zibo Hengtuo Analysis Instrument Co., Ltd., Shandong, China). The platelet adhesion rate was determined using the glass filter method. Fibrinogen levels were obtained using a fully automatic coagulation analyzer (RAC-030; Shanghai Yuyan Scientific Instrument Co., Ltd., Shanghai, China). The red blood cell aggregation index was measured using a fully automatic analyzer (U-3081; Shanghai Yudo Biotechnology Co., Ltd., Shanghai, China).

Oxidative stress: An additional 3 mL of peripheral venous blood was collected to measure the levels of malondialdehyde, superoxide dismutase, and myeloperoxidase using radioimmunoprecipitation technology.

Inflammatory factors: Another 3 mL of peripheral venous blood was collected to assess interleukin (IL)-8 and IL-6 levels using enzyme-linked immunosorbent assay (ELISA kit, batch number: XY-JCSJH-1140; Shanghai Xuanya Biotechnology Co., Ltd., Shanghai, China). C-reactive protein levels were determined using immunoturbidimetry.

Statistical analysis

SPSS 26.0 (IBM Corp., Armonk, NY, United States) statistical software was used for data analysis. Measurement data conforming to normal distribution were described as mean ± SD, and a bilateral t-test was used to compare the means between the two groups. Percentages were calculated for categorical data, and inter-group comparisons were performed using the χ^2 test. A P value < 0.05 was considered statistically significant.

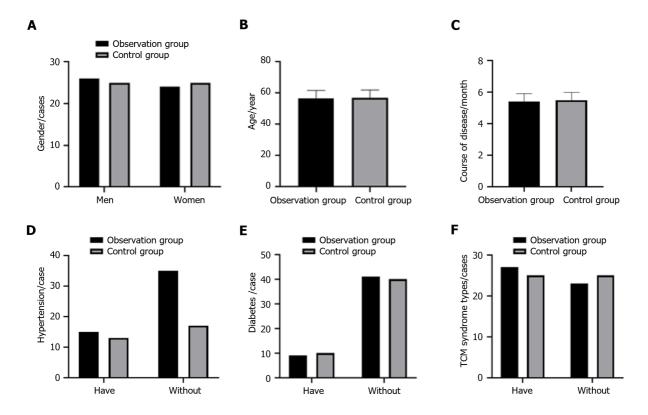


Figure 1 Comparison of two groups of data. A: Sex; B: Age; C: Course of disease; D: Hypertension; E: Diabetes; F: Traditional Chinese medicine (TCM) syndrome types

RESULTS

Comparison of clinical efficacy between two groups

The study group exhibited a total clinical efficacy rate of 94.00%, significantly higher than the 72.00% observed in the control group (P < 0.05) (Figure 2).

Comparison of ankle/brachial artery pressure ratio between two groups

Post-treatment, the ankle-brachial artery pressure ratio in the study group surpassed that of the control group (P < 0.05) (Figure 3).

Comparison of ankle/brachial artery pressure ratio between two groups

After treatment, the ankle-brachial artery pressure ratio in the study group surpassed that of the control group (P < 0.05) (Figure 3).

Comparison of hemorheological indicators between two groups

In the study group, levels of various indicators such as whole blood viscosity (12.74 ± 2.06) mPa/s, plasma viscosity (1.83 \pm 0.11) mPa/s, fibringen (3.30 \pm 0.21) g/L, platelet adhesion rate (49.87% \pm 10.51%), and red blood cell aggregation index $(1.79\% \pm 0.20\%)$ were significantly lower compared to the control group (P < 0.05) (Figures 4 and 5).

Comparison of TCM symptom scores between two groups

Following treatment, the study group demonstrated significantly lower scores for skin temperature reduction (1.41 \pm 0.26), intermittent claudication (1.30 \pm 0.20), and resting pain (1.23 \pm 0.31) compared to the control group (P < 0.05) (Figure 6).

Oxidative stress indicators

The observed improvement in oxidative stress levels was more significantly pronounced in the study group than in the control group (P < 0.05) (Figure 7).

Inflammatory factor indicators

Levels of inflammatory factors in the study group were considerably lower than those in the control group (P < 0.05) (Figure 8).

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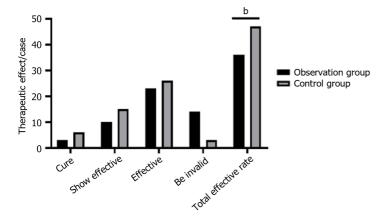


Figure 2 Comparison of clinical efficacy between the two groups. ^bP < 0.05 indicates a statistically significant difference between the control group and the study group.

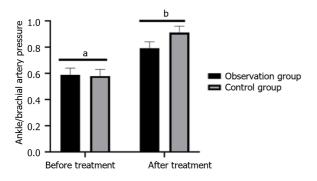


Figure 3 Comparison of ankle-brachial artery pressure ratio between two groups. ^aP > 0.05 indicates no significant difference between the study and control groups; ^bP < 0.05 indicates that the difference between the study and control groups was statistically significant.

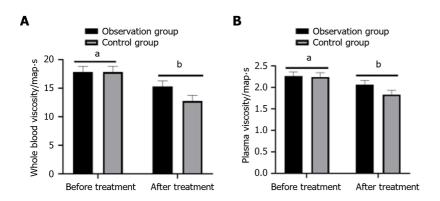


Figure 4 Comparison of hemorheological indicators between the two groups. A: Whole blood viscosity; B: Plasma viscosity. ^aP > 0.05 indicates no significant difference between the study and control groups; ^bP < 0.05 indicates that the difference between the study and control groups was statistically significant.

DISCUSSION

ASO typically arises as a comorbid condition in conjunction with the progression of atherosclerosis. Atherosclerosis induces hemodynamic abnormalities, increasing blood viscosity and consequent blood stasis, predisposing individuals to abnormal coagulation function. Thrombosis is more likely to develop in regions of vascular constriction throughout the body[14-16]. Resting pain is a predominant clinical manifestation of ASO, characterized by persistent limb pain during periods of rest. It is a primary clinical symptom of Fontaine grade III[17]. The onset of resting pain in patients with ASO signals a potential risk of impending ischemic necrosis in the affected area, necessitating preventive measures to avert necrosis resulting from severe ischemia. While some patients resort to medication for relief, primarily non-steroidal and opioid analgesics, their rapid efficacy is counteracted by the risk of dependency and various side effects, limiting their frequent use. TCM attributes the onset of ASO to vascular pathologies, particularly choroidal obstruction. Factors such as overexertion, emotional instability, and external influences can disrupt bodily fluid and blood flow, leading to meridian

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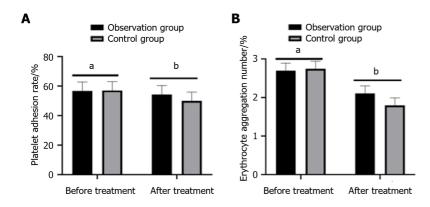


Figure 5 Comparison of hemorheological indicators between the two groups. A: Platelet adhesion rate; B: Erythrocyte aggregation number. ^aP > 0.05 indicates no significant difference between the study and control groups; ¹P < 0.05 indicates that the difference between the study and control groups was statistically significant.

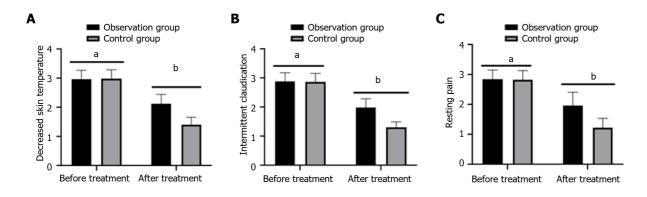


Figure 6 Comparison of traditional Chinese medicine symptom scores between the two groups. A: Skin temperature; B: Intermittent claudication; C: Resting pain. ^aP > 0.05 indicates no significant difference between the study and control groups; ^bP < 0.05 indicates that the difference between the study and control groups was statistically significant.

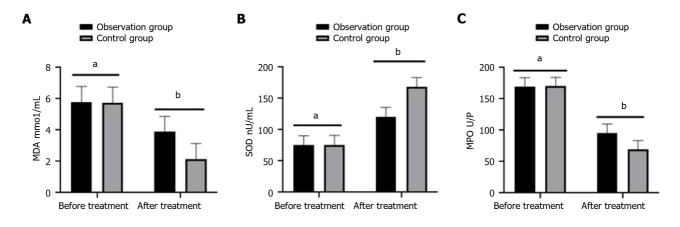


Figure 7 Oxidative stress indicators. A: Malondialdehyde (MDA); B: Superoxide dismutase (SOD); C: Myeloperoxidase (MPO). ^aP > 0.05 indicates no significant difference between the study and control groups; ^bP < 0.05 indicates that the difference between the study and control groups was statistically significant.

blockages caused by blood stasis, which impedes limb nourishment and precipitates ASO[18]. In the initial stages of treatment, attention should be placed on strategies such as warming the meridians, dispersing cold, detoxification, heat clearance, dampness removal, and collateral unblocking. In the later stages, attention should shift to processes such as kidney tonification, blood nourishment, promotion of blood circulation, and detoxification[19]. Acupuncture and moxibustion are primary TCM modalities for addressing surgical ailments, capable of extracting external and internal toxins. The embedding of ear point beans is a pivotal component of acupuncture and moxibustion therapy, known for its minimal toxicity and side effects, significant clinical efficacy, and straightforward application. This method is increasingly adopted in pain management for diverse conditions[20].

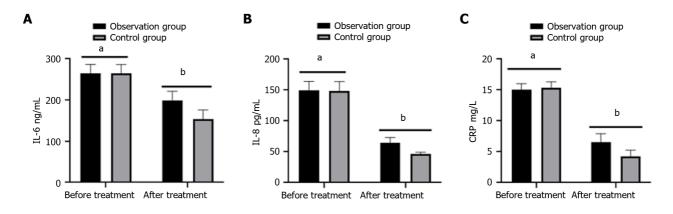


Figure 8 Inflammatory factor indicators. A: Interleukin (IL)-6; B: IL-8; C: C-reactive protein (CRP). ^aP > 0.05 indicates no significant difference between the study and control groups; ^bP < 0.05 indicates that the difference between the study and control groups was statistically significant.

The research results reveal a substantially superior total clinical efficacy in the study group compared to the control group, underscoring the favorable therapeutic outcomes associated with the combination of ear point embedding beans and Wenjing Sanhan prescription. The Wenjing Sanhan prescription, predominantly comprising Chinese medicinal materials such as *Aconite*, *Wulingzhi*, and *Safflower*, is prepared *via* water decoction, preserving the biological activity of the medicinal components and enhancing coagulation. Pharmacologically, *Safflower* contains potent compounds such as *Safflower* ketone and *Safflower* glycoside, which intervene in the coagulation cascade by inhibiting the synthesis, activation, and activity of coagulation factors and diminishing platelet aggregation, thereby regulating blood coagulation capacity. This mechanism stimulates endothelial cells to produce nitric oxide, facilitating vascular smooth muscle relaxation, vasodilation, enhanced blood flow, and improved circulation[21]. The ear acupoints hosting the embedded beans correspond to the body's meridians and organs, serving as reservoirs and sources of qi. By utilizing the inherent property of Wangbuliu seeds for continuous movement, the therapy aims to unblock meridians. Moreover, it employs acupuncture and moxibustion techniques, encompassing needle insertion, retention, movement, and initiation, to sustain a lasting and stable therapeutic effect[22]. This combination treatment significantly reduces platelet aggregation and improves the patient's symptoms.

The ankle-brachial artery pressure ratio primarily assesses ischemia severity in patients. The results of this study demonstrated a significantly higher ankle-brachial artery pressure ratio in the study group than in the control group, alongside significantly reduced hemorheological indicators such as whole blood viscosity, plasma viscosity, fibrinogen, platelet adhesion rate, and red blood cell aggregation index. This result indicates that the combination therapy of ear point embedding beans and warming meridians to dispel cold effectively enhances the ankle-brachial artery pressure ratio in patients with ASO and resting pain, alleviates limb ischemia, and reduces blood viscosity. This efficacy may be attributed to warming meridian and cold-dispersing formula components such as Aconite, which restores Yang and relieves adverse reactions; Wulingzhi, which breaks through blood and promotes blood circulation; Puhuang, which promotes blood circulation, hemostasis, and the resolution of blood stasis; Litchi seeds, which enhance qi circulation and disperse nodules; and Wuyao, which relieves qi stagnation and depression. The combined action of these ingredients effectively dispels cold and resolves blood stasis. Modern pharmacological studies have shown that aconite and Wulingzhi can mitigate blood hypercoagulability in patients by modulating pathways such as glucose and glycerophospholipid metabolism, inhibiting platelet aggregation, and exhibiting robust biological activity [23]. Angelica sinensis contains various compounds such as Rongben lactone and sodium ferulic acid, which possess the ability to decrease blood viscosity, enhance prothrombin time, lower plasma fibrinogen levels, shorten the electrophoresis time of platelets and red blood cells, and improve blood coagulation by inhibiting the synthesis of coagulation factors [24]. The Zhongshenmen point for embedding ear acupoints lies at the junction of the middle and lower thirds of the line between the pressure drop point and pelvic point. Acupuncture and moxibustion on this point exhibit significant sedative and analgesic effects. The Sympathetic point, positioned at the inner upper part of the inner third of the lower ear wheel, is one of the five blood-activating points. Acupuncture and moxibustion at this point can alleviate pain, relieve spasms, and regulate the contraction and relaxation of blood vessels. The hot acupoint at the midpoint of the line connecting the coccyx and abdomen is crucial for promoting blood circulation and unblocking meridians, thereby significantly enhancing peripheral blood circulation. The combined application of these points can dilate blood vessels, elevate the anklebrachial artery pressure ratio, reduce blood viscosity, and ameliorate limb ischemia in patients [25].

Our comparison of TCM symptom scores between the two groups revealed significantly lower scores for skin temperature reduction, intermittent claudication, and resting pain in the study group following treatment compared to the control group. This finding indicates that combining ear acupoint embedding and warming meridians with a cold-dispersing formula alleviates skin temperature reduction, intermittent claudication, and resting pain in patients with ASO, yielding a favorable therapeutic outcome. The efficacy of this treatment stems from the components within the warming meridians and cold-dispersing formula: *Yujin* promotes qi circulation and relieves depression, cools blood, and breaks through blood stasis; *Myrrh* relieves pain and stimulates blood circulation; and *Xiangfu* soothes the liver, regulates qi, and relieves pain. The synergistic action of multiple drugs achieves the therapeutic goals of warming meridians, dispersing cold, removing dampness, unblocking collaterals, and reducing pain. Moreover, ginger-processed aconite regulates PGE2 and adrenaline, inducing thermal-related effects[26]. In the study by Dong *et al*[27], the Wenjing Sanhan

formula was employed to treat rheumatoid arthritis of the wind-cold dampness type, yielding significant analgesic effects consistent with the findings of this study. Treatment involving embedding beans in ear acupoints enhances peripheral blood circulation and elevates skin temperature by stimulating the patient's hot acupoints. The subcortical acupoint of the vascular system at the center of the buried bean ear acupoint is pivotal for regulating cerebral cortex function; it is positioned at the front and lower part of the inner side of the ear screen. Acupuncture can transmit nerve impulses to the brain, thereby influencing central function. This transmission enables the hypothalamus to modulate sympathetic and parasympathetic nerves to regulate the body's balance and nutritional status; it governs the hypothalamic-pituitary system, impacting the dynamic equilibrium of humoral hormones in the body, and triggers non-specific protective behaviors, improving immune factors to alleviate pain. The synergistic effect of this combination therapy yields favorable therapeutic outcomes.

Ear point embedding beans exert significant sedative and analgesic effects on the Shenmen point through acupuncture and moxibustion. Similarly, the Sympathetic point, one of the five blood-activating points, responds to acupuncture and moxibustion by relieving pain, easing spasms, and regulating blood vessel contraction and relaxation[24]. Ear point embedding beans combined with warming meridians and cold-dispersing formulas represent TCM therapies with targeted and comprehensive regulatory effects. The warming meridians and cold-dispersing formula effectively warm and unblock the meridians, promote the circulation of qi and blood, and improve the rheological properties of blood. The research results suggest that this combined approach of TCM and medication can effectively reduce oxidative stress levels in patients with ASO. The efficacy of these treatments stems from the abundance of active ingredients such as cinnamic acid and eugenol. These compounds act as scavengers for free radicals, engaging with them to reduce accumulation and damage. They provide electrons or hydrogen atoms, stabilizing free radicals and mitigating their damage to cells, thereby lowering oxidative stress levels. TCM theorizes that ear acupoints are interconnected with the body's meridians and organs, serving as reflex areas for the human nervous system. Stimulating these acupoints triggers a response in the nervous system, regulating the activity of the neuroendocrine system and consequently influencing oxidative stress. Furthermore, our results showed that the study groups exhibited lower inflammatory factor levels than the control group. This observation indicates that the combined approach of ear point embedding beans and warming meridians with a cold-dispersing formula reduces inflammatory factor levels in patients. This effect can be attributed to the active compounds such as quercetin and kaempferol in the Wenjing Sanhan formula, which possess potent antiinflammatory properties. These compounds act on targets such as IL-6, influencing inflammatory and associated apoptotic pathways, thereby exerting anti-inflammatory effects[28]. Burying beans in specific ear acupoints stimulates nerve endings, influencing corresponding organs and systems. This method regulates immune system function through neural reflex mechanisms, diminishing inflammatory reactions and enhancing immunity. Combining these treatment methods improves inflammatory factor levels by regulating immune system function, and promoting blood and qi circulation. A study by scholars such as Lin et al [25] has shown that treating lower-limb ASO with warming yang, dispersing cold, and promoting blood circulation yielded a clinically effective rate of 93.33%, significantly inhibiting inflammatory factors, aligning with our study results.

CONCLUSION

In summary, combining ear point embedding beans and warming meridians with the cold-dispersing formula alleviates resting pain in patients with lower-limb ASO. This approach significantly increases the ankle-brachial artery pressure ratio, reduces hemorheological indicators, and improves TCM symptom scores. It demonstrates substantial clinical efficacy, and warrants further promotion and application in clinical settings. However, due to the limited number of cases in this study, future research should involve a larger sample size for more comprehensive investigations.

FOOTNOTES

Author contributions: Li J designed the research; Li YP performed the research and wrote the paper; Su T, Su ZH, and Xue XL contributed new reagents or analytic tools; Shi HR analyzed the data.

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