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*Review*

## Treatment as Prevention: A Review of the Use of Traditional Chinese Medicine in High-Risk Diabetic Foot

**Meilan Li<sup>1</sup>, Jie Ji<sup>1</sup>, Lifeng Ma<sup>2,\*</sup>**

<sup>1</sup>School of Nursing, Dali University, Dali, China

<sup>2</sup>Shanghai Seventh People's Hospital, Shanghai, China

\*Corresponding author: Lifeng Ma, 2865067429@qq.com

### Abstract

Diabetic foot (DF) has emerged as one of the most common chronic consequences of diabetes mellitus, characterized by prolonged disease duration, high treatment costs, a poor prognosis, and a high disability rate. Diabetic high-risk foot is the early stage of diabetic foot, the “disease prevention” of “treating no disease”, which provides a critical window for clinical prevention and treatment. Traditional Chinese medicine (TCM) has emphasized the importance of preventive health care since ancient times. External therapies such as acupuncture, massage, acupoint injection, foot bath fumigation, and moxibustion have the advantages of simplicity, precise efficacy, and fewer side effects in preventing and treating diabetic high-risk foot. The multidisciplinary synergistic model formed by TCM complementary therapies and modern medical treatments, such as nutritional, peripheral nerve, and blood glucose regulation, provides new ideas for establishing standardized prevention and treatment protocols. In this paper, studies related to TCM-related complementary therapies for diabetic high-risk foot are systematically reviewed. Current evidence shows that commonly used traditional Chinese medicine external therapies have different effects on improving high-risk feet in the elderly. TCM fumigation has the best effect on improving nerve conduction velocity in high-risk feet. In the future, biological research can be strengthened to explore the specific mechanism of action.

### Keywords

Diabetic high-risk foot, External Chinese medicine treatment method, Treatment of undiagnosed disorder, Review

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## 1. Introduction

According to the International Diabetes Federation (IDF)'s most recent estimations in 2021, diabetes mellitus is highly common among people over the age of 65 [1,2]. China, the United States, and India have the most diabetic patients over 65, with prevalence rates ranging from 14.9% to 25.0%. The prevalence of diabetes in China is 10.6% in people aged 20-79 years, with a prevalence of 141 million people, making it the country with the largest number of diabetic patients in the world [2].

The incidence of diabetic foot (DF) increases with the duration of diabetes mellitus. It is assumed that between 19%-34% of the estimated 537 million people with diabetes worldwide will develop diabetic foot ulcers (DFUs) in their lifetime [3], with the prevalence of diabetic foot as high as 8.1% among people with diabetes over the age of 50 years, with a two-year mortality rate of 51% and a limb amputation rate of more than 50% [4]. Older patients with diabetic foot have a longer duration of disease, more comorbidities, and a higher risk of amputation [5]. Therefore, early prevention and treatment of the diabetic foot is important to promote and maintain the health status of diabetic patients, especially elderly diabetic patients. Studies have shown that effective preventive measures for high-risk diabetic foot and mitigation of adverse effects can reduce the rate of diabetic foot amputation by 49% to 85%, showing that prevention is better than cure [6].

Diabetic high-risk foot is an early stage of the diabetic foot and is defined as the presence of risk factors for foot ulceration without the development of a foot ulcer. A multicenter cross-sectional study in the United Kingdom that included 6,487 patients with diabetes showed an overall detection rate of 28.5% for diabetic high-risk foot [7]. One of the major reasons for the difficulty in early identification of high-risk foot and the low detection rate is that hypesthesia caused by diabetic peripheral neuropathy impairs the patient's perception of foot abnormalities. Neurologic function testing on diabetes patients found that around 60% to 90% of diabetic individuals have varied degrees of neuropathy, with 30% to 40% of these people exhibiting no subjective symptoms, and the nerve damage is often permanent and irreversible [4,6]. The elderly is a special population group characterized by declining cognitive function, existence of comorbidities, use of multiple medications, and complex medication regimens, which pose a major challenge to the management of type 2 diabetes mellitus. The prevalence correlated with the duration of diabetes, which reached 44% of diabetic patients aged 70 to 79 years [1]. This article provides an overview of the importance of prevention of high-risk diabetic foot, the current status and problems of early prevention, and the interventional measures of external treatment with Traditional Chinese medicine (TCM) for early prevention, to provide reference for clinical care and research.

## 2. Chinese and Western Medical Understanding of the Diabetic High-Risk Foot

In 2015, the International Working Group on Diabetic Foot (IWGDF) clearly defined diabetic high-risk foot as "diabetic patients without active ulcers, but with peripheral neuropathy, with or without foot deformity or lower extremity vascular lesions, or a history of foot ulcers, or a history of amputation of the lower extremity or foot" [8]. According to the Wagner Diabetic Foot Classification Criteria (Figure 1), there are grades 0 to 5. Grade 0: no signs of foot ulceration, but there is a risk; Grade 1: superficial ulceration, no infection, mainly neuropathic; Grade 2: deeper ulceration, with tissue infection, no osteomyelitis or deep abscess; Grade 3: deep ulceration, with abscess or osteomyelitis; Grade 4: confined gangrene, with neuropathy; Grade 5: gangrene of the whole foot [9]. Wagner grade 0 is defined as DF with risk factors for foot ulceration but without ulceration, also known as diabetic high-risk foot.



**Figure 1.** Wagner classification of diabetic foot.

The TCM guidelines and expert consensus define diabetic high-risk foot as “gangrene diabetic foot disease-diabetic arterial occlusive disease of the limb without ulceration.” [10]. The onset of the disease is characterized by poor Qi and blood. The veins and channels are not smooth, causing meridian obstruction, and gradually affect the skin, muscles, veins, nerves, and bone lesions. Serious cases can involve the five viscera and six bowels. In the advanced stages, disorders of Qi and blood impair circulation further. The balance of Qi and blood, as well as Yin and Yang, is disrupted, leading to the accumulation of phlegm, dampness, and toxic stagnation. The veins and collaterals become thin and blocked, depriving the skin, tendons, and muscles of nourishment. This pathological progression ultimately contributes to the development of diabetic foot.

### **3. Feasibility of Chinese Medicine’s Idea of “Treating the Future Disease” in the Prevention and Treatment of High-Risk Diabetic Foot**

Diabetic foot is challenging to treat, making prevention crucial. Effective management of high-risk diabetic foot can significantly reduce disability rates. Western therapies for DF include foot care and infection management, blood sugar control, such as taking metformin, improving blood supply, and the common use of methylcobalamin to provide nutrients to nerve cells. However, treatment outcomes have been lacklustre. Only 24% or 30% of DFUs heal within 12 or 20 weeks, respectively, and patients are susceptible to serious complications, including wounds, osteomyelitis, cellulitis, and amputation [11]. Up to 40% of DFUs may require amputation, and following a major amputation, 50% of patients require another major amputation within two years. The relative mortality rate after amputation is about 50%, second only to lung cancer (86%) and higher than colorectal (39%) or breast cancer (23%) [12].

Western drug therapy alone only relieves and controls existing clinical symptoms in patients with DF. Chinese medicine can alleviate the adverse effects of diabetic high-risk foot as an adjunctive treatment. The IWGDF emphasizes that interventions for DFUs based on a multidisciplinary team approach with systematic and comprehensive education and preventive measures can significantly improve the prognosis and reduce the rate of amputation by 49%-85%[8]. External treatment of diabetic foot in TCM is a major feature of TCM therapy. The Chinese Diabetic Foot Prevention and Control Guidelines (2019) state that prevention is better than cure for diabetic foot, and that the occurrence of diabetic foot can be reduced by strengthening the management of high-risk diabetic foot to detect, diagnose, and treat high-risk foot at an early stage [13]. Diabetic foot is difficult to treat and prevention is better than cure. The Clinical Practice Guidelines for the Prevention and Management of the Diabetic Foot state that the five cornerstones of preventing the diabetic foot are identification of the diabetic foot at risk, regular screening of the diabetic foot at risk, education of the patient, their family and healthcare professionals, appropriate footwear for daily use, and treatment of the risk factors for ulceration [10].

The theory of “treating the disease before it occurs” has three levels of significance : (1) prevention of disease before it occurs, which requires improvement of living habits and strengthening the body; (2) preventing the change of the disease after it occurs, which suggests early diagnosis and treatment; and (3) prevention of recurrence of the disease, which means that active measures can be taken to promote the recovery of the organism after the disease, and to prevent the disease from recurring and reduce the after-effects [12]. As far as diabetic foot is concerned, early treatment can prevent the disease from changing from light to heavy and from surface to inside. Therefore, early treatment of diabetic foot is very important. Especially when the diabetic foot grade 0 timely control the development of the disease, delay or even block its development from grade 0 to grade 1 will greatly reduce the disability and mortality rate of patients. Multiple guidelines recommend continuous, vigilant, and regular foot examinations for early detection and prevention of diabetic foot ulcers, integrating the concept of “treating the future illness” with clinical nursing to improve the prognosis of patients will be the focus of future research.

### **4. Application of External Treatment of Chinese Medicine in the Prevention and Treatment of Diabetic High-Risk Foot**

With the application of Chinese medicine in the care of diabetes mellitus patients, Chinese medicine nursing is more standardized and scientific, and the guidance of clinical patient care is more practical and effective. TCM nursing is guided by evidence-based thinking and supported by TCM nursing techniques, which can effectively improve the prognosis of patients by dredging the meridians and activating the lateral branches to help the normal function of Qi and blood.

#### **4.1 Chinese Medicine Fumigation**

Chinese medicine fumigation is a therapeutic method that uses medicines decocted in a broth and fumigated or drenched on the skin or affected area while it is warm. Generally, the medicinal soup is first smoked with steam and then washed when the medicine cools down. With the help of drug action and heat effect, this therapy acts on the body through the skin and mucous membranes, which can stimulate vasodilatation of the extremities, promote local blood and lymphatic reflux, and play the role of activating blood circulation, relieving pain, dispersing cold, and replenishing Qi. Fumigation avoids the hepatic first-pass effect through percutaneous absorption of the medicinal ingredients, and its thermal effect stimulates microcirculation to increase local blood flow by 30%-45% [14]; typical protocols, such as the

addition of Bai Shao and Gan Cao Tang [15-16], significantly improves the speed of nerve conduction by 15.2% and reduces the Toronto Clinical Scoring System (TCSS) score by 40.7% at 40-42°C [17]. However, the risk of elderly patients experiencing delayed onset of cold injuries increased by 3.8 times, suggesting the use of intelligent temperature-control devices ( $\pm 0.5^\circ\text{C}$  accuracy) and a single session length of  $\leq 10$  minutes [18]. Elderly DF patients are often accompanied by vascular and neuropathy. These lesions affect the patient's foot blood circulation and nerve function. An over 10-minute foot soak will cause a decrease in sympathetic excitability and an increase in vagal tone, resulting in an increase in heart rate and a decrease in blood pressure [18]. When Chinese medicine fumigation is carried out, all the blood is quickly concentrated in the lower limbs, causing a transient insufficient blood supply to the brain and the heart. This will lead to dizziness, panic, and chest tightness, and even induce cardiovascular and cerebrovascular diseases. Preventive measures can be taken in the form of smart temperature-controlled foot bath tubs and controlled foot soaking time.

#### 4.2 Acupuncture Point Patching

Acupuncture point patching, also known as acupoint therapy, is based on the meridian theory, the precise role of drugs in the disease-related points (such as A Yes point), with the help of medicinal ingredients percutaneous absorption and meridian stimulation, regulating the balance of yin and yang in the internal organs and promoting qi, blood and meridians, so as to achieve the purpose of prevention and treatment of diseases [19]. On the one hand, the action of the skin and mucous membrane penetration to avoid the first-pass effect of the liver, to enhance drug targeting; on the other hand, through the stimulation of acupuncture points to stimulate the whole body response, through the meridian conduction to achieve qi and blood harmonisation [20]. Clinically, astragalus, cinnamon, rhizoma ligustici, chuanxiong and xinxin are commonly used to be ground into powder, and then made into paste with water or vegetable oil, or supplemented with solidifying agents such as petroleum jelly and rice vinegar to make patch preparations [21]. The combination of acupoints was foot Sanli and Sanyinjiao, together with the identification and selection of acupoints, and the patch was applied for 4 hours daily [20-22]. Chen et al used safflower-cinnamon-chuanxiong combination patch to apply foot-sanli and sanyinjiao, and the clinical symptom improvement rate of the patients improved by 32.5% compared with the control group [21]. Li et al study further confirmed that bilateral Chungquan acupoints and sanyinjiao patches could reduce the Chinese medicine evidence scores by 48.3%, and inflammatory factor IL-6 by 41.2% ( $P < 0.05$ ) [22].

Limitations: This therapy is mostly used as an auxiliary means, and its therapeutic efficacy is limited mainly due to two aspects: firstly, the length of the conventional 4-6 hours of application is insufficient, resulting in the drug absorption rate of only 63% of the theoretical value [22]; secondly, the incidence of adhesive tape-induced atopic dermatitis in elderly patients can be up to 12.7% due to the high sensitivity of the skin, which manifests itself in redness, swelling and itching, and makes it easy to interrupt the treatment [21]. To optimise efficacy and reduce the risk of allergy, the following measures are recommended: (1) use a mild medical cleanser to remove keratin and oil from the skin surface before applying the adhesive tape to enhance drug penetration; (2) apply a thin layer of petroleum jelly to enhance the skin barrier function (thickness  $\leq 0.5$  mm); and (3) prolong the duration of the adhesive tape to 6-8 hours to improve bioavailability [23].

#### 4.3 Acupoint Injection

Acupoint injection is a combination of chemical stimulation of drugs and mechanical stimulation of needling acting on meridians to produce the effect of promoting nerve repair and nerve nutrition. Zhu randomly divided 120 patients with DF into a study group and a control group [24]. The control group received basic symptomatic treatment with Western medicine, while the research group received acupoint injections of Lanxessin in addition to the same Western medical treatment. Based on the basic symptomatic treatment of Western medicine, the efficacy of acupoint injection for the treatment of diabetic peripheral neuropathy of the splenic phlegm-dampness type was obvious. It can inhibit inflammation, improve oxidative stress, and reduce the damage of vascular endothelial function. Zhao divided 70 patients with type 2 diabetes mellitus high-risk foot into two groups [25]. For the conventional treatment of diabetes, the control group was treated with microprobe, and the treatment group was treated with saffron injection acupoint injection for the control group.

Acupoint injection of traditional Chinese medicine can significantly reduce the MDNS scores and signs and symptoms scores of DPN patients and improve the quality of life. Although acupoint injection can promote the recovery of nerve function, repeated needling of the affected limbs of DF has a potential risk of infection. These include an increased risk of infection, aggravation of pain due to repeated needling, and occasional bleeding at the injection site. In patients with existing skin damage, the likelihood of developing foot ulcers is significantly higher [26]. Apply light pressure to the needle puncture site for a few moments with a sterile dry cotton ball to prevent bleeding and hematoma formation. If bleeding occurs, apply pressure until bleeding stops. Advise the patient to keep the site clean and dry within 24 hours after the needling and avoid water to prevent infection. If there is slight redness, swelling, pain, and other reactions at the site of needling, it is generally a normal phenomenon and cold compresses can be applied locally.

#### 4.4 Moxibustion

Moxibustion is divided into direct moxibustion and indirect moxibustion. Direct moxibustion can be divided into scar moxibustion and no scar moxibustion. Indirect moxibustion can be divided into interstitial ginger moxibustion, interstitial garlic moxibustion, interstitial salt moxibustion, and interstitial appendage cake moxibustion [27]. The clinical effectiveness of moxibustion in treating DPN has been widely recognized. Recent studies showed that moxibustion can increase serum superoxide dismutase concentration, reduce free-radical production, prevent impairments of nerve tissues resulting from free-radical accumulation, and alleviate neuro-inflammation possibly by inhibiting NF- $\kappa$ B and activating Nrf2 [27]. Zheng treated 70 cases of DPN patients with pave moxibustion therapy [28]. The treatment group used methylcobalamin treatment plus pave moxibustion therapy and found that pave moxibustion therapy significantly improved clinical symptoms and nerve conduction velocity after 2 courses of treatment. Wei Xiang et al. observed 60 cases of diabetic peripheral neuropathy patients who were hospitalized and found that thunder fire moxibustion therapy can achieve the effect of warming meridians and opening collaterals through the meridian and acupoints through the meridian sensory transmission together and treat diabetic peripheral neuropathy [29].

Elderly people have thinner skin and lower tolerance to high temperatures and are prone to burns when moxibustion is performed. Secondly, symptoms of diabetes are manifested by dry mouth and thirst, which are aggravated by moxibustion (fire). Moxibustion treats diseases through warm and hot stimulation, but elderly people are weak and prone to Yin deficiency and fire [30]. When performing moxibustion treatment, symptoms such as dry mouth, fire, or allergic skin reactions such as rashes may result from warm and hot stimulation. Reducing the incidence of burns can be achieved by increasing rounds and observing the skin for 5-10 minutes.

#### 4.5 Acupressure

Acupressure improves the function of the five viscera by stimulating the qi of the meridians, and its mechanism is mainly reflected in three aspects: (1) promoting microcirculation in the endings of the limbs, so that the local skin temperature is elevated by 1.2-2.3°C (verified by infrared thermography) [31, 32]; (2) increasing nerve sensitivity, and the threshold of vibration sensation is lowered by 38.7% ( $P<0.01$ ) [32]; (3) accelerating the process of nerve repair, which is indicated by the measurement of the total peroneal nerve conduction velocity (TPNCV) motor nerve conduction velocity (MNCV) was elevated by 1.8 m/s [33]. Guo gave the methylcobalamin group oral methylcobalamin tablets, 0.5 mg each time, 3 times a day [33]. The acupressure group was given ten acupressure points, including Qiaogong, Neiguan, Blood Sea, Huizhong, Chengshan, Ashigangsanli, Sanyinjiao, Taixi, Taichong, Neitin. In the acupressure group, 10 specific acupoints were selected, with each point stimulated for 3 minutes, followed by continuous massage lasting approximately 20 minutes. Treatments were administered five times per week over a period of two weeks. This intervention resulted in significant improvements in clinical symptom scores and TCSS scores.

Although acupressure is convenient, patients may lack a correct understanding of acupressure. Elderly diabetic high-risk foot will have lower limb vascular lesions, and the extrusion during massage may damage the inner wall of blood vessels, leading to thrombosis [34]. Those with venous thrombosis already formed, blind massage may lead to thrombus dislodgement, triggering serious complications such as pulmonary embolism [35]. When patients continue self-massage at home after discharge, improper techniques, such as incorrect acupoint location, inappropriate methods, or excessive pressure, may lead to discomfort, lower limb pain, or even injury [36]. Therefore, proper training in acupoint identification and massage intensity is essential. It is recommended that massage be performed by trained professionals, as incorrect application may compromise therapeutic outcomes and fail to achieve the desired results.

### 5. Conclusion

Diabetic high-risk foot patients belong to the category of “gangrene”, “tendon gangrene”, “pulse paralysis” [37,38]. The intervention of external treatment of Chinese medicine on diabetic high-risk foot mainly relies on a triple pathophysiological mechanism: firstly, through fumigation and moxibustion to elevate the local temperature and increase blood flow by  $\geq 30\%$  through vasodilatation to improve microcirculatory disorders [39]; secondly, with the help of Chuanxiongizine and other Chinese medicines to promote the increase in the expression of nerve growth factor (NGF) and delay neurodegeneration; thirdly, through the inhibition of the TNF- $\alpha$ /IL-6 pathway by safflower flavonoids to reduce inflammatory factors by  $\geq 40\%$  to regulate metabolic inflammation [40]. High-frequency analysis of acupoints showed that foot Sanli (8 times) and Sanyinjiao (6 times) were the best matching acupoints [22,24,28-31], and saffron (7 times) and chuanxiong (5 times) were the main medicines [20,22,24-27,33]. Traditional Chinese medicine fumigation, which has obvious therapeutic effectiveness, was used as an adjunctive therapy, and the rate of improvement in nerve conduction velocity was up to 25.3% [41].

At present, the research of TCM external treatment for diabetic foot is mostly based on clinical observation. The research of the mechanism of action is relatively small, and its biological research should be strengthened to explore the key links and targets of the specific mechanism of action. Furthermore, review of the literature has found that the length of the TCM external intervention program is relatively short. The length of the intervention can be increased or followed up to observe the changes of patients' long-term indicators, to improve the application and treatment of external Chinese medicine in the clinical management of high-risk foot in elderly diabetes.

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Not applicable.

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Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

## Conflict of interest

The authors declare that they have no competing interests.

## Authors' Contributions

Meilan Li wrote the main manuscript text and carried the analysis. Jie Ji, Lifang Ma designed the project and the experiments. All authors reviewed the manuscript. The authors declare that no Gen AI was used in the creation of this manuscript.

## Abbreviations

DF: diabetic foot

DFU: diabetic foot ulcers

IDF: International Diabetes Federation

IWGDF: International Working Group on Diabetic Foot

MNCV: motor nerve conduction velocity

NGF: nerve growth factor

TCM: Traditional Chinese medicine

TCSS: Toronto Clinical Scoring System

TPNVCV: total peroneal nerve conduction velocity

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